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Implementation of the Policy of Enhanced Recovery after Surgery in Gynecologic Oncology

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ABSTRACT

Background: Enhanced Recovery after Surgery (ERAS) is now firmly established as a global surgical quality improvement initiative that results in both clinical improvements and cost benefits to the healthcare system.
Objective: The aim of this work was to evaluate the impact of the ERAS on outcome of gynecologic oncology surgery.
Patients and Methods: A case study was carried out in Zagazig University Hospital during the period from August 2021 and February 2022. The study included 30 patients presenting for gynecological oncologic surgeries. They were classified into two groups: Group I (the ERAS group) included 15 patient who were exposed to the mean of enhanced recovery protocols. Group II (the conventional group) included 15 patients who were treated with the standard care known in the literature. All patients were subjected to general clinical examination, laboratory investigations and radiological studies.
Results: The catheterization period, movement time, audible intestinal sound, oral intake, time until discharge, and need for opiates were all significantly shorter in the ERAS group. While the mean of the universal pain score was significantly higher in the conventional group, 3.5 compared to 1.9 in the ERAS group.
Conclusions: Implementation of the policy of enhanced recovery after surgery (ERAS) in gynecologic oncology was associated with an overall improvement in postoperative outcomes.
Keywords: ERAS, Gynecologic oncology, Surgery, Enhanced recovery after surgery.

INTRODUCTION

Enhanced Recovery after Surgery (ERAS) is a perioperative quality-improvement program that uses evidence-based interventions within the preoperative, intraoperative, and postoperative phases of surgical care. ERAS pathways have been implemented in several surgical specialties and have proven beneficial for both the patient and health care systems [(1)].

Surgical stress forces the body into a highly catabolic state with increased cardiac demands, relative tissue hypoxia, increased insulin resistance, impaired coagulation profile, and altered pulmonary and gastrointestinal functions. The body's response to surgical stress results in organ dysfunction, increased morbidity, and, ultimately, delayed convalescence. The ERAS programs aim to maintain normal physiology perioperatively and optimize patient outcomes by introducing interventions that have been proven to either decrease surgical stress or help the body mitigate the negative consequences associated with it [(2)].

Patients with cancer undergoing open surgical procedures are at greatest risk for postoperative complications with morbidity rates for laparotomy in the range of 20-30% [(3)]. ERAS Pre-operative recommendations include permission of oral intake of clear fluids up to 2 hours before surgery, use of carbohydrate loading and avoidance of mechanical bowel preparation. Intra-operative recommendations include deep vein thrombosis and antimicrobial prophylaxis, maintenance of euvolemia and recommend the use of regional anesthesia. Post-operative recommendations include initiation of regular diet within 24 hours, avoidance of peritoneal drainage and nasogastric tubes, multimodal opioid-sparing analgesia, removal of the urinary catheter within 24 hours and early active mobilization [(4)].

ERAS pathways improve the length of hospital stay, pain control, and hospital cost in patients undergoing high-risk gynecologic oncology open surgeries. The benefits of these pathways have been demonstrated in several recent studies from a small number of specialized centers in both gynecologic and gynecologic oncology patients [(5)].

The aim of this study was to evaluate the impact of the ERAS on outcome of gynecologic oncology surgery.

PATIENTS AND METHODS

The number of patients included in the study was 30 patients presenting for gynecological oncologic surgeries. They were classified into 2 groups: Group I (the ERAS group) included 15 patient who were exposed to the mean of enhanced recovery protocols, and group II (the conventional group) included 15 patients who were treated with the standard care known in the literature.

Inclusion criteria: Patients who were referred for elective gynecological oncologic surgeries. Patients who have complete mental clarity. Age >18 years.

Exclusion criteria:

Patients with bowel resection. Patients with intestinal injuries. Patients with advanced gynecological cancer. Patients receiving treatment for chronic pain**.** Patients with coagulation disorders or organ failure or severe dysfunction (heart, renal, pulmonary, hepatic). Patients with previous abdominal oncology surgery**.**

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Patients admitted to intensive care unit (ICU) postoperatively for more than one night.

