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Initiation of an enhanced recovery protocol after cesarean delivery in the University Hospital in Serbia: a randomized comparison with existing management

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Abstract:

Background: *Enhanced Recovery After Surgery (ERAS) programs have been introduced in many areas of clinical practice in recent years, to improve the patient's recovery, increase patient satisfaction and shorten length of hospital stay. This study investigated feasibility of an ERAS protocol after cesarean delivery in a system where long-acting neuraxial opioids are not available.* **Materials and Methods:** *200 parturients were randomly assigned to either an enhanced recovery group (E) or a control group (C) receiving standard care. After delivery, parturients in group E received ultrasound-guided quadratus lumborum block. On the day of surgery, both groups received intravenous analgesia. On the first post-operative day, patients in group E transitioned to oral analgesics, while group C continued intravenous analgesia. On the second post-operative day, both groups received oral analgesics. Data collected included total dose of analgesics used in the first 24 hours; pain scores at rest and with movement; patient satisfaction; and length of hospital stay. Six weeks after surgery, parturients received a questionnaire for postpartum depression assessment.* **Results:** *Group E reported better pain control with lower pain scores in all times (at rest and with movement), which was statistically significant, as was patient satisfaction.* **Conclusion:** *Enhanced recovery protocols after cesarean delivery can improve postoperative recovery in low- and middle-income countries where long-acting neuraxial opioids may not be available. Protocols need to be individually tailored for each institution in coordination with the health care system.*

Key words: *obstetrics, cesarean section, analgesia, enhanced recovery after surgery.*

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Declarations of interest: none.

Main Points

- Long-acting neuraxial opioids (LANOs) are part of most enhanced recovery after cesarean (ERAC) delivery protocols.
- LANOs are not available in many low- and middle income countries.
- Bilateral quadratus lumborum block can substitute for LANOs in ERAC protocols.
- Parturients report lower pain scores and greater satisfaction with such protocols.

Introduction

Over the past two decades, several protocols have been developed and implemented to improve the post-operative recovery phase for surgical patients. These protocols have been developed primarily on a surgical specialty or procedure-specific basis, but have gradually expanded in scope to cover a range surgical procedures[1,2]. Such protocols have been broadly classified as Enhanced Recovery After Surgery (ERAS) protocols, but all aim to improve the surgical experience for the patient, to increase satisfaction, to improve pain control, speed recovery, and shorten hospital stays.

Cesarean delivery (CD) is one of the most commonly performed surgical procedures in much of the world, and there have been a number of efforts to apply ERAS protocols to post-cesarean recovery in recent years. Virtually all of these protocols share a common framework, beginning with patient education and the importance of patient participation in their own care. All incorporate the use of neuraxial anesthesia, post-operative non-steroidal analgesics anti-inflammatory medication, early ambulation and diet advancement[3,4].

While use of long-acting, lipophilic intrathecal or epidural opioids (as a part of multimodal analgesia) is foundational in most developed countries, in some areas such medications are either not available, or face restrictions on their use[5–8]. In Serbia, no long-acting opioids for neuraxial administration are available, with shorter acting medications such as fentanyl being the sole option. To compensate for this, nerve blocks such as the quadratus lumborum block (QLB) are sometimes used to prolong analgesia. We present a randomized trial of an ERAS protocol for cesarean section, tailored for a Serbian hospital with no long-acting lipophilic opioids available for neuraxial administration. As an alternative, bilateral quadratus lumborum block type 1 (QLB) performed with ultrasound (US) guidance was administered, and was compared to the existing postoperative management without the QLB.

Our hypothesis was that this ERAS protocol would provide better pain control (lower pain scores) and analgesic consumption after CD, compared to existing standard management. Earlier mobilization, earlier feeding and improved patient satisfaction were examined as secondary outcomes.

Methods

The trial was approved by the Clinical Center of Vojvodina Ethics Committee in February 2019, and registered on ClinicalTrials.gov (Protocol Record 0712960805046) in August 2019.

Development of the ERAS protocol was based on personal communications and assessment of practices in Serbian hospitals[4]. This survey revealed that some elements of ERAC interventions were in place in many hospitals, but no uniform protocol existed.

Enrollment in the protocol was begun on September 19, 2019. Two obstetricians screened patients who were scheduled for planned cesarean delivery near term. A week prior surgery, the ERAS protocol was explained to patients in the obstetric clinic by their obstetrician and they received a written instruction informing them of the procedures. Patients were prospectively randomized to two groups, group E (ERAS) and group C (Control). Exclusion criteria included any co-morbidities which could prolong length of stay (LOS), and included diabetes, hypertension, use of pain-relieving medications prior to delivery and patient refusal. One-hundred parturients were enrolled in each group (Figure 1).

