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ORIGINAL ARTICLE:

Assessment of Enhanced Recovery Protocols in Elective Cesarean Sections

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ABSTRACT

Background: One of the procedures that is carried out the most frequently globally is the Caesarean section (CS). The introduction of enhanced recovery (ER) for planned CS to enable earlier discharge is receiving a lot of interest. The aim of this study was to assess the enhanced recovery protocols versus the standard care in elective cesarean section and to introduce enhanced recovery protocols to Zagazig University maternity hospitals and Al-Ahrar Teaching Hospital to decrease hospital stays and opioid use.

Methods: This non-randomized controlled trial included patients attending Zagazig University Hospitals and Al-Ahrar Teaching Hospital for elective caesarean sections in the period between September 2018 and August 2019. The number of patients included in the study was 96 patients classified into two groups. A general clinical examination, laboratory investigations, and radiological studies were done. A Cesarean section for all patients of both groups was performed.

Results: Regarding the opiates used during the process of recovery for pain control in both groups, the overall mean of both groups was 0.25 ± 0.342 amp. and 1.156 ± 0.463 amp. in group (a) and group (b) respectively, where there was a significant statistical difference between the two groups.

Conclusions: When enhanced recovery after surgery (ERAS) protocols are used in elective cesarean sections, patients treated with these protocols benefit from earlier ambulation, earlier resumption of intestinal sounds, earlier oral intake tolerated, decreased catheterization time, decreased amounts of opiates used and their obvious side effects, an improved satisfaction score, and decreased pain.

Keywords: Cesarean, Enhanced, Recovery, Protocols.

INTRODUCTION

One of the procedures that is carried out the most frequently globally is the Caesarean section (CS). There is evidence that an increasing percentage of all CS in several nations comes from planned or "elective" operations. Despite efforts to reverse this trend, the rate of elective CS keeps increasing. Compared to spontaneous delivery, birth by CS is associated with a longer hospital stay, and the majority of women stay in the hospital for at least two days following a scheduled CS surgery [1].

Therefore, the perioperative management of childbirth by preplanned CS and postoperative care constitutes a significant care and financial burden for the countries. It's important to note that the majority of women having these elective surgeries are young and healthy. They not only have the ability to heal rapidly, but the arrival of a new child offers a special motivation to do so. This group of women might perhaps be discharged from the hospital the day following surgery, which would reduce their need for inpatient care by more than half and save obstetric units money [2].

The introduction of enhanced recovery (ER) for planned CS to enable earlier discharge is receiving a lot of interest. An improved recuperation regimen after elective surgery is not a novel idea. Enhancing recovery aims to improve patient care in a number of areas, enabling early

discharge without compromising patient happiness or the standard of treatment [3].

This broad acceptance is undoubtedly a result of the accumulating evidence that the use of improved recovery programs results in advantages including lower morbidity, shorter hospital stays, and a quicker return of patients to routine activities [4].

This study aimed to assess the enhanced recovery protocols versus the standard care in elective cesarean section and to introduce enhanced recovery protocols to Zagazig University maternity hospitals and Al-Ahrar Teaching Hospital to decrease hospital stays and opioid use.

METHODS

Technical design:

This non-randomized controlled trial included patients attending Zagazig University Hospitals and Al-Ahrar Teaching Hospital for elective caesarean sections in the period between September 2018 and August 2019. The number of patients included in the study was 96 patients classified into 2 groups: the study group that included 48 patients who were exposed to the means of enhanced recovery protocols, and the control group, which included 48 patients who were treated with the standard care known in the literature. The study involved pregnant women who are attending the assigned hospitals for elective caesarean sections and have the following criteria: primigravida or multiparous women, age between 18 and 35 years old, with a body mass index (BMI) less than 30, medically free, having a single intrauterine viable pregnancy, of gestational age between 34 w+0d and 42 w+0d. We excluded patients aged less than 18 or above 35 with any maternal medical disease (diabetes mellitus, hypertension, cardiac diseases, thyroid diseases, etc.) that was either chronic or pregnancy complicated. Exclusion criteria also included multiple gestations, any evidence of active maternal or fetal infections, a non-sound postoperative history of the previous section as postpartum hemorrhage (PPH), a history of pulmonary embolism, deep venous thrombosis (DVT), wound sepsis, rupture of the uterus, ectopic pregnancy or myomectomy, and a complicated pregnancy as placenta previa or placenta accreta.

