

# Effect of Fast-Track Surgery under ERAS protocol in Laparoscopic Hysterectomy: A Randomized Controlled Trial

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## ABSTRACT

**Background and Objective:** Fast-track surgery (FTS) consists of different pathways to decrease surgical complications and improve outcomes and patient satisfaction. FTS in an elective gynecologic laparoscopic surgery has not been well assessed. No consensus guidelines have been developed for gynecologic laparoscopic surgeries. The purpose of this study is to evaluate enhanced recovery after surgery (ERAS) for total laparoscopic hysterectomy.

**Methods:** 260 patients underwent for laparoscopic hysterectomy surgery. All patients were divided into two groups as follows: one group received traditional laparoscopic hysterectomy surgery and the intervention group was treated under ERAS protocol. ERAS protocol includes not receiving preoperative mechanical bowel preparation and laxatives as well as fasting 6 h and not drinking liquids 2h before surgery. The patients were allowed to resume the ordinary diet 6h post-operation. Ondansetron 4 mg were prescribed after surgery for nausea and vomiting, pain was controlled with non-narcotic analgesics diclofenac suppository 100 mg/q12 h and paracetamol 1000 mg/q6 h until discharge. Urinary catheter was removed whenever possible and early ambulation occurred 6h after the surgery.

**Results:** A total of 260 patients were studied. Regarding the length of hospitalization, significant differences were shown between the groups ( $P < 0.001$ ). Return to daily functions was occurred earlier in the fast-track surgery group than another group. Complications and VAS pain scores showed no significant differences between the groups.

**Conclusion:** Our results show that ERAS surgery has fewer side effects and better outcomes which make it more suitable for patients undergoing laparoscopic hysterectomy.

**Keywords:** Enhanced Postsurgical Recovery, Laparoscopy, Surgery, Hysterectomy

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## Introduction

Hysterectomy is the most frequent gynecological surgery (1,2). 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. Luckily, hysterectomy has often been associated with satisfying results over the two centuries, and more lately Reich *et al.*, standardized laparoscopic method for it. Obviously, laparoscopic

hysterectomies lead to the above-mentioned outcomes in comparison with abdominal hysterectomies (3,4). In spite of these minimally invasive approaches, abdominal hysterectomy is still the most common method and over 50% of hysterectomies are yet being carried out classically via laparotomy (1). Fast-track surgery or enhanced recovery after surgery (ERAS) was introduced by Kain in the early 1990. ERAS is a type of care in surgeries reducing the physiological stress response and organ dysfunction due to surgery. It consists of different pathways to decrease surgical complications, improve outcomes and patient

satisfaction (5). It provides more quickly recovery and rapid return to normal function. The main purpose of this program is to improve recovery after the surgery, resulting in earlier hospital discharge with better outcomes (5,6). ERAS reduces the physical and psychological impact of elective gynecological surgery on the patient and shortens the length of stay (7-12) and returning to normal activity. The advantages of FTS documented in abdominal surgery most likely extend to laparoscopic surgery. However, FTS in elective gynecologic laparoscopic surgeries has not been well studied. No consensus guidelines have been developed for gynecologic laparoscopic surgery, although surgeons have attempted to introduce slightly modified FTS programs for patients undergoing such surgeries. In previous studies, laparotomy and FTS has been studied and the greatest outcome was earlier hospital discharge. The purpose of this study is to evaluate ERAS for total laparoscopic hysterectomy.