The complete ERAS protocol (group E) is presented in Figure 2.

The complete control protocol (group C), usual post-cesarean management, is presented in Figure 3.

Two days prior to surgery, group E patients were assessed in the anesthesiology preoperative clinic where they were again informed by the anesthesiologist about the Protocol procedure. A minimum of 6 hours of fasting prior to surgery was enforced, with clear liquids allowed up to 2 hours prior to surgery.

Patients in group E were admitted to the hospital the morning of their scheduled delivery, had no bowel preparation and received acetaminophen 1g PO one hour before surgery. They received metoclopramide 10 mg intravenously (IV) and antibiotics (cephalosporine first or second generation) 30 minutes before the delivery.

Spinal anesthesia was performed with hyperbaric bupivacaine 12–15 mg and fentanyl 25 mcg with the parturient in the sitting position. Upon confirmation of an T4 level of anesthesia, surgery was begun. Intraoperative fluid therapy included Ringer's lactate solution 25–40 ml/kg of body weight. Phenylephrine boluses was used for hypotension correction. After delivery, patients received a slow oxytocin bolus IV (5 IU) and 10 IU was added to the intravenous infusion. Delayed cord clamping was per-

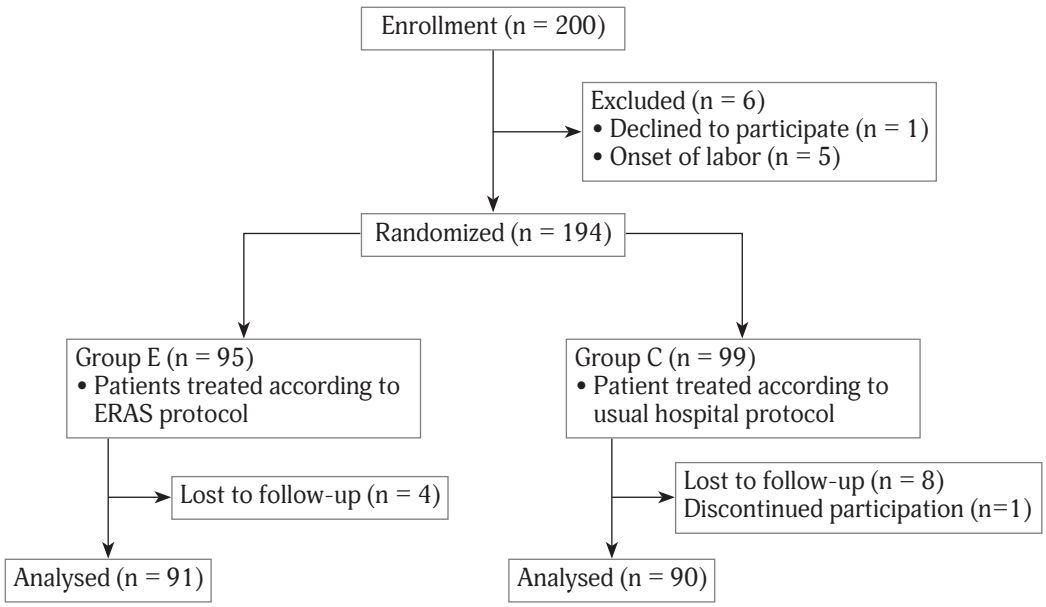


Fig. 1. Randomization Flowchart

formed, and the first skin-to-skin contact between mother and baby occurred in the operating room.

At the end of procedure (fascia closure) all patients received ketorolac 30 mg IV. After surgery was completed, group E patients received bilateral quadratus lumborum block type 1 (QLB) with bupivacaine 0.25% and dexamethasone (4 mg total) under the ultrasound guidance. The volume of bupivacaine (40–60 ml) was based on patient weight. Active warming in the operating room was not employed due to the short duration of surgery (under 30 min).

Postoperative analgesia was begun with NSAID (ketorolac 30 mg/6 h IV) in combination with acetaminophen 1 g/6 h IV. In case of severe breakthrough pain (VAS > 5/10), metamizole 2.5 mg IV or tramadol 50 mg IV was administered. Oxytocin 15–30 IU/l was continued in the intravenous infusion during first 24 h. All surgeries in group E were completed by 2 pm.

