Original Investigation

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Enhanced Recovery After Surgery (ERAS) Protocol Versus Standard Care in Elective Cesarean Delivery: A Prospective Randomized Controlled Trial

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ABSTRACT

Objective: Enhanced recovery after surgery (ERAS) protocols are designed to accelerate postoperative recovery, improve maternal comfort, and reduce complications in cesarean deliveries. Evidence regarding their effectiveness in elective cesarean sections in our country remains limited.

Methods: This prospective, open-label, randomized controlled trial was conducted at our hospital between October and December 2022. A total of 84 pregnant women (≥37 weeks, American Society of Anesthesiologists physical status I-II) scheduled for elective cesarean delivery were randomized equally to either the ERAS protocol (n=42) or standard care (n=42). The primary outcome was the 24-hour postoperative visual analog scale (VAS) pain score. Secondary outcomes included 48-hour VAS score, time to first passage of flatus, and postoperative nausea. Time to oral intake and time to first mobilization were recorded as process measures reflecting protocol adherence.

Results: As expected from the ERAS protocol design, oral intake [4.00 h (4.00-5.00) vs. 13.00 h (11.00-14.75)] and mobilization [4.00 h (4.00-5.00) vs. 6.00 h (5.00-6.00)] occurred significantly earlier in the ERAS group ($p<0.001$), reflecting protocol adherence rather than independent clinical effects. The ERAS group also experienced earlier breastfeeding initiation [3.00 h (2.00-4.00) vs. 5.00 h (4.00-6.00), $p<0.001$] and earlier first passage of [7.00 h (6.00-9.00) vs. 13.00 h (11.00-15.00), $p<0.001$]. Pain scores were significantly lower in ERAS patients at 24 hours [3.50 (2.00-4.00) vs. 6.00 (5.25-7.00)] and 48 hours [1.00 (1.00-2.00) vs. 3.00 (2.00-3.25)] ($p<0.001$). Postoperative nausea rates were comparable between groups (11.9% vs. 16.7%, $p=0.755$), and no major complications occurred.

Conclusion: The ERAS protocol for elective cesarean delivery significantly accelerates functional recovery, reduces postoperative pain, and facilitates earlier breastfeeding without increasing complications.

Keywords: Enhanced recovery after surgery, cesarean section, postoperative pain

INTRODUCTION

Background and Rationale

Cesarean delivery has become one of the most frequently performed major surgical procedures worldwide, with rates exceeding 30% in many countries (1). This rising trend poses new challenges in postoperative management, particularly in pain control, early mobilization, recovery of gastrointestinal function, initiation of lactation, and discharge planning. Inadequate postoperative care can lead to complications such as ileus, infection, thromboembolism, delayed mobilization, and prolonged hospitalization, ultimately increasing maternal morbidity and healthcare costs (2).

Enhanced recovery after surgery (ERAS) protocols were developed to accelerate postoperative recovery and reduce complications, and they have recently been adapted to obstetric surgery (3,4). ERAS represents a multidisciplinary, evidence-based approach spanning the preoperative, intraoperative, and postoperative periods. It emphasizes patient education, shortened fasting, early oral intake, multimodal non-opioid analgesia, prompt mobilization, and structured discharge planning (4-7). International studies and meta-analyses have shown that ERAS in cesarean delivery shortens hospital stay, reduces postoperative pain, decreases opioid use, facilitates early breastfeeding, and improves maternal satisfaction (7-9). Furthermore, large analyses report that ERAS protocols reduce hospital length of stay (LOS),

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by an average of 7.5 hours, lower pain scores by approximately 1.2 points, and provide a cost advantage without increasing complications (1,5,6).

Objectives

The primary objective of this study was to evaluate the effect of ERAS protocols on 24-hour postoperative pain scores. Secondary objectives included assessing their impact on functional recovery, maternal comfort, early breastfeeding in elective cesarean deliveries, gastrointestinal recovery, and the occurrence of complications, to determine the potential benefits and harms of ERAS compared with standard care.

METHODS

This prospective, open-label, randomized controlled trial compared an (ERAS) protocol with standard perioperative care in elective cesarean deliveries. The trial followed a parallel-group superiority design with a 1:1 allocation ratio and was conducted at the University of Health Sciences Türkiye, Gaziosmanpaşa Training and Research Hospital, Department of Obstetrics and Gynecology between October and December 2022. Ethical approval was obtained from the institutional Clinical Research Ethics Committee (decision no: 126, date: September 27, 2023), and all participants provided written and verbal informed consent in accordance with the Declaration of Helsinki. The trial was registered at ClinicalTrials.gov (Identifier: NCT07104890). No changes to the protocol or outcomes were made after study initiation.

