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Original Article

Anaesthesia Section

Comparison of Enhanced Recovery after C-section versus Traditional Protocol in Elective Caesarean Section: A Randomised Clinical Trial

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ABSTRACT

Introduction: Caesarean delivery is a common obstetric procedure associated with complications such as pain, nausea, infection and thromboembolic events. Enhanced Recovery After Caesarean (ERAC) is a multimodal strategy designed to minimise these complications facilitate faster recovery and enhance patient satisfaction.

Aim: To compare the effectiveness of ERAC versus traditional protocols in elective caesarean sections.

Materials and Methods: This randomised, single-blind clinical trial was conducted at Pandit Deendayal Upadhyay Medical College, Rajkot, Gujarat, India, from December 2022 to March 2024 involved 150 American Society of Anaesthesiologists Physical Status (ASA-PS) grade II and III patients undergoing elective lower-segment caesarean sections under spinal anaesthesia, divided into two haemodynamics: Haemodynamic T (Traditional protocol, n=75) and Haemodynamic E (ERAC protocol, n=75). The parameters assessed were mobilisation time, time to first oral intake, pain scores, and complications. Data were analysed using Statistical Package for Social Sciences (SPSS) software version 22.0 and EpiInfo 7. Statistical tests included student's t-test for continuous variables and Chi-square test for categorical variables. A p-value ≤0.05 was considered statistically significant.

Results: Demographic data were comparable in both haemodynamics. Haemodynamic E had significantly earlier mobilisation (11.32±2.45 vs. 24.02±4.13 hours, p<0.0001) and oral intake (6.8±0.98 vs. 9.4±1.5 hours, p=0.02). Readiness for discharge was faster in Haemodynamic E (1.7±0.71 vs. 2.9±0.79 days, p<0.0001). ERAC also resulted in lower Intraoperative Nausea and Vomiting (IONV) (28% vs. 57.3%, p=0.0005) and reduced postoperative pain (p<0.01).

Conclusion: ERAC protocol significantly enhances recovery, improving pain management, mobilisation, oral intake, and mother-newborn bonding, leading to higher patient satisfaction and earlier discharge readiness compared to traditional approaches. These findings support its widespread implementation in caesarean deliveries.

Keywords: Early mobilisation, Patient satisfaction, Postoperative pain, Postoperative recovery, Readiness for discharge

INTRODUCTION

The ERAS is a concept that incorporates several evidence-based perioperative care strategies to accelerate patient recovery. It was initially introduced by Kehlet in 1997 to reduce the length of hospital stays in open sigmoid resections. ERAS standardises perioperative management and provides a reproducible improvement in the quality of care. Early trials on ERAS procedures in colorectal surgery reported shorter hospital stays, fewer readmissions, lower postoperative complications and greater patient satisfaction. Since then, ERAS protocols have been widely adopted across other surgical specialties addressing key factors that delay recovery, such as inadequate pain management, delayed return of bowel function, and prolonged immobility [1]. The introduction of ERAC in 2018 and its multidisciplinary framework is supported by the Society for Obstetric Anaesthesia and Perinatology (SOAP) consensus statement [2].

ERAC is an interdisciplinary approach introduced in 2018, following the success of ERAS protocols in other surgical fields. It involves a collaborative effort among anaesthesiologists, obstetricians, nurses, neonatologists, paediatricians, pharmacists, hospital administrators, and support systems [3]. ERAC, a multidisciplinary approach that reduces the hospital stay and optimises perioperative care which is influenced by multiple factors, such as adequate pain and fluid management, early mobilisation, earlier start of oral food. ERAC is best understood as a continuum of care, beginning with antepartum optimisation followed by intrapartum anaesthetic management, and concluding with postpartum inpatient care and outpatient support [4].

The ERAC components include good perioperative nutrition and hydration, limited fasting, carbohydrate load, early postoperative oral intake, removal of urinary catheter, postoperative mobilisation, promoting better maternal and foetal bond and readiness of discharge, reduce length of stay and improve maternal and neonatal outcomes [5]. Despite the growing implementation of ERAC protocols globally, there are few comparative studies evaluating effectiveness of ERAC against traditional perioperative care in elective caesarean deliveries, particularly in diverse clinical settings [6,7]. This study focuses on quantifying both maternal recovery and discharge readiness using ERAC versus conventional protocols, offering a structured evaluation of clinical outcomes in a real-world obstetric population. Most existing evidence is observational and has assessed data on discharge readiness, maternal-neonatal bonding, and long-term recovery outcomes [6].