Deep venous thrombosis (DVT) prophylaxis with low molecular weight heparin (LMWH) was begun 12 h after delivery. First oral intake with clear fluids (tea or water) was begun in the late afternoon (7–8 h after the surgery), and in the evening (at 8 pm), early mobilization was actively encouraged. If the mother could walk with the assistance of the nurse, the urinary catheter was removed around 10pm; otherwise, it was removed on the first post-operative day.

Visual analog pain scores (VAS, 0–10) were recorded at rest and with movement at 3 h, 6 h, 12 h, and 24 h after completion of surgery. VAS scores were also recorded at rest and with movement daily on post-operative days (POD) 1, 2, and 3. Pain intensity was rated on a scale of 0–10, with 0 being no pain and 10 the worse pain imaginable.

Beginning POD 1, no IV fluids were administered and oral intake of liquids and solid food was encouraged. On POD 1–3, patients received scheduled oral analgesics: acetaminophen 1g PO/8 h and ibuprofen 600 mg/8 h PO. If the postoperative course was uncomplicated, breast feeding was satisfactory and the infant's neonatal course was normal, patients were discharged to home on POD 3.

The principle investigator (BP) contacted patients by phone one week postpartum for follow-up, to assess any residual pain. They were also asked to rate their in-hospital experience and their experience with postpartum nursing care (scale 0–10, with 0 being very poor and 10 being excellent). Patients were asked if they would repeat the same treatment for a subsequent cesarean delivery, and if they would recommend the program to her relatives and friends. They were asked for an explanation why they would or would not recommend the program.

At six weeks postpartum, all patients received and were asked to complete the 10-item Edinburgh Postnatal Depression Scale[5].

Patients in group C were admitted one day prior to surgery and were assessed by anesthesiologist in anesthesia clinic. They received DVT prophylaxis with LMWH 12 h before scheduled surgery, following standard practice in the facility.

On the morning of surgery, group C received a bowel preparation. Otherwise, preoperative management and intraoperative management of anesthesia in the operating room was identical to group E patients.

At the completion of surgery, scheduled postoperative analgesia was begun with NSAID (ketorolac 30 mg/6 h IV) in combination with acetaminophen 1 g/6 h IV. In case of