Participants and Eligibility Criteria

Pregnant women 18 years of age or older, at or beyond 37 weeks' gestation, scheduled for elective cesarean delivery, and classified as American Society of Anesthesiologists (ASA) physical status I or II were eligible. Exclusion criteria included emergency cesarean delivery; obstetric complications (preeclampsia, placenta previa, placental abruption, fetal distress, or cord prolapse); chronic medical conditions; ASA III or higher; and refusal of spinal anesthesia. All cesarean sections were performed by experienced obstetric surgeons, and anesthesia was provided by trained anesthesiologists.

Outcomes

The primary outcome of this study was 24-hour postoperative visual analog scale (VAS) pain score.

Secondary outcomes included:

- 48-hour VAS score
- time to first passage of flatus
- postoperative nausea
- postoperative complications

Time to oral intake and time to mobilization were recorded as process measures reflecting ERAS protocol adherence, rather than independent clinical outcomes.

Interventions

In the ERAS group, preoperative fasting was minimized (solids up to 6 h, clear fluids up to 2 h before surgery).

Prophylactic antibiotics were administered 30-60 min before incision, and pneumatic compression stockings were applied. Multimodal non-opioid analgesia, consisting of paracetamol and diclofenac, was used. Postoperatively, gum chewing was initiated immediately; oral fluids were started at 2 h; solid foods were started at 4 h; the urinary catheter was removed at 4 h; and out-of-bed mobilization began at 6 h.

The control group received standard care: overnight fasting; delayed oral intake until the first flatus; urinary catheter removal at 6h; and analgesia with paracetamol and diclofenac, and pethidine if required. Concomitant care, including oxytocin infusion and routine postoperative monitoring, was identical in both groups.

Randomization and Blinding

Participants were randomized in a 1:1 ratio using simple randomization. A total of 84 identical slips of paper were prepared—42 labeled "ERAS" and 42 labeled "Control,"—and placed in an opaque container. The slips were thoroughly shuffled, and each participant randomly selected one slip to determine group allocation.

Allocation concealment was ensured because all slips were identical and the container was opaque; thus, group assignment remained unknown until a slip was drawn.

Implementation

Participant enrollment and randomization were performed by the study research nurse. Because the study was open-label, participants, care providers, and outcome assessors were not blinded; participants and care providers were aware of group allocation immediately after randomization.

Sample Size and Power Analysis

The sample size was calculated based on the primary outcome of 24-hour postoperative VAS pain scores. According to previous literature and clinical expectations, we assumed a mean difference of 2 points between the ERAS and control groups, with an estimated standard deviation (SD) of 1.5 points, corresponding to a Cohen's $d \approx 1.33$ (large effect size). Using a two-tailed $\alpha = 0.05$ and 80% power, the minimum required sample size was 18 participants per group (total 36). To enhance robustness and account for potential dropouts, we planned to enroll 42 participants per group (84 total).

Post-hoc power analysis based on the observed VAS pain score

differences confirmed very large effect sizes (Cohen's d≈2.44 at 24 h and 1.53 at 48 h), providing nearly 100% statistical power with the achieved sample size.

Statistical Analysis

All analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using the Shapiro-Wilk test within each study group. Variables that followed a normal distribution were expressed as mean ± SD and compared using the independent-samples t-test. Variables that were not normally distributed were expressed as the median (interquartile range, 25^{th}-75^{th} percentiles) and compared using the Mann-Whitney U test. Categorical variables were expressed as numbers (percentages) and compared using Fisher's exact test.

VAS scores at 24 and 48 hours were analyzed using a linear mixed-effects model with fixed effects for group, time, and the group × time interaction and a random intercept for each participant. The Holm correction was applied to adjust for multiple comparisons. Exact p-values are reported, except where p<0.001.

RESULTS

A total of 84 women were enrolled and randomized equally into the ERAS group (n=42) and the control group (n= 42). All participants received their assigned interventions and were included in the primary outcome analysis. There were no post-randomization exclusions or losses to follow-up.

Recruitment and follow-up occurred between October and December 2022, and the study concluded as planned.

Both interventions were delivered as intended, and adherence to the assigned protocols was complete. The ERAS group followed the enhanced recovery pathway with early oral intake, mobilization, and non-opioid multimodal analgesia, while the control group received standard care with delayed oral intake and conventional analgesia. Concomitant care, including oxytocin infusion and standard postoperative monitoring, was identical in both groups.

Baseline characteristics were similar between the groups, including age (27.6±4.87 vs. 27.90±5.13 years), body mass index (27.83±3.39 vs. 28.65±3.33 kg/m^2), ASA status, parity, and history of previous cesarean delivery (all p>0.05). Baseline characteristics were comparable between groups (Table 1).

Primary Outcome (Table 2)

The ERAS group had significantly lower postoperative pain scores at 24 hours than the control [3.50 (2.00-4.00) vs. 6.00 (5.25-7.00); p<0.001].