All patients were subjected to thorough clinical evaluation with emphasis on full history taking (personal, present, past, family, obstetric, contraceptive and menstrual history). General clinical examination and laboratory investigations according to the type of the cancer and suggestions of Committee of Multidisciplinary team of Zagazig Gynecologic Oncology Unit. Lab investigations include complete blood count (CBC), liver function tests, kidney function test, coagulation profile, random blood sugar, viral markers (HBV, HCV) and tumor markers (CA 125, CEA, CA 19-9 and alpha fetoprotein) in cases of ovarian cancer. Radiological studies include pelvi-abdominal ultrasound, MRI with contrast examination of the pelvis, chest x-ray and chest CT with contrast. Electrocardiogram, upper and lower endoscopy and cystoscopy if indicated.

The ERAS group:

Using of short-acting volatile anesthetics or continuous infusion of propofol is recommended to allow rapid surfacing of anesthesia. Avoid administration of NG tube and its removal at the end of operation if used. Pre-warming of fluids before infusion during operation to maintain normothermia. Antibiotic prophylaxis: patient receive cefotax (1g or 2g IV) before skin incision. Maintain intraoperative euvolemia by decreasing crystalloid administration and increasing colloid if needed. Administration of prophylaxis for postoperative nausea and vomiting: dexamethasone 4 mg IV once plus droperidol 0.625 mg IV once half hour before incision, and primpran amp IV once half hour before incision closure. Minimize long-acting opiates. After incision closure, injection of bupivacaine at incision site or TAP BLOCK. Injection of acetaminophen IV at the end of the operation for patients tolerate it. Trying to limit prophylactic peritoneal drains and vaginal pack.

The Conventional group:

Use anesthetic agent as usual. Avoid administration of NG tube and its removal of at end of the operation if used. Maintain intraoperative euvolemia by decreasing crystalloid administration and increasing colloid if needed. Antibiotic prophylaxis: patient receive cefotax (1g or 2g IV) before skin incision. Administration of prophylaxis for postoperative nausea and vomiting (zantac amp IV plus primpran amp IV half hour before incision). Use opiates as needed.

Follow up:

Early removal of catheter as early as possible, immediately after surgery or after 6 hours postoperatively. Early mobilization (the patient gets out of the bed a minimum 2 hours on the day of the surgery and then 6 hours per day until discharge). Antibiotics were given after 12 hours from exiting the surgery. Pain score was assessed using Universal Pain Tool after complete recovery. The patient discharge criteria included tolerating diet, ambulatory, and pain well controlled on oral analgesia.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures were coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data, qualitative were represented as number and percentage. Quantitative continues group was represented as mean ± SD, the following tests were used to test differences for significance: difference and association of qualitative variable by Chi square test (X^2) and differences between quantitative independent groups by t test. P value was set at ≤ 0.05 for significant results & < 0.001 for high significant result.

RESULTS

This study showed that, in terms of age and BMI, there was no statistically significant difference (p value > 0.05). When the ERAS group was compared to the conventional group, the mean age was 47.0 ± 17.4 and 48.9 ± 14.8 years respectively, and the mean BMI was 34.3 ± 7.3 and 33.8 ± 5.7 respectively. In terms of parity, both groups had a majority of multiparous women, with no significant differences between them (Table 1).

Table (1): Demographic and parity data, and its relationship between the studied groups

	ERAS group T=15 F (%)	**Conventional group T=15 F (%)**	**Test (P)**
Age (years)			
Mean ± SD	47.0 ± 17.4	48.9 ± 14.8	-0.32
Range	19-74	20-70	(0.75)
BMI (kg/m^2)			
Mean ±SD	34.3 ± 7.3	33.8 ± 5.7	0.22
Range	21-50	22-40	(0.83)
Parity			
Virgin	3 (20.0)	2 (13.3)	0.94
Parous women	12 (80.0)	13 (86.7)	
Number of parity	T= 12	T=13	
Median (range)	4±0.71	5± 1.01	0.88

There was no significant difference between groups in terms of pathological results (p value > 0.05), as both groups had 4 (26.7%) cases of cancer endometrial. The ERAS group had 4 (26.7%) cancer cervix and 7 (46.7%) cancer ovary, compared to 3 (20.0) and 8 (53.3) in the conventional group (Table 2).