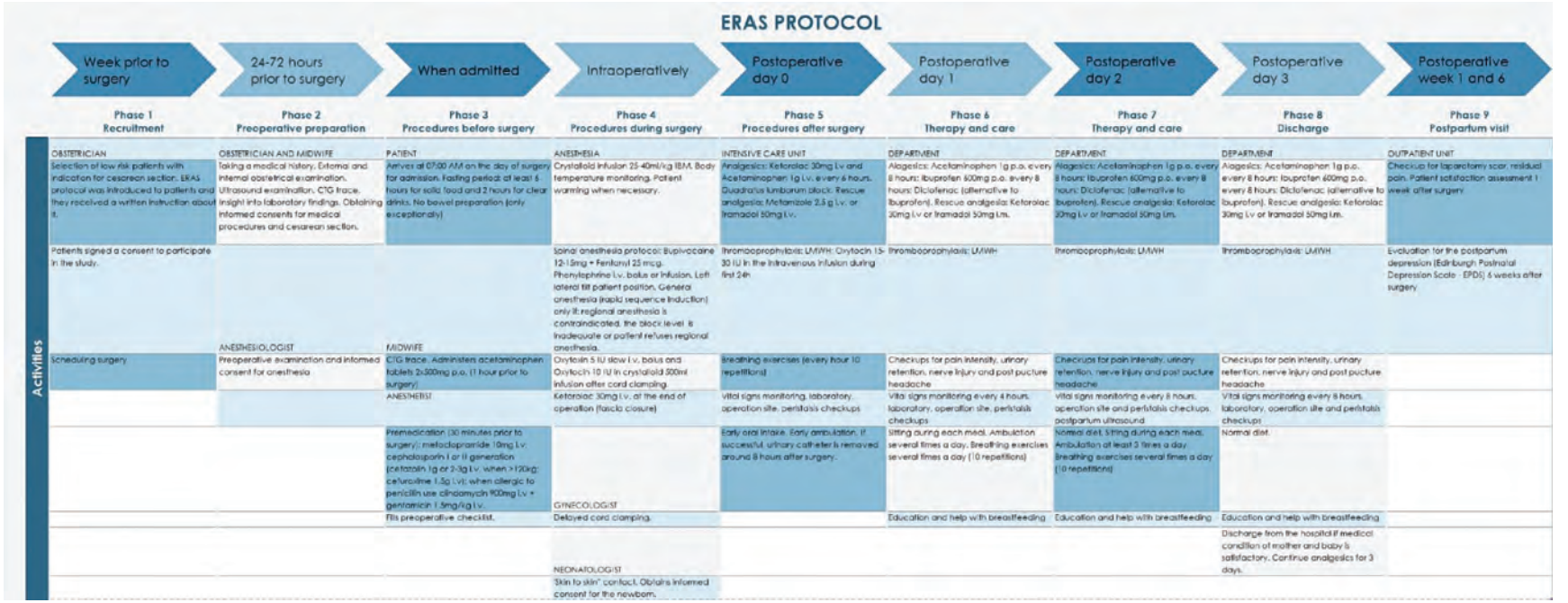


Fig. 2. Complete study protocol for ERAS group

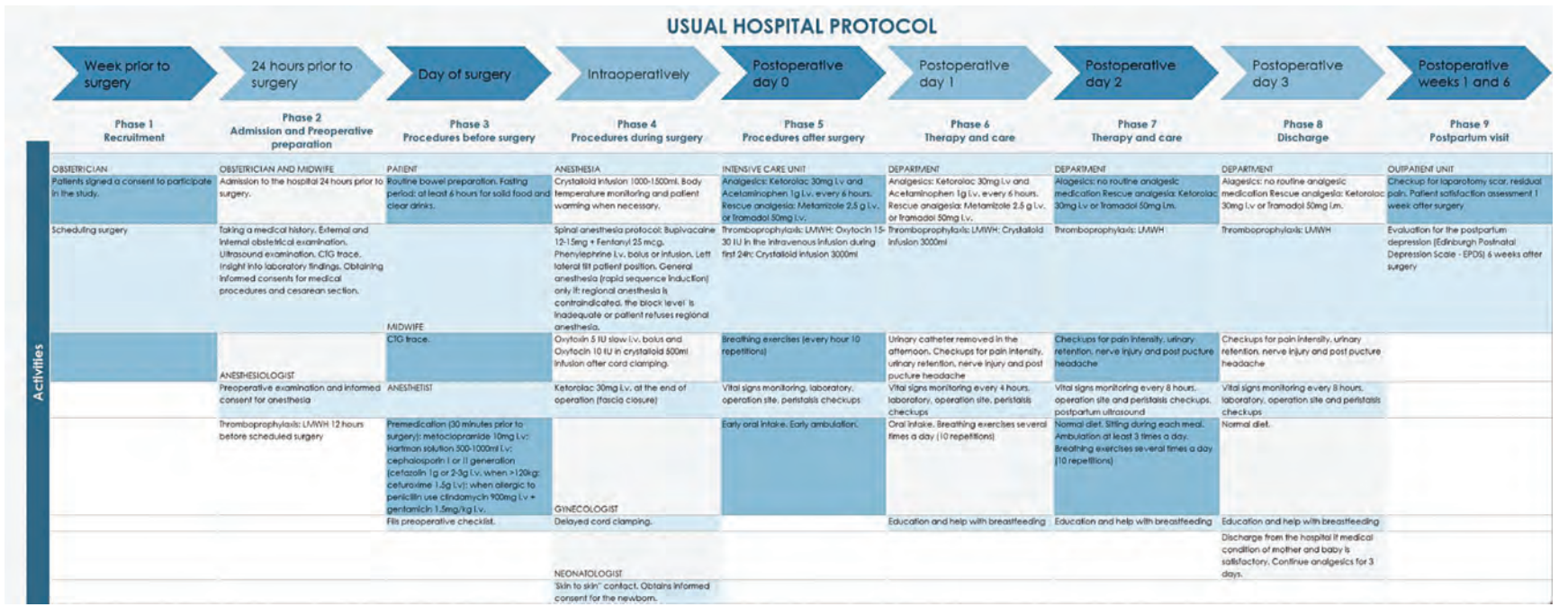


Fig. 3. Complete study protocol for control group

severe breakthrough pain (VAS > 5/10), metamizole 2.5 mg IV or tramadol 50 mg IV was administered. Oxytocin 15–30 IU/l was continued in the intravenous infusion during first 24 h. DVT prophylaxis with LMWH was resumed 12 h after delivery. First oral intake with clear fluids (tea or water) was begun in the late afternoon (7–8 h after the surgery), and in the evening (at 8 pm) was first mobilization actively encouraged. Pain intensity was rated on a scale of 0–10, with 0 being no pain and 10 the worse pain imaginable.

