International Journal of Psychosocial Rehabilitation, Vol. 24, Issue 10, 2020
ISSN: 1475-7192

Improvement of Outcome after implementation Of Enhanced Recovery After Surgery For Gynecologic/ Oncology Surgery

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Abstract

Background:*Enhanced recovery programs (ERPs) are evidence- based protocols designed to improve functional rehabilitation after surgery. They lead to improvement in patient outcomes while reducing hospital length of stay. This study aimed to compare surgical outcomes between women undergoing major gynecologic surgeries before and after implementation of ERS protocols.* ***Methods:****This erceptive observationally study was carried out on patients attending Zagazig university hospitals for elective gynecological oncologic surgeries in the period between August 2018 and August 2019. This study included 54 patients who were presenting for elective gynecological oncologic surgeries were classified into 2 groups. Group 1 include 27 patients were exposed to the ERAS protocol regimen for the pre, intra and postoperative care. Group 2 include 27 patients were exposed to the conventional care known in the literature. Clinical outcomes and compliance were obtained using the ERAS Interactive Audit System.****Results:*** *This study the mean of length of stay was found to be 38.29±4.95 hours in group A and 68.44±6.5 hoursin group B indicating significant difference between the two groups of the patients (p value <0.001), Postoperative complications rate was 7.4% in group A vs. 11.1% in group B with no significant difference between the two groups (p value <0.05).****Conclusions:*** *Systematic implementation of ERAS gynecologic oncology guidelines across a healthcare system improves patient outcomes and saves resources.*

Key words:*Enhanced recovery programs (ERPs), Improvement of outcome, Gynecologic oncology.*

I. INTRODUCTION

The enhanced recovery after surgery concept emerged as a multimodal approach directed at optimizing the patient experience, standardizing perioperative care, and improving surgical outcomes[1].

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Enhanced recovery programs (ERPs) are evidence- based protocols designed to improve functional rehabilitation after surgery. They lead to improvement in patient outcomes while reducing hospital length of stay.

Over the previous decade, important progress has been achieved in both benign and oncologic gynecologic surgery, including further refinement of minimally invasive surgery, introduction of the sentinel lymph node concept, individualized lymphadectomy for endometrial cancer, and adopting of optimal cytoreduction to no visible residual disease for patients with ovarian cancer. These practice changes have reduced surgical morbidity, shortened recovery, and improved oncologic outcomes [2- 4].

Key components of enhanced recovery protocols include comprehensive patient education including patient goals and 1) expectations around surgery, 2) markedly diminished duration of the fasting period preoperatively and active use of oral carbohydrate and electrolyte fluids up until presentation for surgery,3) multimodal pain control regimen including nonopioid analgesic agents and regional anesthesia to reduce opioid use, and 4) quick resumption of a normal diet and activity. Trials of these protocols have been performed in a myriad of surgical settings and have shown, almost uniformly, improved results such as decreased length of stay and improved surgical outcomes [5,6] .

Individual components of perioperative care have increasingly been evaluated from an evidence-based perspective, resulting in the creation of so-called "enhanced recovery" pathways (ERP)[7].This study aimed to compare surgical outcomes between women undergoing major gynecologic surgeries before and after implementation of ERS protocols.

II. METHODS:

After obtaining approval of the ethics committee, This erceptive observationally study was carried out on patients attending Zagazig university hospitals for elective gynecological oncologic surgeries in the period between August 2018 and August 2019. This study included 54 patients who were presenting for elective gynecological oncologic surgeries were classified into 2 groups. Group 1 include 27 patients were exposed to the ERAS protocol regimen for the pre, intra and postoperative care. Group 2 include 27 patients were exposed to the conventional care known in the literature. Patients' age was ranged from 23-80 years in both groups with mean age of 51.25 years in group (A) and 56.55 years in group (B) without significant difference between the two groups. Also the mean GA and mean Hb concentration and PLT count in both groups were with insignificant difference between the two groups.

The work was carried out for studies involving humans in accordance with the World Medical Association's Code of Ethics (Helsinki Declaration).