## Materials and Methods

The present clinical study was done at the Gynecologic Department, Iran University of Medical Sciences, Rasool Akram Medical Complex from October 2019 to February 2020. The study protocol was approved by the Local Ethical Committee (IR.IUMS.REC.1398.724) and written consent was obtained from the patients before enrollment in the study. The trial was registered in the Iranian Registry of Clinical Trials; IRCT20191123045476N1. Previous studies have shown that the required sample size should be 140 in each group, according to the confidence coefficient of 0.05 and the study power of 90%. In this non-blinded RCT, 280 patients presenting with total laparoscopic hysterectomy were included in both groups. Block random allocation (with a 1:1 allocation) was done. Patients' variables included age, co-morbidities (diabetes, hypertension, pulmonary compromise etc), weight, height and body mass index (BMI). Details included the procedure performance, operating time, infection, intraoperative blood loss (BL), preoperative hemoglobin (Hb), postoperative Hb and Hb change, whether patients tolerated early oral feeding (EOF) and complications were collected and date of discharge. Post hospitalization admissions and complications were also recorded. Inclusion criteria were: age  $\geq 40$  and  $< 60$  years, uterine benign disease, and indication for total laparoscopic hysterectomy. The exclusion criteria were untreated anemia, infection, underlying diseases such as uncontrolled cardiopulmonary disease, gastrointestinal disease or any underlying disease, affecting the performance of the procedure and post-operative healing, age less than 40 or more than 60 years, malignant changes, conversion to laparotomy, severe mental or neurological illness, underlying disease which may change the quality of

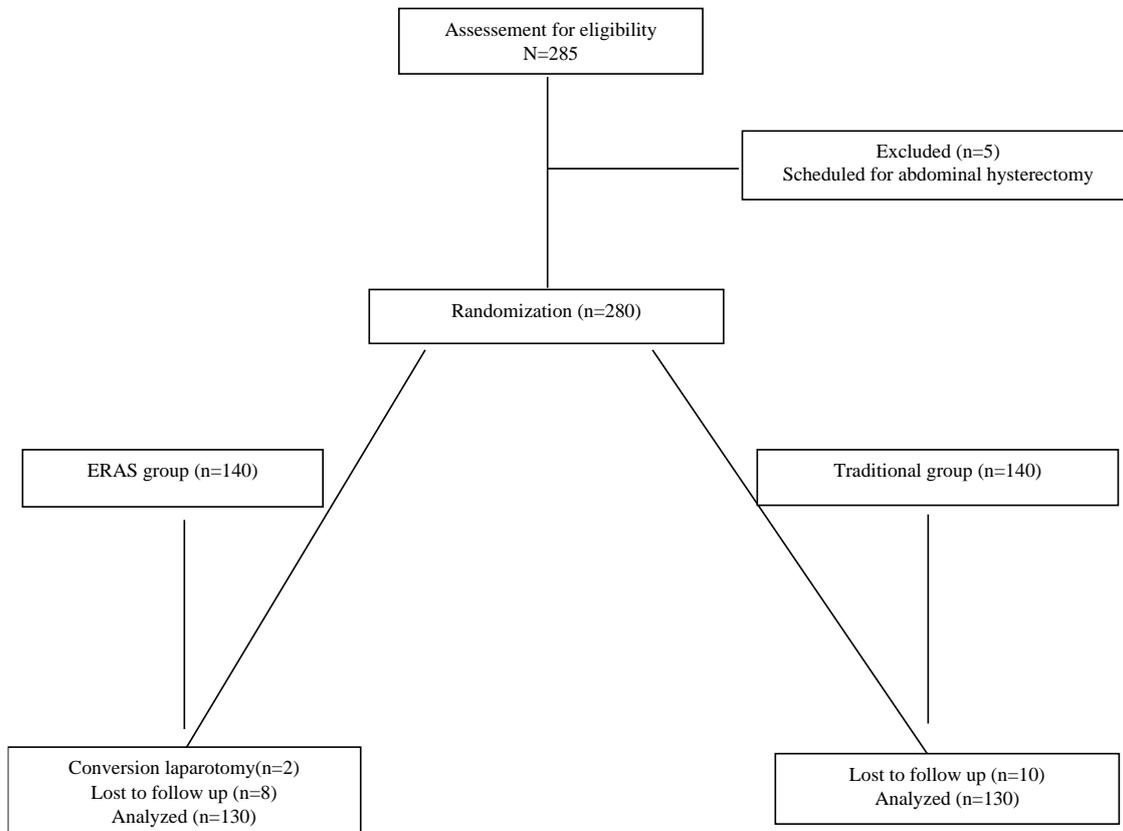
life, and nutritional condition (e.g., liver cirrhosis and renal disease).