Table (2): The distribution of pathology among the studied groups

	ERAS Group (T=15) F (%)	**Conventional group (T=15) F (%)**	**Test (P)**
Pathology			
➢ Cancer cervix	4(26.7)	3(20.0)	0.21
➢ Cancer endometrium	4(26.7)	4(26.7)	(0.90)
➢ Cancer ovary	7(46.7)	8(53.3)	

Except for the preoperative use of antibiotics and thrombolytic agents as prophylaxis, there was a statistically significant difference (p value 0.05) between the studied groups in terms of preoperative (CHO load, fasting hours, and analgesics), with the ERAS group having significantly lower preoperative (CHO load, fasting hours, than the conventional group (Table 3).

Table (3): Pre-operative preparation among the studied groups

	ERAS Group T=15 F (%)	**Conventional group T=15 F (%)**	**T-test P**
CHO load			
➢ Yes	**15(100.0)**	**0(0.0)**	**(0.00*)**
➢ No	**0(0.0)**	**15(100.0)**	
Solid fasting (h)			
Mean ± SD	**6.1 ± 0.5**	**12.3 ± 1.8**	**12.0**
Range	**(6-7)**	**(11-13)**	**(0.00*)**
Oral fasting (h)			
Mean ± SD	**4.3 ± 0.6**	**12.1 ± 1.3**	**14.7**
Range	**(4-5)**	**(12-13)**	**(0.00*)**
Prophylaxis use of antibiotic	**15(100.0)**	**15(100.0)**	**----**
Prophylaxis against thrombus	**15(100.0)**	**15(100.0)**	**----**
Preoperative analgesics			
➢ Acetaminophen	**13(86.7)**	**0(0.0)**	
➢ Acetaminophen with NSAID	**2(13.3)**	**0(0.0)**	**0.00***
➢ No	**0(0.0)**	**15(100.0)**	

NSAID: Non-steroidal anti-inflammatory drugs. CHO: Carbohydrates. *p there was a statistical significant difference

There was no significant difference between groups in terms of the use of nasogastric tubes or the type of anesthesia (p value > 0.05). Regarding the need for intraoperative fluid opiate, the use of drains and the use of transversus abdominis plane (TAP) block, they were significantly (p value < 0.05) lower in the ERAS group compared to the conventional groups (Table 4).

Table (4): Operative data among the studied groups

	ERAS Group T=15 F (%)	**Conventional group T=15 F (%)**	**Test (P)**
Type of anesthesia ➢ General ➢ Spinal	 10(53.3) 5 (46.7)	 14 (80.0) 1 (20.0)	 3.33 (0.07)
Intra-operative fluid (Unit) Mean ± SD Range	 2146.7 ± 756.7 1000-3500	 2733.3 ± 622.9 1500-3500	 2.32 (0.03*)
Opiates use ➢ No ➢ Yes	 10(66.7) 5(33.3)	 0(0.0) 15(100.0)	 0.00*
Drain use ➢ No ➢ Yes	 11(73.4) 4(26.6)	 0(0.0) 15(100.0)	 0.00*
Nasogastric tube	0(0.0)	2(13.3)	0.48
Vaginal pack	0(0.0)	0(0.0)	-------
TAP BLOCK ➢ No ➢ Yes	 9(60.0) 6(40.0)	 15(100.0) 0(0.0)	 0.00*

*p there was a statistical significant difference TAP--- transversus abdominis plane

The catheterization period, movement time, audible intestinal sound, oral intake, time until discharge, and need for opiates, they were all significantly (p 0.05) shorter in the ERAS group. While, the mean of the universal pain score was significantly higher in the conventional group, 3.5 ± 0.5 compared to 1.9 ± 0.6 in the ERAS group (Table 5).