Inclusion criteria: Patients who are referred for hysterectomy and/or pelvic or para-aortic lymphadenectomy for gynecological cancer (cervical, endometrial, ovarian cancer, or other including borderline ovarian tumor, endometrial hyperplasia and cervical intraepithelial neoplasia). **Exclusion criteria:**Patients with bowel resection. Patientswith intestinal injuries.Post-operative admission to intensive care unit (ICU) for more than one night.

All patients were subjected to thorough clinical evaluation with emphasis on: Full medical and surgical history ,General clinical examination, Laboratory investigations;according to the type of the cancer and suggestions of committee of Multidisciplinary team of zagazig gynecological and obstetrics unit: complete blood count (CBC), liver function tests (LFT), kidney function test (KFT), coagulation profile, random blood sugar (RBS), viral markers (HBV, HCV), tumor markers (CA 125, CEA, CA 199, Alpha Fetoprotien) [in cases of ovarian cancer]. Radiological studies: pelvi-abdominal ultrasound, MRIwith dye examination on the pelvis, chest x-ray and electrocardiogram, CT with contrast, upper and lower endoscopy and cystoscopy if indicated.

Techniques:

Day before surgery:

The study group decrease the fasting period, Give fluids rich in carbohydrates. The control group complete fasting up to 12 hours for solids and fluids from the time of the operation. No carbohydrate loading preoperatively.

Day of surgery:

The study group preemptive analgesia: multimodal analgesic includes; celecoxib 200mg PO, gabapentin 600mg PO, and acetaminophen 975mg PO. Bowel preparation: no systemic use of mechanical bowel preparation, rectal enemas still used. Prewarming the patient with blankets prior to entering the operating room to increase core temperature prior to surgery.

The control group no preemptive analgesia is given preoperatively. Mechanical bowel preparation is used.

Intra operative

All patients of both groups used general anesthesia . 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 removal it 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 2 g 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 4mg IV once plus droperidol 0.625 mg IV once half hour before incision, and granisetron 0.1 mg IV once half hour before incision closure. Use opiates as needed.

The study group: After incision closure; injection of bupivacaine at incision site.Injection of ketorolac 15 mg IV at the end of the operation for patients tolerate it. Trying to limit prophylactic peritoneal drains . Use minimally invasive surgical techniques..

Postoperative:

All patients of both groups early strolling, Administration of thromboembolism prophylaxis; Enoxaparin 40 mg SC with sequential compression devices. patient receive clear fluids in the recovery room , as tolerated and receive a soft diet on POD 1. IV fluids decreased to 40 ml/h on POD 0 and stopped at 8:00 AM on POD 1. Early removal of catheter as early as possible, immediately after surgery or after 6 hours postoperatively.

The patient get out of the bed a minimum 2 hours on the day of the surgery and then 6 hours per day until discharge.

Antibiotics: is given after 12 hours from exiting the surgery. Pain score is assessed using Universal Pain Tool after complete recovery. The patient discharge criteria included tolerating diet, ambulatory, and pain well controlled on oral analgesia.

Statistical Analysis:

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

III. RESULTS:

This study showed that age was distributed as 51.25±16.1 and 56.55±11.94 respectively and BMI 26.09±2.19 and 25.54±2.36 respectively with no significant difference between studied groups, regarding parity majority of both group were >2 with no significant difference between groups. **Table (1)**

There was no significant association or difference between groups (P value considered significant if p value < 0.05). **Table (2)**

There was no significant association or difference between groups. **Table (3)**

There was no significant difference between groups regard HB or PLT as they were distributed as 11.82±0.56 and 11.74±0.71 & 236.74±30.3 and 248.96±38.9 respectively. **Table (4)**

ERP group were significantly shorter regard Catheterization period, Operative time, Movement time, Audible int sound, Oral intake and Time until discharge (P-value considered significant if p value < 0.05) . **Table (5)**

ERP were significantly needed less opiate. **Table (6)**

Pain was significantly lower at ERP group but satisfaction was significantly higher at ERP group. (P value is significant if < 0.05). **Table (7)**