### ERAS program

The patients received multivitamins tablets a week before the surgery and continued them for one month after the operation. They also received 200 ml of carbohydrate-rich drinks four times a day before the surgery and two doses on the morning of the operation. The patients fasted 2 h for liquids and 6 h for solids. The patients did not undergo mechanical bowel preparation either orogastric mouth or rectal enteral cleansing material pre-operation. Prophylactic IV antibiotic (cefazolin 2 gIV) was given at the beginning of the surgery. Orogastric tube, abdominal drain and urinary catheter are routinely used in these surgeries and their benefits are limited and should not be applied, as they boost morbidity and extended hospital stay. Thromboembolism prophylactic strategy including subcutaneous enoxaparin 40 mg was given 12 h before the surgery and sustained as 40 mg once daily until discharge. All the surgeries were performed under general anesthesia and the propofol was used for intravenous induction. Isoflurane was used for maintenance. A urinary catheter was inserted in all patients at the beginning of the procedure. All orogastric tubes were removed at the end of the surgery before extubating the patient. We protected our patients from hypothermia by means of systematic use of an active warming device. A single dose of ondansetron 4 mg/IV was given preoperatively. Intra-operative fluids) lactated Ringer's 4 ml/kg/h (were given intravenously. excluding the replacement of blood loss. Ondansetron was also received if there was nausea or vomiting postoperatively. Patients could get out of the beds 6h after the surgery and then a semi-liquid diet was restarted for the patients. In case of no inconvenience, the regular diet was resumed for the patients, 10 h post-procedure. Patients were advised to chew gum in order to reduce the risk of postoperative ileus. The urinary catheter was removed 8h after the surgery and intraperitoneal drains were removed whenever possible. All patients were treated effectively if there were symptoms such as pain, nausea, and vomiting. Diclofenac Suppository 100 mg every 12 h was prescribed postoperatively with regular paracetamol 1000 mg every 6h. The traditional group underwent traditional management before the surgery. The patients received bisacodyl suppository and mechanical bowel preparation until watery stool; all patients started fasting at 12 AM regardless of the time of the surgery. Prophylactic IV antibiotic and thromboembolism prophylactic strategy were the same as the ERAS group. A single dose of promethazine 25 mg was received preoperatively and administered if nausea or vomiting occurred postoperatively. The urinary catheter was removed 24 h after the surgery. Also, intraperitoneal drains were

removed 24-48 h after the surgery. The patients started liquids 24 h after the surgery and also got out of bed 12-24 h after. Opioid analgesics like pethidine 50 mg/IM/q 4-6h was given to patients in the traditional group to relieve pain after the surgery. All

Patients in two groups were followed up 2nd and 4th weeks after the surgery through phone interviews to record any postoperative complications or readmission in other hospitals.



**Figure 1.** CONSORT diagram of the study

## Result

The present study included 280 patients who were candidates for elective hysterectomy surgery. Finally, 260 patients followed up for 30 days. One hundred and thirty patients finished the study in the traditional protocol group and 130 patients in the ERAS group. There was no significant difference between the two study groups regarding demographic data (Table 1). The median age of the patients was 45 years. The mean operation time in both groups was 1-3 h. Median blood loss (BL) at surgery was 50-100 ml in the ERAS group and 175 ml in the traditional one. The patients were discharged when they reported no pain by receiving oral analgesia, passing flatus and if they were able to eat and drink. Of note, 20 patients were excluded due to refusing to follow up or changing surgery plan to laparotomy. The patients in ERAS group showed a significant difference in the hospital stay than those in the ERAS group; the mean length of hospital stay was calculated based on the time from the end of operation until discharge. In the ERAS group, median discharge time was one day. Overall, 120 patients were discharged on day 1 in the ERAS