On POD 1, the urinary catheter was removed, and patients encouraged to take solid food; the IV infusion remained as support. Postoperative analgesia was the same as on the day of surgery (scheduled intravenous analgesics, ketorolac and acetominophen). On POD 2 and 3, scheduled analgesia was discontinued, and analgesia administered only upon request. If the postoperative course was uncomplicated, breast feeding was satisfactory and the infant's neonatal course was normal, patients were discharged to home on POD 3.

Postpartum follow-up oat one week and six weeks were the same as group E.

Statistical methods

The Microsoft Excel 2016 statistical package was used for data processing. Sample size calculation showed a minimum of 70 patients required in each group for parameters alpha = 0.05, beta = 0.2, with a power of 80%.

Numerical data are presented in the form of mean values (average values, median) and measures of variability (range of values, standard deviation), and attributive data were presented using frequencies and percentages.

The comparison of the values between two groups for numerical data was performed using the Student's t-test or non-parametric Mann – Whitney test, while the one-way analysis of variance (ANOVA) or non-parametric Kruskal-Wallis test were used to compare values between three or more data groups. Testing for the difference in frequency for attribute data was performed by applying the $\chi 2$ test. Univariate and multivariate regression analysis were used in order to examine the correlation between two or more characteristics. A value of $p < 0.5$ was considered statistically significant.

Results

In this study 199 subjects were enrolled of which 5 were excluded at the beginning of study because of the onset of labor or patient request, and 12 subjects did not complete the 6 weeks follow up. A total of 93 subjects in group E and 89 subjects in group C completed the protocol (Figure 3).

Table 1 shows demographic characteristics of both groups. The number of pregnancies ($p = 0.65$) and number of previous cesarean deliveries ($p = 0.06$) were similar between groups. On average, subjects were pregnant for the second time and had one previous cesarean section.

The two groups were comparable in level of education ($p = 0.24$), number of pregnancies ($p = 0.65$) and number of previous cesarean sections ($p = 0.06$). On average, subjects were pregnant for the second time and had one previous cesarean section.

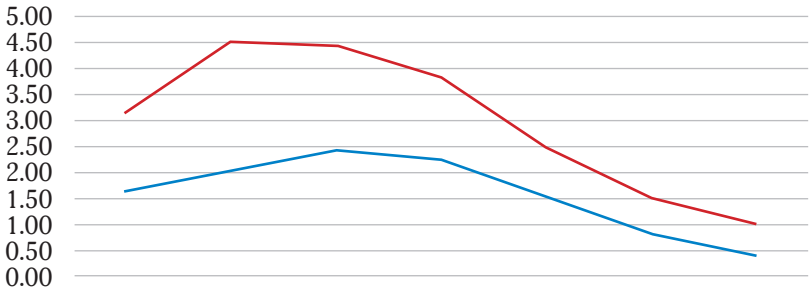
Aggregate VAS pain score was significantly lower at all measured time points in group E compared to group C, both at rest (1.60 vs. 3.01; $p = 0.02$, Figure 4) and with movement (3.07 vs 4.85; $p = 0.005$, Figure 5).

At rest, the average intensity of pain (PI) was the highest 6 hours after cesarean section (CS) in group C and 12 hours after CS in group E (PI 4.53 vs. 2.43, respectively). With movement, the average intensity of pain was highest 12 hours after CS in both group C and group E (PI 6.8 vs. 4.26, respectively).

Figure 6 shows the consumption of on-demand "rescue" pain medications during the first three postoperative days for each group. Patients in group C required a higher total number of doses of rescue pain medication than group E patients (355 vs. 170; $p < 0.001$). In first 24 hours more doses were used in group C than in group E (tramadol, 175 vs. 150; $p = 0.048$; metamizole, 18 vs. 6; $p = 0.005$, respectively). On POD1 more doses of tramadol were used in group C than in group E (158 vs. 13; $p = 0.000$), while on POD2 and POD3 there was no significant difference.