Table (1):Demographic and obstetric characters distribution between groups

			ERP Group (N=27)	Control Group (N=27)	t/ X^2	P
Age			**51.25±16.1**	**56.55±11.94**	**-1.373**	**0.176**
BMI			**26.09±2.19**	**25.54±2.36**	**0.894**	**0.376**
Gravidity	**Virgin**	**N**	**6**	**0**	**6.94**	**0.074**
		%	**22.2%**	**0.0%**		
	P 0	**N**	**5**	**5**		
		%	**18.5%**	**18.5%**		
	1-2	**N**	**3**	**4**		
		%	**11.1%**	**14.8%**		
	>2	**N**	**13**	**18**		
		%	**48.1%**	**66.7%**		
Total		**N**	**27**	**27**		
		%	**100.0%**	**100.0%**		

Table (2): Pathology finding distribution between groups

			Group		Total	X^2	P
			ERP Group (N=27)	**Control group (N=27)**			
Pathology	**Cervical**	**N**	4	2	6	0.87	0.66
		%	14.8%	7.4%	11.1%		
	Endometrial	**N**	10	10	20		

		%	37.0%	37.0%	37.0%		
	Ovarian	N	13	15	28		
		%	48.1%	55.6%	51.9%		
Total		N	27	27	54		
		%	100.0%	100.0%	100.0%		

Table (3): Complications and outcome distribution among the two groups

			Group		Total	X^2	P
			ERP Group (N=27)	Traditional group (N=27)			
Complications	None	N	25	24	49		
		%	92.6%%	88.9%%	90.7%		
	Complicated	N	2	3	5	0.22	0.63
		%	7.4%	11.1%	9.3%		
ICU admission	-VE	N	27	26	53		
		%	100.0%	96.3%	98.2%		
	+VE	N	0	1	1	1.01	0.31
		%	0.0%	3.7%	1.8%		
Re admission	-VE	N	27	27	54		
		%	100.0%	100.0%	100.0%	0.00	1.00
	+VE	N	0	0	0		
		%	0.0%	0.0%	0.0%		
Total		N	27	27	54		

	%	100.0%	100.0%	100.0%		

Table (4): Lab parameters distribution between groups:

	ERP Group (N=27)	**Traditional group (N=27)**	**t**	**P**
HB level	11.82±0.56	11.74±0.71	0.443	0.660
PLT count *1000	236.74±30.3	248.96±38.9	-1.357	0.181

Table (5): Different Times distribution between groups:

	ERP Group (N=27)	**Control group (N=27)**	**t**	**P**
Catheterization period	8.0±1.46hr	18.03±3.1hr	-15.129	<0.001**
Operative time	189.25±31.7min	198.55±21.89min	-1.6243	0.0987
Movement time	11.59±1.11hr	24.4±1.3hr	-38.684	<0.001**
Audible int sound	8.37±1.27hr	18.55±1.25hr	-29.628	<0.001**
Oral intake	9.44±1.15hr	20.51±1.39hr	-31.749	<0.001**
Time until discharge	38.29±4.95hr	68.44±6.5hr	-19.148	<0.001**

Table (6): Opiate needed distribution between groups:

	ERP Group (N=27)	**Control group (N=27)**	**t**	**P**
Opiates need	1.37±0.54	4.9±1.05	-15.445	0.00**

Table (7): Pain and satisfaction scores distribution between groups

	ERP Group (N=27)	Control group (N=27)	t	P
Pain score	2.88±0.75	5.07±0.82	-10.153	<0.0001
Satisfaction score	7.18±0.73	5.81±0.73	6.844	<0.0001

IV. DISCUSSION

In this study, Ageranged from 23-80 years with mean age of 51.25±16.1 years in group A and age ranged from 23-80 years with a mean age of 56.55±11.94 years without any significant difference between the two groups.

Also, The mean body mass index BMI **(**calculated as weight [kg]/[height (m)]2) was 26.09±2.19 for group A and 25.54±2.36 for group B and there was no significant difference between the two groups.

In the pre operative laboratory investigations , in this study were done with special emphasis on HB % and Plt count where according to blood hemoglobin concentration the mean HB concentration was 11.82±0.56 gm % for group A and 11.74±0.71 gm % for group B with no significant difference between the two groups and according to the platelet count the mean was 236.74±30.3 for the group A and 248.96±38.9 for group B and also there was no significant difference between the two groups.