group. In the traditional group, 35 patients discharged on day one (P value: 0.001). Postoperative nausea and vomiting (PONV) were observed 24 h after the surgery. It was graded as visual analog scale (VAS) for nausea and vomiting, ranging from 0 to 10 (0= "no nausea"; 10= "worst nausea"). There was a significant difference between the groups. Although 22 patients in both groups mentioned severe nausea and vomiting which has not been controlled with routine management, postoperative nausea VAS was higher in traditional group. (P value: 0.02) (Table 2). Vomiting was recorded 24h after the surgery (Table 2). Vomiting VAS score was significantly lower in the ERAS group in comparison with the traditional one (P value: 0.001).

Thrombosis was evaluated by Doppler ultrasound in the patients with DVT symptoms after the surgery and the difference was not statistically significant. (Table 3) Out of bed which means early mobilization was recorded. The mean hours in the ERAS group were 6 h and in the traditional one was 18 h (P value: 0.002) (Table 2). In our study, no cuff dehiscence occurred. There were no significant differences in

febrile morbidity, blood transfusion, return to OR, death, ICU admission, readmission, bowel injury between the two groups. There was no thrombotic event in the ERAS group compared with 3 patients in the traditional group, but it was not statistically

significant. Another evaluation of ERAS surgery is the time that patients return to their daily routine functions. The mean days were 10 in the ERAS group compared with 21 days in the traditional group.

**Table 1.** Demographic and surgical data

Demographics/surgical details	ERAS protocol (n=130)	Traditional protocol(n=130)	P value
Age, year	45±8.231	48±7.832	>0.05
Body mass index (BMI)	27.11±3.102	29.03±4.725	>0.05
Underlying Comorbidity			>0.05
Diabetes	8	9	
Hypertension	17	15	
Underlying disease			>0.05
Abnormal uterine bleeding	46	53	
Uterine fibroma	37	30	
Adenomyosis	24	20	
Endometriosis	12	16	
Endometrial hyperplasia	11	11	

**Table 2.** Mean score of pain and nausea and vomiting VAS (visual analog score; ranging from 0 to 10 (0= “no nausea”; 10= “worst nausea”) and mobilization time after the surgery

	ERAS protocol group	Traditional protocol group	P value
Pain VAS SCORE	7	6	>0.05
Nausea (VAS score)	3	7	0.02
Vomiting (VAS score)	4	8	0.001
Mobilization time after surgery	6	18	0.002

**Table 3.** Complication of patients in ERAS and traditional group

Post-operative complication	ERAS protocol N (%)	Traditional protocol N(%)	P value
cuff dehiscence	0	0	
Post-operative fever T>38.3at 24 h after surgery	20 (15.3%)	35(26.9%)	0.4
Blood Transfusion	2(1.5%)	4(3.0%)	0.5
Return to OR	1(0.76%)	2(1.5%)	0.5
Death	0	0	
ICU admission	0	3(2.3%)	0.5
Urologic Injury	5(3.8%)	4(3.0%)	0.3
Readmission	4(3.0%)	5(3.8%)	0.2
Bowel injury	0	0	
Post-operative thrombosis based on Doppler Ultrasonography in symptomatic patients	0	3(2.3%)	0.5

## Discussion

ERAS protocols have been introduced for different surgeries to reduce patient’s stress and organ dysfunction (13,14). These protocols include no bowel preparation before surgery, perioperative opioid-sparing analgesia, avoidance of nasogastric tubes and drains, management of postoperative nausea and vomiting, and early mobilization and oral feedings (8). Our study demonstrated nausea and vomiting were significantly lower in fast-track protocols in comparison with traditional protocols whereas post operation pain and complication has not been enhanced. We showed that thrombotic events have been decreased in ERAS group by means of the ERAS protocol, although this decline was not significant statistically. We had 9 cases of readmission, 5 and 4 patients in the ERAS and