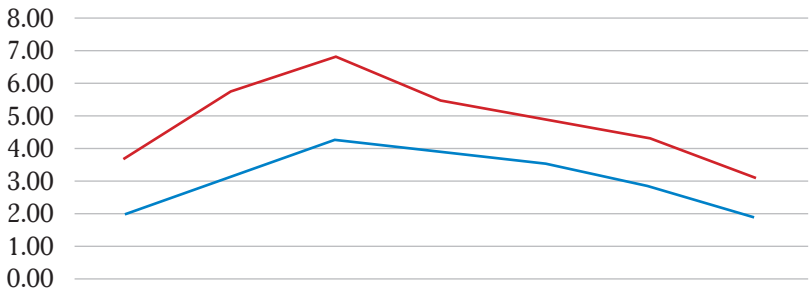
Table 1. Demographic characteristics of the subjects

	Mean		SD		Maximum		Minimum		P-value
	Group E	Group C	Group E	Group C	Group E	Group C	Group E	Group C	
Age (year)	33	31	4.6	5.3	42	43	22	18	0.15
Height (cm)	169	168	5.8	6.2	185	180	153	150	0.25
Weight (kg)	80	81	12.0	14.5	124	116	60	46	0.63
BMI (kg/m^2)	28	29	4.3	4.6	50	44	22	20	0.37



	3 h after CS	6 h after CS	12 h after CS	24 h after CS	POD1	POD2	POD3
Group E	1.66	2.07	2.43	2.26	1.49	0.83	0.42
Group C	3.17	4.53	4.46	3.84	2.48	1.55	1.02

Fig. 4. Aggregate Visual Analogue Pain scores (VAS, 0–10) reported by patients



	3 h after CS	6 h after CS	12 h after CS	24 h after CS	POD1	POD2	POD3
Group E	1.98	3.16	4.26	3.85	3.52	2.80	1.91
Group C	3.71	5.76	6.80	5.44	4.89	4.26	3.12

Fig. 5. Aggregate Visual Analogue Pain scores (VAS, 0–10) reported by patients

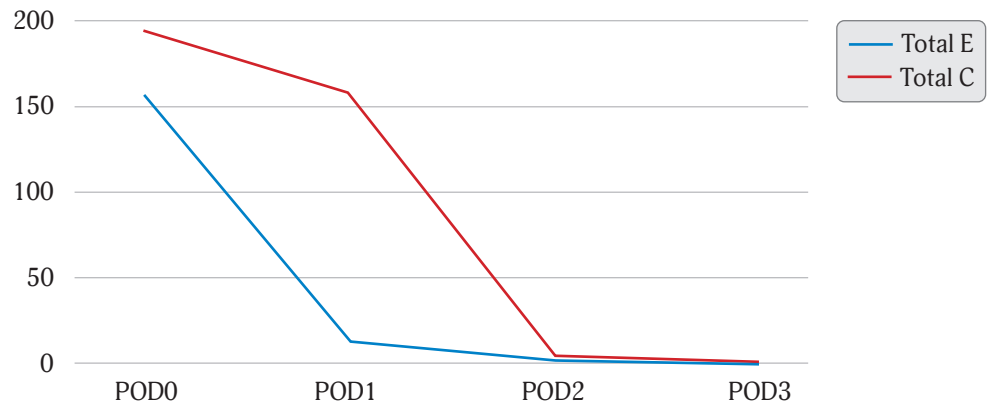


Fig. 6. Number of doses of on-request analgesic medications by postoperative days (Aggregate Group totals)

Oral intake started earlier in group E and was on average 7±1.7 vs. 8±1.8 (p = 0.02) hours after CS. Urinary catheter was removed on POD 0 in 83.5 % of subjects in group E compared to 1.0 % in group C (p = 0.000). All subjects in group E could urinate spontaneously after removing urinary catheter on POD 0. There were significantly more subjects in group E who had spontaneous bowel emptying on POD1, POD2, and POD3 (10.3 % vs. 2.04 %, p = 0.02; 26.31 % vs. 14.28 %, p = 0.04; 48.42% vs. 27.83 % p = 0.003). Fewer patients in the ERAS group reported difficulties with lactation (p = 0.002).

One week following CD parturients were contacted by phone by the principal investigator (BP). No significant differences between the groups were reported for residual pain.

Subjects were asked about their experience in operating theatre, overall satisfaction with treatment in hospital and home care service. Subjects in group E were more satisfied with experience in operating theatre ($p = 0.36$, Figure 7a) though this did not reach statistical significance. Satisfaction with overall hospital stay was significantly better in group E ($p = 0.02$, Figure 7b), while there was no difference in satisfaction with home care service ($p = 0.73$).

Six weeks following CD parturients were contacted by phone by BP and all were sent the 10-item Edinburgh Postnatal Depression Scale (range, 0–30). Tests were received back from 92 subjects from group E and 91 subjects from group C. This response six weeks after delivery showed subjects from group E had significantly lower scores (4.9 ± 3.7 vs 6.0 ± 3.9, $p = 0.025$) than group C, which indicates lower risk for development of a depressive episode.