In the preoperative period the patients of the study group was instructed to omit food intake 6 hours prior to the operation and the drinking was continued up to 2 hours before the surgery as the current practice guidelines for obstetric anesthesia from the American Society of Aneshesiologists (ASA)unlike the control group where food and drinks was prohibited up to 6 hours before the operation was done.

The type of cancers are distributedamong the two groups with ovarian cancer 48.1% (13 patient) in group A VS 55.9% (15 patient) in group B , cervical cancer 14.8% (4 patient) in group A VS 7.4% (2patient) in group B and endometrial cancer was the same in both groups 37.0% (10 patient).

The pre and postoperativecare in both groups was given antibiotics as guidelines to prevent wound infections as discussed by **Morrill et al, [8] and Nelson et al, [9]** and the thrombo-prophylaxis also was administrated as guidelines discussed by **Gadducci et al, [10]** with no data was drawn to compare between both groups for any significant difference.

According to**Han-Geurts et al, [11]**in gynecology and gynecologic oncology populations, early enteral intake was associated with a faster return of bowel function and a decreased length of stay without an increase in postoperative complications.

In the current study,the patients were instructed to begin oral intake as soon as possible in the study group and after removal of NG tube and presence of bowel sounds and movement in the control group where

the mean time until the first oral intake was 9.44±1.15 hours in group A and 20.51±1.39 hours in group B and there was very significant difference between the two groups without any draw backs on the patients, these results were in agreement with what **Renaudet al, [12]**The proportion of patients who resumed a diet before the second postoperative day was significantly higher in the ERAS group (94% vs. 81%, P = 0.01),also according to **Minig et al, [13],** eighty-nine percent of the patients in the 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 with TOF group (Table 3). Fifty-eight percent 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 =<.001. but according to **Kalogera et al, [6]**, It is important to note that early feeding is associated with a higher rate of nausea, but not vomiting, abdominal distension, or nasogastric tube use. Patient satisfaction with control of vomiting in one series was over 90% with early feeding despite a higher incidence of nausea in the enhanced recovery group.

In this study intestinal movement resumption and hearing intestinal soundswere the most important concerns where the mean time until intestinal sounds resumption was 8.37±1.27 hour in group A and 18.55±1.25 hours in group B where was a very significant difference between the two groups , these results were also concordant with what **Kalogeraet al, [6]** has published that Women in the case group had a 1-day earlier return of bowel function compared with the historic controls (P,.001).but these are in contrast towhat **Macmillan, [14]**has published earlier in his study where he found that first bowel movement reported (2.8 6 0.7 versus 2.2 6 1.2 days, P 5 .07), early versus late feeding groups, respectively, were similar between groups. Also this study is in contrast to what **Minig et al, [13]**has published that there were no significant differences in term of intestinal bowel recovery between the groups except for the time of passage of flatus, which was faster in patients who received EOF (P = 0.034).

Traditional teaching and intuition suggests that early mobilization decreases pulmonary complications such as atelectasis, decreases insulin resistance, prevents loss of muscle mass, and shortens the interval to return of bowel function. Conversely, immobilization is associated with increased risk of thromboembolism and decreased oxygen delivery to tissues as discussed by **Vlug MS et al, [15] .**In the current study, early mobilization of patients was instructed where the mean time until first patient ambulation was 11.59±1.11 hour in group A and 24.4±1.3 hours in group B where was a significant difference between the two groups, the results drawn from this study were in agreement was the results of **Nikodemskiet al, [16]** in their study where they have found that Post-operative early mobilisation on the day of surgery was achieved in 45% of the study group patients. On the other hand, none of the control group patients mobilised on the day of the operation (p<0.0001). In regards to eating post-operatively, 13% of patients in the study group compared to 1% in the control group opted to eat the first meal on the day of surgery. This rate was increased on the first postoperative day, with 79% of the study group compared to 8% in the control group eating their first meal (p < 0.0001).