Secondary Outcomes (Table 2)

VAS scores at 48 hours remained significantly lower in the ERAS group [1.00 (1.00-2.00) vs. 3.00 (2.00-3.25), p<0.0019].

Time to first passage of flatus was significantly earlier in the ERAS group [7.00 (6.00-9.00) vs. 13.00 (11.00-15.00), p<0.001].

Postoperative nausea rates were similar between the groups (11.9% vs. 16.7%, p=0.755).

No major complications or readmissions were observed.

Time to initiation of breastfeeding was significantly earlier in the ERAS group [3.00 (2.00-4.00) vs. 5.00 (4.00-6.00), p<0.001].

Table 1. Baseline characteristics of ERAS and control groups

Variable	ERAS (n=42)	Control (n=42)	p-value
ASA score (n, %) I II	39 (92.9%) 3 (7.1%)	35 (83.3%) 7 (16.7%)	0.312
CS type Primary Secondary	11 (26%) 31 (73%)	7 (16%) 35 (83%)	0.426
Parity (n, %) 1 2 3 4 5 6	11 (26.2%) 12 (28.6%) 7 (16.7%) 6 (14.3%) 4 (9.5%) 2 (4.8%)	6 (14.3%) 7 (16.7%) 17 (40.5%) 6 (16.3%) 5 (11.9%) 1 (2.4%)	0.195
	Mean ± SD	Mean ± SD	
Age (years)	27.60±4.87	27.90±5.13	0.778
BMI (kg/m^2)	27.83±3.39	28.65±3.33	0.269

Note: Data are presented as mean ± SD for continuous variables and n (%) for categorical variables. Independent samples t-test was used for continuous variables and Fisher's exact test for categorical variables
ASA: American Society of Anesthesiologist, SD: Standard deviation, BMI: Body mass index, ERAS: Enhanced recovery after surgery

Table 2. Postoperative recovery outcomes in ERAS vs. control groups

Variable	ERAS (n=42)	Control (n=42)	p-value
Time to first Passage of flatus (hours)	7.00 (6.00-9.00)	13.00 (11.00-15.00)	<0.0001
VAS score (24 h)	3.50 (2.00-4.00)	6.00 (5.25-7.00)	<0.0001
VAS Score (48 h)	1.00 (1.00-2.00)	3.00 (2.00-3.25)	<0.0001
Time to oral intake (hours)	4.00 (4.00-5.00)	13.00 (11.00-14.75)	<0.0001
Time to first mobilization (hours)	4.00 (4.00-5.00)	6.00 (5.00-6.00)	<0.0001
Time to initiation of breastfeeding (hours)	3.00 (2.00-4.00)	5.00 (4.00-6.00)	<0.0001
Postoperative Nausea n (%)	5 (11.9%)	7 (16.7%)	0.755

Data are presented as median (IQR) used for non-normal continuous variables, and n (%) for categorical variables. Mann-Whitney U test was used for continuous variables and chi-square test for categorical variables
VAS: Visual analog scale, ERAS: Enhanced recovery after surgery, IQR: Interquartile range

Linear mixed-effects modeling demonstrated:

- Significant group effect [β=-3.119, 95% confidence interval (CI) -3.602 to -2.636, p<0.001],
- Significant time effect (β=-3.548, 95% CI -3.894 to -3.201, p<0.001),
- Significant group × time interaction (β=1.595, 95% CI 1.105 to 2.085, p<0.001).

These findings indicate that ERAS significantly reduced pain and altered the trajectory of pain reduction over time.

As expected from the ERAS protocol design, time to oral intake [4.00 (4.00-5.00) vs. 13.00 (11.00-14.75)], and time to mobilization [4.00 (4.00-5.00) vs. 6.00 (5.00-6.00)] were earlier (p<0.001). These reflect protocol adherence rather than independent treatment effects. After Holm correction, significant differences remained for VAS at 24 h and 48 h and for time to first flatus. Nausea and readmission were not significant after adjustment.

The differences in 24-hour and 48-hour VAS scores corresponded to very large effect sizes (Cohen's d≈2.44 and 1.53, respectively), confirming that the study achieved nearly 100% statistical power for the primary and key secondary outcomes despite the moderate sample size.

DISCUSSION

This randomized controlled trial demonstrated that the ERAS protocol significantly improved the primary outcome, 24-hour postoperative pain (VAS score), as well as secondary outcomes including 48-hour VAS score and time to first passage of flatus, compared to standard care. These findings indicate that ERAS accelerates multidimensional functional recovery, including improved pain control and gastrointestinal recovery (4,10,11). Oral intake and mobilization occurred earlier in the ERAS group, as dictated by the protocol, and reflected adherence to the enhanced recovery pathway rather than independent clinical effects.