Table (5): Post-operative among the studied groups

	ERAS Group T=15 F (%) Mean ± SD	**Conventional Group T=15 F (%)** Mean ± SD	**Test (P)**
Intravenous fluid	2166.7 ± 645.5	2833.3 ± 361	3.49 (0.00*)
Drain removal (days)	1.8 ± 0.6	3.5 ± 0.9	5.19 (0.00*)
Movement time (hours)	5.6±0.7	20..4±2.7	16.8 (0.00*)
Start of feeding (hours)	7±1.6	14.6±3.7	7.23 (0.00*)
Intestinal sound	6.3±1.5	14.6±3.7	7.92 (0.00*)
Urine catheter removal (hours)	5.2±0.9	11±2.2	7.29 (0.00*)
Universal pain score	1.9±0.6	3.5±0.5	7.53 (0.00*)
Post- operative analgesics ➢ NSAID ➢ Acetaminophen ➢ Acetaminophen + NSAID ➢ Opiate	 2(13.3) 4(26.7) 9(60.0) 3(20.0)	 0 0 15(100.0) 15(100.0)	 0.00*
Hospital Stay (days)	2.3±1.0	3.3±1.0	5.38 (0.00*)

*p there was a statistical significant difference

This table showed that the frequency of post-operative complications, including surgical site infection, hospital readmission, paralytic ileus, and other complications, was significantly (p value < 0.05) higher in the conventional group compared to the ERAS group (Table 6).

Table (6): Post-operative complications among the studied groups

	ERAS Group T=15 F (%)	Conventional group T=15 F (%)	test P
Surgical site infection			
➢ No	15(100.0)	11 (73.3)	(0.099)
➢ Yes	0(0.0)	4 (26.7)	
Hospital readmission			
➢ No	13(86.7)	10 (66.7)	1.67
➢ Yes	2(13.3)	5 (33.3)	(0.19)
Paralytic ileus	0(0.0)	5 (33.3)	(0.04*)
DVT	0(0.0)	0(0.0)	
Other complication			
➢ No	13(86.7)	13(86.7)	
➢ Yes	2(13.3)	2(13.3)	

* P- there was a statistical significant difference. /DVT: Deep venous thrombosis

DISCUSSION

In this study, age ranged from 19-74 years with a mean age of 47.0 ± 17.4 years in ERAS group and age ranged from 20-70 years with a mean age of 48.9 ± 14.8 years in conventional group without any significant difference between the two groups. Also, the mean body mass index BMI (calculated as weight [kg]/ [height (m)]^2) was 34.3 ± 7.3 for ERAS group and 33.8 ± 5.7 for conventional group and there was no significant difference between the two groups.

The type of cancer pathology was distributed among the two groups with ovarian cancer 46.7% (7 patient) in ERAS group VS 53.3 % (8 patient) in conventional group, cervical cancer 26.7% (4 patient) in ERAS group VS 20% (3 patient) in conventional group and endometrial cancer was the same in both groups 26.7% (4 patient).

In the preoperative period the patients of the ERAS group were instructed to have carbohydrate load and given light meal food up to 6 hours before the operation and the drinking was continued up to 2 hours before the surgery as reported by **Gustafsson *et al.* [6]** unlike the conventional group where food and drinks were prohibited up to 12 hours before the operation was done.

The pre and postoperative care in both groups, they were given antibiotics as guidelines to prevent wound infections as discussed by **Nelson *et al.*[7]** and the thrombo-prophylaxis also was administrated as guidelines discussed by **Lyman *et al.*[8]** with no data were drawn to compare between both groups for any significant difference.