traditional group, respectively, without any significant differences. In the ERAS groups, the readmissions were due to the repair of urologic injury, whereas in the traditional group’s readmissions were because of thrombotic event and repair of urologic injury. ERAS provides earlier discharge with better patient outcomes. Most of the evidence supporting FTS has been published in the field of colorectal surgery (7,9,13,15,16). In a study, in 2010, 47 patients underwent ERAS protocol by a multidisciplinary team. The patients’ compliance to the ERAS protocol was 93% and duration of hospital stay was 3 days. Perioperative mortality was nil. Results show that ERAS protocol for colorectal surgery allows faster recovery and also lower days of hospital stay in comparison with traditional protocol (17). There are increasing reports in the gynecological literature to

improve outcomes (18, 19). In a study (2012) Carter performed laparotomy for gynecological cancer in three hundred and eighty-nine patients and used fast-track management (18). Median length of stay (LOS) was 3 days. Early oral feeding tolerance was 95% and readmission rate was 4%, and 0.5% of the patients underwent 2<sup>nd</sup> operation. There were 2 bladder injuries (0.5%), and thromboembolism was 1%. The mentioned study is considered a valuable essay in the literature regarding fast-track surgery in gynecology and gynecologic oncology. In the, mentioned study, the fast track surgery was conducted for patients with cancer. They concluded that there was no evidence from high-quality studies to support or refuse the use of perioperative enhanced recovery programs for gynecological patients with cancer (18). So, further well-designed RCTs with standard FT programs are needed to discuss. Enhanced recovery protocol, as a multidisciplinary management precipitates post operation recovery, decline complications and in terms of economy, decrease healthcare costs. Although there is no general consensus in the laparoscopic field in fast-track protocol, laparoscopists attempted to design a modified fast-track guideline in laparoscopy. Our study seeks to demonstrate if the ERAS protocol, despite a negligible rate of complication, could attain early hospital discharge after laparoscopic hysterectomy. Previously, in conventional programs, surgeons applied chemical and mechanical bowel preparation preoperatively, and used intravenous fluid in order to maintain fluid balance before operation. During the surgery, the patients received volume to keep filling pressures at the end of the operation; surgeons often utilized pelvic drains to prevent fluid collection. Regarding the starting diet, the patients began clear liquid 1-2 days after the surgery by starting bowel sounds then gradually returned to a light diet, and eventually a regular diet 2-3 days post-operation. In the traditional protocol, the patients stayed in an average time of 2-3 days post-surgery (20). As a result of proven improvement in Patients' outcomes, recently FTS or enhanced surgical recovery protocol has received remarkable appreciation. The gravitation of this management is due to earlier discharge, and reduced the postoperative length of stay (LOS). The purpose of our study is to illustrate patient outcomes and probable subsequent complications following earlier discharge after laparoscopic hysterectomy. In colorectal surgery, the advantages of fast-track surgery were evaluated. The result of their study was the same as our study. Two hundred and fifty patients underwent laparotomy. Length of stay and readmission was different in the ERAS group (17). Basile Pache et al in 2019 demonstrated that costs significantly decrease by means of fast-track surgery in gynecologic surgery (21). Implementation of the ERAS program causes a high level of patients' satisfaction in undergoing gynecologic surgery regardless of noticeable benefits such as short length

of hospital stay according to a retrospective study by Ferraioli (22). On the other hand, Pache et al. showed fast-track surgery performance remarkably declines overall costs of care in gynecologic surgery (21). In a study (2020), 107 patients were under oncological gynecologic surgery. No significant difference was shown in the length of hospitalization. Complications and cost of surgery were lower in the ERAS group in comparison with the traditional group (23).

## Conclusion

In this study, we evaluated the result of fast-track surgery protocol in laparoscopic hysterectomy. Our results showed that length of hospitalization and return to daily routine function was obviously short in this method. Moreover, complications such as nausea and vomiting were decreased by using fast track surgery.

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## Conflict of Interest

The authors declared that they have no conflict of interest.

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