Postoperative pain analgesiain the study group multi-modal analgesia consisting of NSAIDs combined with Paracetamol with Opiates used in breakthrough pain episodes not responding to analgesia for 2 hours in addition of local infiltration of the incision line with bupivacaine was used while in the control group Opiates analgesia with either NSAIDs or Paracetamol only was used. In this study the mean amount ofopiatesused was 1.37±0.54 ampoule morphine in group A and 4.9±1.05 ampoule morphine in group B where was a significant

difference between the two groups. These results were concordant with what**Kalogera et al, [6]** had published where they have found that women in the case group received significantly less opioids (80% reduction in first 48 hours after return to room) with an increase in the use of scheduled nonsteroidal anti-inflammatory drugs, acetaminophen, and tramadol. Patient-controlled analgesia was infrequently required in the women in the case group compared with the historic controls (women in the enhance recovery group: 27 [33%] compared with women in the historic control group:77 [98.7%], P,.001).

The pain score of the patients in this studywas assessed used the universal pain assessment tool for patients in the two groups where the scale is from (1 to 10) in which (1)mean no pain at all and (10) mean severe agonizing un-tolerable pain, where the mean pain score was 2.88±0.75 for group A and 5.07±0.82 for group B with significant difference between the two groups. These results was like those has published earlier that ERPS patients reported lower maximum pain scores in the post-anesthesia care unit (three vs six P< 0.0001) and on postoperative day 1 (four vs six; P= 0.002) these results are in contrast to what **Minig et al, [13]**has published thatpostoperative median pain score the was similar between groups. Also, these results are in contrast to what has published that immediate postoperative pain scores did not differ significantly between patients in the case group and patients in the control group on postoperative day 0 (2.4 compared with 2.6, P=.24).

In the current study, Satisfaction scores of the patients was done using a scale from 0-10 where (0) was not satisfied at all and (10) was very satisfied from which the overall mean satisfaction score was concluded to be7.18±0.73 in group A and 5.81±0.73 in group B where there was a significant difference between the two groups. These results were concordant with what was published by **Ottesen et al,[17]** where in their study, 92.7% of the patients stated that their hospitalization was “as expected,” “easier than expected,” or “much easier than expected.” Most patients were satisfied with their hospital LOS; only a small percentage of patients of less than 5% (2/41) reported feeling “a little pressure put on them toward discharge,” among which one was discharged on postoperative day 8. In a 0 to 10 scale of “how acceptable the program and advice had been,” the median score was 10. Patient satisfaction rates have universally been reported high ranging from 75% to 95% across studies. Also in the study by **kalogera et al, [6] ;**patient satisfaction was high in all studied aspects of perioperative care including patient education, quality of care during hospitalization, the discharge process, and pain management with 90-90% rating satisfaction as excellent or very good. In contrast towhat **Polle et al, [18]** has concluded in their study where they stated that "Total patients' satisfaction score was comparable in both groups (50.4 and 49.8 of a potential 80 points in the FT and TC groups, respectively; p = 0.84)".

Hospital stay reductionis also one of the goals of ERPS protocols where in this study the mean of length of stay was found to be 38.29±4.95 hours in group A and 68.44±6.5 hours in group B indicating significant difference between the two groups of the patients and these results were in agreement with the results that published by **Nelson et al, 2017 [9]** which showed a decrease of the median LOS (2.5 days [0 to 11] vs. 3 days [1 to 14]; p=0.002) and proportion of discharged patient at target LOS of 2 days (45% vs. 24%; p=0.002).

V. CONCLUSIONS

Implementation of enhanced recovery pathways (ERAS) in gynecological oncologic surgery was associated with an overall improvement in postoperative outcomes. The implementation of a successful ERAS

program lead to early ambulation, early oral intake, earlier return of intestinal sounds, decreasing time of catheterization, decreasing incidence of PONV and IONV, acceptable pain management with reduced opioids, reducing length of stay with stable readmission and morbidity rates, good patient satisfaction, and substantial cost reduction.

VI. Recommendation

Current study recommends tomake systematic efforts that are needed for active diffusion of the ERAS perioperative care model and should be considered standard of care in gynecological oncologic surgery.

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