Preoperative analgesia in ERAS group, multi-modal analgesia consisting of acetaminophen or NSAIDs combined with acetaminophen while in the conventional group no role for preoperative analgesia, as guidelines discussed **[9].**

In the current study, drain used in 4 cases (26.6%) in ERAS GROUP and in 15 cases (100%) in conventional group and avoid nasogastric tube and vaginal pack in ERAS group, there was significant difference between the two groups. Gynecologists have inserted peritoneal drains to decrease intraperitoneal fluid collections, decrease rates of infections, and as a mirror to diagnose intra-abdominal bleeding and anastomotic leaks. However, studies have concluded that insertion of these drains is not correlated with decreased rates of infection or postoperative fluid collections. In contrast, use of drains may result in increased rates of infections of the abdominal cavity by tracking infection from the skin and can cause bleeding and pain **[10].** Peritoneal drains also disturb mobilization, which is mainstay for the success of ERAS.

In the current study, TAP block used in 9 cases (60%) of ERAS group and not used in conventional group. Usage of TAP blocks have shown a reduction in immediate intra- and post-operative opioid use in open abdominal surgeries as opiate used in 5 case (33.3%) of ERAS group and used in 15 case (100%) of conventional group. There was significant difference between the two groups that agrees with **Peltrini *et al.* [11]** who published sixteen and data showed that TAP block is a safe procedure associated with a significant reduction in the pain score at rest [$p < 0.05$] and on coughing or movement [$p < 0.05$] at 24 h after surgery and a significant decrease in morphine consumption in the TAP block group the day after surgery [$p < 0.001$]. Despite, administration of TAP blocks, remains controversial in Gynecologic Oncology. **Bisch *et al.* [12]** showed that 120 patients were included in the analysis, 82 patients had a TAP block, while 38 did not. After adjusting for potential confounders, there was no difference in median 24 hours opioid consumption (p=0.29) between patients receiving TAP block compared to those without.

According to Huang *et al.* [13], early enteral intake was associated with a faster return of bowel function and a decreased length of stay without increase in postoperative complications.

In the current study, the patients were instructed to begin oral intake as soon as possible in the ERAS group and presence of bowel sounds and movement in the conventional group where the mean time until the first oral intake was 7 ± 1.6 hours in ERAS group and

20.4 ± 2.7 hours in conventional group and there was significant difference between the two groups without any draw backs on the patients. These results are in agreement with what **Renaud *et al.*** [14], and to **Minig *et al.*** [15]**,** 89% of the patients in the Early oral feeding (EOF) group were able to resume solid oral intake on the first postoperative day, with no statistically significant difference in the incidence of nausea and vomiting compared to Traditional Oral Feeding (TOF) group. 58% of the patients in the TOF branch expressed their desire to resume oral feeding earlier. Also the mean level of overall postoperative satisfaction was significantly higher in patients who received EOF (P =<0.001). But, it is important to note that early feeding is associated with nausea, but not vomiting, abdominal distension or need for nasogastric tube use as reported by **Kalogera *et al.*** [16].

In this study the mean time until intestinal sounds resumption was 6.3 ± 1.5 hour in ERAS group and 14.6 ± 3.7 hours in conventional group, which was highly significant between the two groups. These results agree with **Boitano *et al.*** [17] but are in contrast to what **Charoenkwan *et al.*** [18] has published that there were no significant differences for the time of passage of flatus (P = 0.15).

In our study, early mobilization of patients was instructed where the mean time until first patient movement was 5.6 ± 0.6 hour in ERAS group and 20.4 ± 2.7 hours in conventional group where there was a significant difference between the two groups. This result is in agreement with the results of **Nikodemski *et al.*** [19] in their study where they found that post-operative early mobilization on the day of surgery was achieved in 45% of the study patients group. On the other hand, none of the control group patients mobilized on the day of the operation (p < 0.0001). In contrast, **de Almeida *et al.*** [20] published that there were no differences between groups regarding clinical outcomes or complications related to the exercises.