Of the subjects in the ERAS protocol group, 96% stated they would repeat the same care in their next pregnancy and 98% would recommend this protocol to relatives and friends. The most common explanations subjects gave were: faster recovery, easier ambulation, less pain and shorter hospital stay.

Discussion

Multimodal analgesia is a very important part of an ERAS protocol. In our hospital, preservative-free morphine is not available for neuraxial administration[4]. Trans-versus abdominis plane block, QLB or wound infiltration are possible alternatives which may substitute and improve analgesia after surgery[10–15]. Our results with QLB showed significantly better pain control in group E compared with the control group, both at rest and with movement. In this regard, it is comparable to reports of ERAS protocols which use long-acting neuraxial opioids[11,16–17].

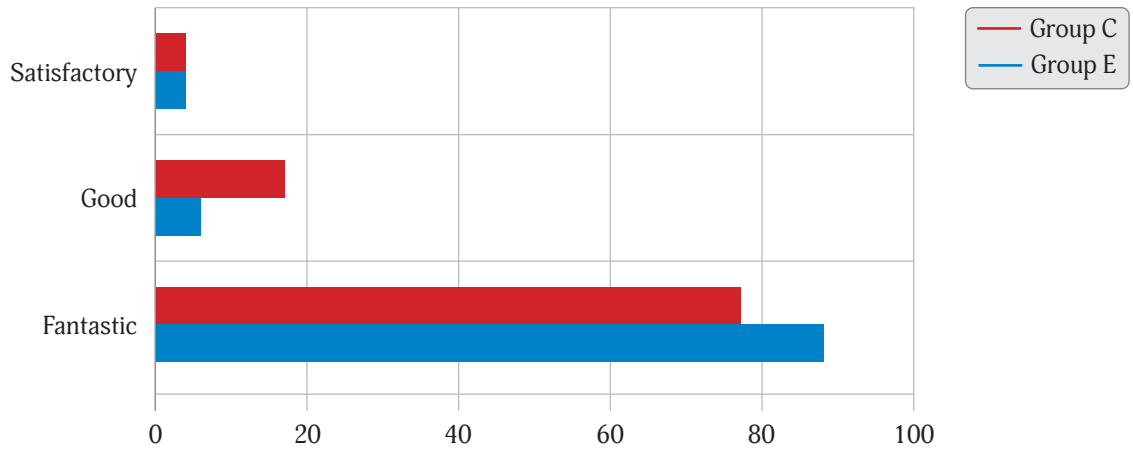


Fig. 7a. Maternal satisfaction with cesarean delivery (Number of patients)

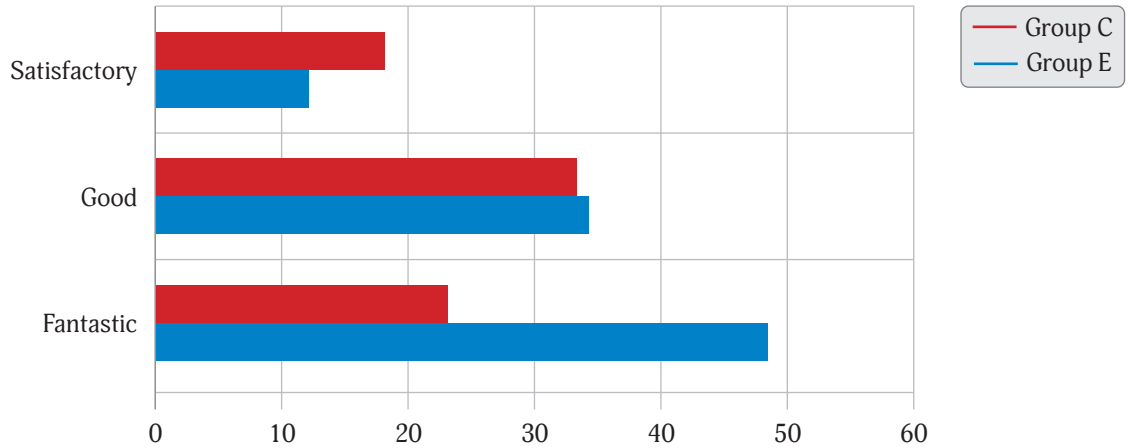


Fig. 7b. Maternal satisfaction with hospital course (Number of patients)