Methods:

Full medical and surgical histories were taken from the patient, with special emphasis on the obstetric, gynecological, and menstrual histories. A general clinical examination and laboratory investigations were done. Radiological studies, such as a trans-abdominal 2D ultrasound examination, were done to assure the dating of the patient, ascertain the gestational age of the fetus, and exclude any abnormalities. A cesarean section for all patients in both groups was performed. On the day before surgery for the study group, we minimized the fasting period, i.e., no solid food after midnight (or six hours preoperatively) was allowed.

Hydrating well was guaranteed during the fasting period (drinking two glasses of water prior to going to bed and two glasses of water prior to travelling to the hospital). Carbohydrate loading (optional) was done through the ingestion of apple juice prior to travelling to the hospital. On the day of surgery, pain prophylaxis was achieved by taking 1 gram of acetaminophen orally two hours before surgery.

Thromboprophylaxis was given to patients with a high risk of DVT formation. Intraoperatively, spinal, or general anesthesia was used according to the patient's condition. Antibiotic prophylaxis was administered according to known protocols. We avoided routine administration of the NG tube and its removal at the end of the operation if it were used. We continued using pre-warmed fluids during the operation to maintain normothermia throughout the operation (36–38 degrees). We used short-acting anesthetic agents when possible. Dexamethasone (8 mg IV) and ondansetron (4 mg half an hour before incision) were administered as prophylaxis for postoperative nausea and vomiting. Using minimally invasive surgical techniques and closure of the skin by subcuticular sutures, we also maintained euvolemia, prevented hyper- or hypovolemia from happening, and depended mainly on colloids. Long-acting opiates were minimized and I.V. ketorolac (15–30 mg) at the end of the operation was administered. Injection of subcutaneous tissue, skin, and fascia with local bupivacaine was done. We removed Foley's catheter at the end of the operation, or maximally 3 hours postoperatively, and delayed the cord clamping of the baby. Postoperative inpatient VTE risk assessment and thromboembolism prophylaxis were done by first ambulation within 3 hours postoperatively for at least 6 hours per day and following the standard VTE prophylaxis regimen. The patient was allowed to drink just after exiting the OR, and food was allowed for 4 hours postoperatively. Acetaminophen, 1 gm orally or IV every 8 hours, and after 8 hours from the last dose of analgesia, intraoperatively, were administered. NSAIDS (Voltaren) were given either orally, IM, or rectally twice daily if oral intake was not tolerated. In breakthrough pain (pain not responding to treatment for two hours), morphine 2mg up to 10mg was given IM or IV. For nausea and

vomiting, ondansetron (4mg IV) and/or promethazine (0.625mg IV) were given. Early removal of the catheter and early ambulation were done. Antibiotics were given after 12 hours of exiting the OR, according to the known regimens. The patient was discharged from the hospital within 24 hours postoperatively after changing the wound dressing. Regarding the control group, the steps were the same as the study group, but the differences were in the following: fasting from all night before the operation and food or fluid was allowed; no removal of the catheter after the operation ended but it was removed after 12 hours; oral intake of food was 12 hours after the end of the procedure; drinking after at least 6 hours; the use of only one drug as an analgesic, either NSAIDS, ketorolac, or opiates; ambulation after 6 hours; intraoperative use of crystalloids for fluid replacement; no subcutaneous injection of local anaesthetic at the end of the operation; and the patient was discharged from the hospital not before 24 hours post-operatively

Administrative considerations:

The Declaration of Helsinki, the World Medical Association's code of ethics for studies involving humans, guided the conduct of the study. The patient provided written informed permission in order to participate in the trial. After getting Institutional Review Board (IRB) permission, the radiodiagnosis and pathology departments of Zagazig University Hospitals gave their approval for the research's implementation.