In this study, early removal of urinary catheter was instructed where the mean time until remove was 5.2 ± 0.9 hours in ERAS group and 14.6 ± 3.7 hours in conventional group where there was a significant difference between the two groups. This result agrees with the results of **Vlug *et al.*** [21] who published that prolonged catheter use is linked to an increased rate of urinary tract infection. In an RCT which examined early removal (1 day) compared to standard removal (approximately 4 days) the prevalence of urinary tract infection was increased to 12% for those in the in standard group and was only 2% in the early removal group (p = 0.004).

Postoperative pain analgesia in the ERAS group, multi-modal analgesia consisted of acetaminophen or NSAIDs combined with acetaminophen and opiates can be used in breakthrough pain episodes not responding to analgesia for 2 hours. While, in the conventional group opiates analgesia with either NSAIDs or paracetamol only was used. In this study the number of patients needed opiates was 3 (20%) in ERAS group and 15 (100%) in conventional group where there was a significant difference between the two groups. These results are concordant with **Bergstrom *et al.*** [22] where they found that ERAS program participants compared to historical patients, ERAS patients required less narcotics. Despite this substantial reduction in narcotics, ERAS patients did not report more pain and in fact reported significantly less pain by postoperative day 3.**The pain score** of the patients in this study was assessed using the universal pain assessment tool for patients in the two groups. The scale is scored from 1 to 10 in which (1) mean no pain at all and (10) mean severe agonizing un-tolerable pain. The mean pain score was 1.9 ± 0.6 for ERAS group and 3.5 ± 0.5 for conventional group with significant difference between the two groups. This is supported with findings of different studies [23].

Hospital stay reduction is also one of the goals of ERPS protocols where in this study the mean length of stay was 2.3 ± 1 days in ERAS group and 3.3 ± 1 days in conventional group indicating significant difference between the two groups of the patients. These results are in agreement with the results published by **Wijk *et al.*** [24], which showed that hospital stay was significantly reduced in the study population after introducing the ERAS protocol from a mean of 2.6 ± 1.1 days to a mean of 2.3 ± 1.2 days (p = 0.011). The proportion of patients discharged at 2 days was significantly increased from 56% pre-ERAS to 73% after ERAS (p = 0.012). In contrast to study by **Bergstrom *et al.*** [22] where there were no differences in length of stay.

In this study, postoperative ileus rate was 0% in ERAS group vs. 33.3% in conventional group with significant difference between the two groups. These results agree with the results published by **Boitano *et al.*** [25], which showed that ileus rate was significantly lower in the ERAS group (2.8% vs. 15.7% control group, p < 0.001).

In this study postoperative other complications rate was 13.3% % in ERAS group vs. 46.6% in conventional group with significant difference between the two groups. These results disagree with **Marx *et al.*** [26] which showed that there was no difference in the overall complication rate. Our results agree with meta-analysis study included 16 randomized controlled trials that compared ERAS pathways to conventional postoperative care. ERAS pathways resulted in a significant reduction in complications [27]**.**

In this study hospital readmission was 2 cases (13.3%) in ERAS group vs. 5 cases (33.3) % in conventional group with no significant difference between the two groups. This agrees with study of **Bergstorm *et al.*** [28] who reported that there were no differences in length of stay (5 days) or 30-day readmission rates (9.5% vs 11.9%, p = 0.54) between ERAS and historical patients.

CONCLUSIONS

Implementation of the policy of enhanced recovery after surgery (ERAS) in gynecologic oncology was associated with an overall improvement in postoperative outcomes. The implementation of a successful ERAS policy lead to early movement, early postoperative feeding, earlier return of bowel movement, decreasing time of urinary catheterization, decreasing incidence of DVT and paralytic ileus, pain control with reduced opioids use, reducing length of hospital stay with decrease of readmission and morbidity rates and early return to normal daily activity.

Current study recommends that we should exert efforts for implementation of the ERAS perioperative care policy and it should be considered as standard of gynecological oncology surgery care.

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