Multimodal analgesia has an important role, especially in middle- and low-income countries, where pain control is often less than optimal[16]. The combination of opioids, acetaminophen and NSAID's with peripheral nerve blocks (TAP, QLB or wound infiltration) has been reported to improve analgesia for the parturient[5,6]. Multimodal analgesia may also have the advantage that opioid consumption is usually significantly lower and therefore less likely to impact breastfeeding[11]. The combination of opioids, acetaminophen and NSAID's with peripheral nerve blocks (TAP, QLB or wound infiltration), without neuraxial opioids has been reported to be more comfortable for the parturient[6]. In the current study, during the first 24 hours, pain intensity measured with VAS did not exceed 2.43 (mean) at rest and 4.26 (mean) with movement in the ERAS group; this was significantly lower than in control group, similar to Pan et al's study[18]. In both groups, all analgesic medication was administered on a fixed schedule in the first 24 hours, the only difference being the QLB in the ERAS group. Despite identical analgesic protocols on POD 0, pain ratings were significantly lower in the ERAS group. Also of note, this enhanced analgesia in the QLB group persisted throughout the 72 hour duration of observations in this study.

Other aspects of postoperative recovery were also improved under the ERAS protocol in this series. Oral fluid intake started earlier in the ERAS group. The average time to first oral fluid intake was a mean of 7 hours, which is admittedly much later than in most developed countries[19,20]. Current practice in many hospitals in Serbia withholds oral intake until postoperative day 2 or 3, even POD 4 in some hospitals[4]. Solid food intake was allowed in both groups on POD 1, which is still an uncommon practice in Serbia[4]. Sahar et al[21] and Huang et al[22] showed that early oral intake has a positive influence, with earlier bowel movement, earlier breast feeding, better patient satisfaction and shorter length of stay. Patients in the ERAS group were encouraged to begin oral fluid intake upon arrival in the PACU, as contrasted with the control group, who first allowed oral intake 6 hours after PACU arrival. Junaidi et al[23] showed that early oral intake had no effect on PONV, but did promote earlier postoperative bowel function; spontaneous bowel empting was also significantly earlier in ERAS group in our series.

Early urinary catheter removal is considered very important in ERAS and several authors have showed its advantages compared to delayed catheter removal[24–26]. Our results showed that the urinary catheter could be removed on POD 0 in 83.5% of subjects in group E, compared to 1.0% in group C, and all patients in E group urinated spontaneously after removal. This positively impacted patient motion and satisfaction. Improved patient satisfaction is a very important goal of ERAS protocols and our results showed better overall satisfaction in group E than in group C; this resulted in higher reported recommendation levels among family and friends. This has also been previously noted in prior reporting about ERAS after cesarean delivery, as described by Bollag et al2[9] and Sultan et al[30].

Finally, poor pain control after cesarean delivery has been suggested as a possible factor in the development of post-partum depression in the mother's future life[27,28]; the relationship remains unclear but many recent studies consider this possible cause.

Conclusion

Implementation of an ERAS protocol in our hospital has resulted in more satisfied patients, with improved analgesia after cesarean delivery. In middle income countries, lower resource availability means cost containment for in-hospital stays and reduced analgesic consumption remain important goals. Future studies should focus on both patient education and health care system improvement.

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Початок протоколу прискореного відновлення після кесаревого розтину в університетській лікарні в Сербії: рандомізоване порівняння з існуючим лікуванням

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Анотація:

Довідкова інформація: *Програми покращеного відновлення після хірургічного втручання (ERAS) були запроваджені в багатьох сферах клінічної практики протягом останніх років, щоб покращити відновлення пацієнтів, підвищити задоволеність пацієнтів і скоротити тривалість перебування в лікарні. У цьому дослідженні вивчалася можливість застосування протоколу ERAS після кесаревого розтину в системі, де недоступні нейраксіальні опіоїди тривалої дії. Матеріали та методи: 200 породіль були випадковим чином розподілені до групи покращеного відновлення (E) або контрольної групи (C), які отримували стандартний догляд. Після пологів породіллям групи E була проведена блокада квадратної поперекової кістки під ультразвуковим контролем. У день операції обидві групи отримували внутрішньовенну аналгезію. У перший післяопераційний день пацієнти групи E переходили на пероральні анальгетики, тоді як група C протоколи мають бути розроблені індивідуально для кожної установи у координації з системою охорони здоров'я.*

Ключові слова: *акушерство, кесарів розтин, знеболювання, прискорене відновлення після операції.*