Statistical Analysis:

Data were analyzed by Statistical Package of Social Science (SPSS), software version 24.0 (SPSS Inc., 2016). Continuous data were presented as the mean ± SD if normally distributed or the median (range) if not normally distributed. Normality was checked by the Shapiro test. Categorical data were presented by count and percentage. The chi-squared test is used to discover if there is a relationship between two categorical variables. An independent-samples t-test is used to determine if a difference exists between the means of two independent groups on a continuous dependent variable. A p-value <0.05 indicates a significant difference, and a p-value >0.05 indicates a non-significant difference.

RESULTS

Regarding the type of anesthesia used, the percentage of patients taking spinal anesthesia to those taking general anesthesia was 68.75%: 31.25% and 72.9%: 27.1 % for groups (a) and (b), respectively, as shown in Table 1. Regarding intraoperative and postoperative nausea and vomiting (IONV and PONV, respectively), there is a significant statistical difference between the two groups (Table 2). Regarding the time until first postoperative oral intake was tolerated, the mean time for first oral intake in minutes was 142.083 ± 41.69 min and 375.938 ± 23.94 min for groups (a) and (b), respectively, where a significant statistical difference was found between the two groups. Regarding the time until intestinal sounds were first heard, the mean time in minutes was 249.271 ± 31.72 min and 460 ± 54.24 min for groups (a) and (b), respectively, where there was a significant statistical difference between the two groups. Regarding the first ambulation performed by the patients in both groups, the mean time in minutes showed a significant statistical difference between the two groups (Table 3).

Regarding the opiates used during the process of recovery for pain control in both groups, the overall mean of both groups was 0.25 ± 0.342 amp. and 1.156 ± 0.463 amp. in groups (a) and (b), respectively, where there was a significant statistical difference between the two groups. The mean amount of opiates used in patients undergone spinal anesthesia in both groups was 0.152 ± 0.265 amps and 1.043 ± 0.391 amps in groups (a) and b), respectively, where there was a significant statistical difference between the two groups. The mean amount of opiates used in patients undergone general anesthesia in both groups was 0.467 ± 0.399 amps and 1.462 ± 0.519 amps in groups (a) and b), respectively, where there was a significant statistical difference between the two groups. Within the same group of study, there was a significant statistical difference in the amount of opiates used as analgesics between the patients undergone spinal and general anesthesia where in group (a), the mean amount was 0.152 ± 0.265 amps and 0.467 ± 0.399 amps after spinal and general anesthesia, respectively. In group (b), the mean amount was 1.043 ± 0.391 and 1.462 ± 0.519 after spinal and general anesthesia respectively (Table 4).

Regarding the postoperative pain scores that were measured using the international pain assessment tool chart in both groups of the study, the overall mean showed a significant statistical difference between the two groups. The mean pain scores between the patients under spinal anesthesia in both groups were 2.36 ± 0.82 and 4.91 ±0.78 for group (a) and group (b), where a significant statistical difference was found between the two groups. The mean pain scores between the patients under general anesthesia in both groups were 2.87 ± 0.74 and 5.77 ± 0.6, where we found a significant statistical difference between the two groups. Within the same group of patients studied, a significant statistical difference was found in the

pain scores between patients under spinal and general anesthesia (Table 5).