The true clinical benefit lies in the observed enhancements in gastrointestinal function recovery and substantial reductions in postoperative pain which are in line with studies showing that ERAS protocols accelerate bowel recovery and reduce opioid use without increasing complications (4,12). These improvements strongly support maternal comfort, enhance functional recovery, and allow earlier engagement in newborn care.

The international literature supports our findings. ERAS protocols for cesarean delivery have been associated with reduced hospital LOS, decreased opioid use, and reduced overall costs. Mullman et al. (13) demonstrated that ERAS implementation led to significant reductions in opioid requirements, LOS, and hospital costs. Similarly, Bollag et al. (14) in the (subjective, objective, assessment, plan) consensus statement emphasized the role of ERAS in optimizing maternal outcomes. Pinho and Costa (5) reported that ERAS reduced LOS by 13.8 hours and decreased opioid use (standardized mean difference: -0.91) without increasing complications. Meng et al. (1) further showed a mean LOS reduction of 7.5 hours and a 1.23-point decrease in VAS scores, aligning with the magnitude of effects seen in our study.

In our trial, ERAS resulted in passage of flatus approximately 5.6 hours earlier, a 3.1-point reduction in the 24-hour VAS score, and a 1.5-point reduction in the VAS score at 48 hours compared with standard care. These correspond to very large effect sizes (Cohen's d≈2.44 at 24 h and 1.53 at 48 h), providing nearly 100% post-hoc power despite the moderate sample size. This confirms that the observed differences are both statistically robust and clinically meaningful. Our findings are consistent with meta-analyses showing that ERAS does not increase postoperative nausea, infection, or readmission rates (8). In our study, postoperative nausea was low and comparable between groups; this further supports that ERAS protocols do not compromise maternal comfort or safety. International evidence also corroborates our results: Grasch et al. (6) and Ubom et al. (15) demonstrated reduced opioid use and improved pain control in ERAS pathways, and Mundhra et al. (16) extended these benefits

even to emergency cesarean deliveries. Sultan et al. (17) have highlighted that standardized ERAS protocols optimize both maternal and neonatal outcomes (2). Additionally, simple ERAS interventions such as gum chewing have been shown to enhance bowel function recovery, which aligns with our postoperative management strategy (18).

From a clinical perspective, ERAS accelerates recovery across multiple dimensions, especially pain control, gastrointestinal function, and breastfeeding initiation, while supporting maternal-infant bonding. Earlier oral intake and mobilization primarily reflect protocol adherence and facilitate functional recovery, but they should be interpreted as expected effects of ERAS, rather than independent clinical benefits.

Study Limitations

This study has several limitations. It was conducted in a single tertiary center and had a moderate sample size, which may limit the generalizability of the findings. Although the initial sample size calculation targeted a medium effect size, an a priori calculation based on the primary VAS outcome, together with the very large observed effect sizes ensured nearly 100% statistical power, confirming the robustness of our findings.

Recruitment was time-limited, and long-term maternal and neonatal outcomes were not evaluated. Nonetheless, the prospective randomized design, standardized ERAS implementation, and objective outcome assessment are key strengths of the study. VAS scores were analyzed using a linear mixed-effects model to appropriately account for repeated measurements within individuals. This analysis confirmed a significant group effect, a time effect, and a group × time interaction, demonstrating that ERAS not only reduced pain levels but also altered the trajectory of pain reduction over time. These findings increase the robustness of the results compared with analyses at separate time points.

CONCLUSION

The ERAS protocol in elective cesarean delivery significantly accelerates postoperative functional recovery, reduces pain, and facilitates earlier breastfeeding without increasing complications. Implementation of ERAS pathways can enhance maternal comfort, support early mother-infant bonding, and reduce the length of hospital stay. Future multi-center studies with larger sample sizes and longer follow-up are warranted to validate these findings and assess long-term maternal and neonatal outcomes.

Ethics

Ethics Committee Approval: The study University of Health Sciences Türkiye, Gaziosmanpaşa Training and Research Hospital, Department of Obstetrics and Gynecology between October and December 2022. Ethical approval was obtained from the institutional Clinical Research Ethics Committee (decision no: 126, date: September 27, 2023)

Informed Consent: The all participants provided written and verbal informed consent in accordance with the Declaration of Helsinki.

Footnotes

Author Contributions: Surgical and Medical Practices - E.Y.I., E.S.C., S.S.; Concept - E.S.C., S.S.; Design - E.Y.I., H.B.B.; Data Collection and/or Processing -E.Y.I., H.B.B.; Analysis and/or Interpretation- E.Y.I., H.B.B., S.S.; Literature Search - E.Y.I., E.S.C.; Writing - E.Y.I., E.S.C.

Conflict of Interest: The authors have no conflicts of interest to declare.

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