Regarding the pre-discharge satisfaction score in both groups of the study, the overall mean was 8.229 ± 0.72 and 5.646 ± 0.76 for groups (a) and (b), respectively, where a significant statistical difference was found between the two groups. The mean pre-discharge satisfaction scores between patients under spinal anesthesia in both groups were 8.39 ± 0.66 and 5.77 ±0.73 for group (a) and group (b), where a significant statistical difference was found between the two groups. The mean pre-discharge satisfaction scores between the patients under general anesthesia in both groups were 7.87 ± 0.52 and 5.31± 0.75 where a significant statistical difference between the two groups was found. Within the same group, a significant statistical difference was found in the pre-discharge satisfaction scores between the patients under spinal and general anesthesia in group (a). In group (b), a nonsignificant statistical difference was found between patients taking spinal and general anesthesia (Table 6).

Regarding the time of hospital stay, the mean time of hospital stay in minutes was 841.146 ± 112.54 min and 1356.25 ± 80.43 min in groups (a) and (b), respectively, where a significant statistical difference was found between the two groups. While the range of hospital stay in minutes was (660 min–1110 min) and (1125 min–1495 min) in groups (a) and (b), respectively (Table 7).

Table 1: Type of anesthesia used for patients for both groups and the percentage of each.

Type of anesthesia	Group (A)		Group (B)	
	No.	Percentage	No.	percentage
Spinal anesthesia	33	68.75%	35	72.9%
General anesthesia	15	31.23%	13	27.1%

Table 2: PONV and IONV for both groups of patients

	Group (A)	Group (B)	p-value
PONV & IONV Mean ± SD	0.1667 ± 0.377	0.354 ± 0.483	<0.0366*

IONV: Intraoperative nausea and vomiting; PONV: Postoperative nausea and vomiting

*: Significant

Table 3: Time till 1st oral intake and audible intestinal sound and ambulation in minutes for both groups of patients

Time (minutes)	Group (A)	Group (B)	p-value
Time till first oral intake (Mean ± SD)	142.083 ± 41.69	375.938 ± 23.94	<0.0001*
Time till audible intestinal sound (Mean ± SD)	249.271 ± 31.72	460.0 ± 54.24	<0.0001*
Time till first ambulation was performed (Mean ± SD)	197.187 ± 35.29	389.27 ± 35.04	<0.0001*

*: Significant

Table 4: Mean number of opiates in ampoules used for both groups of patients and for each group taking spinal and general anesthesia.

Opiates ampoules	Group (A)		Group (B)		p-value
Overall opiate use (Mean ± SD)	0.25 ± 0.342		1.156 ± 0.463		<0.0001*
Opiates used in spinal anesthesia group (Mean ± SD)	0.152 ± 0.265	p-value =0.0022*	1.043 ± 0.391	p-value =0.0042*	<0.0001*
Opiates used in general anesthesia group (Mean ± SD)	0.467 ± 0.399		1.462 ± 0.519		<0.0001*

*: Significant

Table 5: Mean pain scores for both groups of patients and for each group taking spinal and general anesthesia.

Pain scores	Group (A)		Group (B)		p-value
Overall pain scores (Mean ± SD)	2.52 ± 0.825		5.146 ± 0.799		<0.0001*
Pain score in spinal anesthesia group (Mean ± SD)	2.36 ± 0.82	p-value =0.0491*	4.91 ±0.78	p-value =0.0009*	<0.0001*
Pain score in general anesthesia group (Mean ± SD)	2.87 ± 0.74		5.77 ± 0.6		<0.0001*

*: Significant

Table 6: Mean pre-discharge satisfaction scores for both groups of patients and for each group taking spinal and general anesthesia.

	Group (A)		Group (B)		p-value
Overall satisfaction scores (Mean ± SD)	8.229 ± 0.72		5.646 ± 0.76		<0.0001*
Satisfaction score in spinal anesthesia group (Mean ± SD)	8.39 ± 0.66	p-value =0.0088*	5.77 ±0.73	p-value =0.0586	<0.0001*
Satisfaction score in general anesthesia group (Mean ± SD)	7.87 ± 0.52		5.31± 0.75		<0.0001*

*: Significant

Table 7: Mean hospital stay and range for both groups of patients.

Hospital stays in minutes	Group (A)	Group (B)	p-value
Range	660 – 1110 minutes	1125 -1495 minutes	<0.0001*
Mean ± SD	841.146 ± 112.54	1356.25 ± 80.43	

*: Significant

DISCUSSION

The term "accelerated patient recovery" (ERAS) refers to an approach that incorporates multiple evidence-based perioperative treatment components. It delivers a repeatable improvement in the standard of care while standardizing perioperative management. Although surgical specialties and institutions have different ERAS procedures in place, the fundamental ideas are the same. These concepts call for preoperative, intraoperative, and postoperative interventions. It tackles the typical factors, such as insufficient analgesia, a poor recovery of bowel function, and a delayed return to ambulation, that cause patient recovery following surgery to be delayed and hospital stays to be prolonged [5].

Many features of current standard postoperative treatment for patients having cesarean deliveries are already in line with those of ERAS. The majority of respondents to a poll of obstetric anesthesiologists in the UK performed in 2013 endorsed the idea of ERAS for cesarean birth, and the majority were either exploring or were in the process of adopting an ERAS protocol at their institutions [2].

In the operating room, the patients were given spinal or general anesthesia either due to patient preference or due to anesthetist preference according to the patient's general conditions, where 68.75% of the patients (33 patients) have taken spinal anesthesia and 31.23% of the patients (15 patients) taken general anesthesia in group (A) and 72.9% (35 patients) have taken spinal anesthesia and 27.1% (13 patients) have taken general anesthesia in group (B). The patients were given IONV prophylaxis and PONV prophylaxis, where ERAS protocol regimen was given for the patients in the study group and conventional regimen in the control group, and the mean was 0.1667 ± 0.377 (8 of 48 patients) in group (A) suffering from IONV and PONV and 0.354 ± 0.483 (17 of 48 patients) in group (B), with a

significant difference between the two groups of patients. These results were concordant with what Kumar et al. published earlier in their study, where they also concluded that using ondansetron is better than metoclopramide in preventing PONV with fewer side effects [6].

Both groups received antibiotics throughout the pre- and post-operative treatment as recommended to avoid wound infection and co-morbidities as discussed by Smaill et al., and thromboprophylaxis was also administered as per the guidelines discussed by Ducloy-Bouthors et al., but no data was drawn to compare the two groups for any significant difference [7, 8].

In the current study, the patients were instructed to begin oral intake as soon as possible in the study group and after 6 hours in the control group as conventional, where the mean time until the first oral intake was tolerated was 142.083 ± 41.69 min in group (A) and 375.938 ± 23.94 min in group (B), and there was a very significant difference between the two groups without any drawbacks for the patients. These findings were in line with prior research by Lee et al., who found that when the ERAS procedure was used on patients who did not have negative outcomes, early postoperative resumption of nourishment rose from 17% to 57% ($p<0.001$) in their study [9].

In this study, intestinal movement resumption and hearing intestinal sounds were the most important concerns. The mean time until intestinal sound resumption was 249.271 ± 31.72 min in group A and 460.0 ± 54.24 min in group B, where there was a very significant difference between the two groups of patients. These findings were in line with earlier research by Guo et al., who examined the effects of delayed oral feeding versus early oral feeding. They discovered that early oral feeding facilitated a quicker return to a regular diet, bowel movements, flatus, and bowel sounds ($P<0.001$ for all). "There are no overt benefits to holding food and fluids after a cesarean. Early oral feeding does indeed have some immediate advantages" **[10].**

In our study, early mobilization of the patients was instructed, and the mean time until 1st patient ambulation was 197.22 ± 35.29 min in the study group and 389.27 ± 35.03 min in the control group, where there was a significant difference between both groups. The results drawn from this study were in agreement with the results of Lee et al.'s study, where they discovered that when ERAS procedures were used on patients having elective cesarean sections, the percentage of early ambulation rose from 33% to 51% [9].

For postoperative pain analgesia in the study group, we used multi-modal analgesia consisting of NSAIDs combined with paracetamol, with opiate analgesia used in breakthrough pain episodes not responding to analgesia for 2 hours in addition to local infiltration of the incision line with bupivacaine, while in the control group we used opiate analgesia with either NSAIDs or paracetamol only. In this study the mean amount of opiates used was 0.25 ± 0.342 ampoule morphine in group (A) and 1.156 ± 0.463 ampoule morphine in group (B) where conventional analgesia was used and there was significant difference between the two groups and mean amount of opiates used in patients undergone spinal anesthesia in both groups was 0.152 ± 0.265 amps and 1.043 ± 0.391 amps in group (a) and group (b) respectively where there was significant statistical difference between the two groups and the mean amount of opiates used in patients undergone general anesthesia in both groups was 0.467 ± 0.399 amps and 1.462 ± 0.519 amps in group (a) and group (b) respectively where there was significant statistical difference between the two groups and within the same group of study there was significant statistical difference in the amount of opiates used as analgesics between the patients undergone spinal and general anesthesia where in group (a) the mean amount was 0.152 ± 0.265 amps and 0.467 ± 0.399 amps after spinal and general anesthesia respectively. In group (b), the mean amount was 1.043 ± 0.391 and 1.462 ± 0.519 after spinal and general anesthesia, respectively. These findings were similarly in line with those of Lee et al., who reported that while use of multimodal analgesics rose from 5% to 87%, opioid intake considerably dropped from 13.1 mg of morphine to 7.7 mg **[9].** According to Adesope et al., in their published study, local anesthetic wound infiltration significantly decreased opioid consumption at 24 h [mean difference −9.69 mg morphine equivalents, 95% confidence interval (CI), −14.85 to −4.52] and also stated that "opioid consumption was reduced in patients who did not receive intrathecal morphine but not in those who received intrathecal morphine" **[11].**

The pain score of patients in this study was assessed using the universal pain assessment tool for patients in both groups, where the scale is from 1 to 10, where 1 means no pain at all and 10 means severe agonizing untolerable pain. The mean pain score was 2.52 ± 0.825 for group A and 5.146 ± 0.799 for group B, with a significant difference between the two groups. There was also a significant difference in the pain scores between patients taking spinal and general

anesthesia in both groups, indicating the superiority of spinal anesthesia over general anesthesia in reducing postoperative pain scores. These findings were similar to those Elgohary et al. reported earlier regarding the pain score in their comparison of accelerated postoperative recovery to standard perioperative care in elective colorectal surgery, where they also discovered a substantial difference between the two research groups [12].

Hospital stay reduction is also one of the goals of ERAS protocols. In this study, the mean hospital stay time was found to be 841.146 ± 112.54 min with a range from 660 min (11 hours) to 1110 min (18.5 hours) in group (A) and 1356.25 ± 80.43 min with a range from 1125 min (18.75 hours) to 1495 min (24.97 hours) in group (B), indicating a significant difference between the two groups of patients. These results were supported by those published by Pilkington et al., which showed a decrease in the range of admission length from 3 to 6 days pre-implementation of ERAS protocols to 1–5 days post-implementation, with an average of 2.5 days after implementation of those protocols [13].

CONCLUSIONS

When enhanced recovery after surgery (ERAS) protocols are used in elective cesarean sections, patients treated with these protocols benefit from earlier ambulation, earlier resumption of intestinal sounds, earlier oral intake tolerated, decreased catheterization time, decreased incidence of PONV and IONV, decreased amounts of opiates used and their obvious side effects, an improved satisfaction score, and decreased pain. We recommend using ERAS for women who come into our hospitals for elective cesarean sections and recommending further research into how well these protocols work for women who come in for emergency cesarean sections.

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