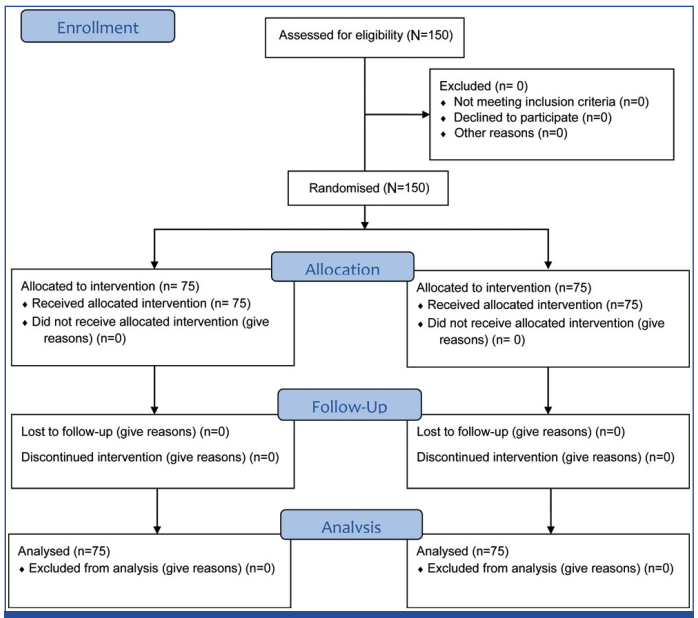
This study aimed to compare the effectiveness of ERAC protocols versus traditional protocols in improving outcomes for women undergoing elective caesarean deliveries. The primary objective was to compare readiness for the discharge and recovery. Recovery was assessed using a combination of clinical and functional parameters like time to ambulation, oral intake and pain scores, while secondary objectives include assessing clinical outcomes between the two

haemodynamics focusing on length of hospital stay, return to normal activities and perioperative complication.

MATERIALS AND METHODS

This randomised, single-blind clinical trial was conducted at PDU Medical College, Rajkot, Gujarat, India, between December 2022 and March 2024. This study was done after approval from the Institutional Ethical Committee (IEC/26/2022) and registration with the Clinical Trials Registry of India (CTRI/2023/02/049782). Informed verbal and written informed consent was obtained from all the participants.

Sample size calculation: As per Gupta S et al., study based on length of hospital stay for emergency caesarean sections was 2.85±0.5 in haemodynamic A (ERAC protocol) vs 5.25±0.61 days in haemodynamic B (Traditional protocol) [6]. Using these values, with a 95% power and a 5% level of significance, the required sample size was 70 and considering drop out 75 patients in each haemodynamic was taken. As per [Table/Fig-1], participants were randomly assigned into two haemodynamics using a computer-generated sequence numbers and allocation concealment was maintained using opaque, sealed envelopes. haemodynamic E received care according to the ERAC protocol, while haemodynamic T followed the traditional perioperative management protocol, with 75 patients in each haemodynamic [Table/Fig-1]. Data were recorded by a blinded anaesthesiologist.



[Table/Fig-1]: Consolidated Standards of reporting Trials (CONSORT) flow diagram.

Inclusion criteria: The study population included pregnant women aged 25 to 40 years, with ASA physical status II-III and a gestational age of more than 38 weeks, scheduled for elective caesarean section.

Exclusion criteria: Women with pre-existing medical conditions such as severe hypertension, severe preeclampsia, diabetes, haemorrhagic disorders, organ dysfunction, epilepsy, neuromuscular diseases, severe anaemia, or those unwilling to participate were excluded.

Study Procedure

In the traditional haemodynamic (haemodynamic T), patients were admitted a day before surgery and kept overnight fasting and routine protocol followed. Postoperative these patients were managed with delayed oral intake, late mobilisation (from the second postoperative day), and catheter removal after more than 12 hours. Haemodynamic E patients were admitted on the day before surgery and as per the ERAC protocol detailed preoperative counselling done, including information about potential risks, expected recovery course, and the benefits of ERAC care. On the day of surgery, 100 mL of non particulate carbohydrate solution (25% dextrose) two hours before surgery was given orally. Both haemodynamics received neuraxial anaesthesia via Subarachnoid Block (SAB) with 2.2 mL of 0.5% bupivacaine heavy using a 25G Quincke spinal needle at the L3-L4 or L4-L5 space. Monitoring included ECG, Non Invasive Blood Pressure (NIBP), and Pulse oximetry (SpO_2), with vitals recorded at baseline, at the time of spinal induction, and at regular intervals up to 60 minutes. haemodynamic T patients received phenylephrine boluses (100-150 mcg) as needed, without active warming, and were given 5 IU i.v., bolus of oxytocin followed by 20 IU in 500 mL RL (0.4 IU/min), along with methylergometrine as needed. Haemodynamic E patients received prophylactic phenylephrine infusion (1-2 mcg/kg/min) to reduce hypotension risk. Active warming techniques and early uterotonic support were employed using oxytocin infusion (0.125-0.250 IU/min) and intramuscular carboprost if required. In the postoperative period, haemodynamic T patients were offered oral fluids after six-eight hours, mobilisation and catheter removal delayed as per routine beyond 12 hours. Haemodynamic E patients received analgesic i.v. paracetamol (1 g) and diclofenac (75 mg), with early initiation of clear oral fluids within two hours. The primary outcomes are readiness of discharge and patient satisfaction. Secondary outcomes are intraoperative haemodynamics, perioperative complication, postoperative pain assessment by VAS score, early oral intake and mobilisation and early breast feeding. Intraoperative haemodynamics were assessed upto 60 minutes from induction. Perioperative complications e.g., nausea/vomiting, headache, hypotension, bradycardia, tachycardia or shivering were noted. Urinary catheter removal and ambulation were encouraged within 6-10 hours. Baby holding time and initiation of breastfeeding within one hour were noted. Pain was assessed using the Visual Analogue Scale (VAS) up to four hours postoperatively, and i.v. tramadol (100 mg) was used as rescue analgesia when VAS ≥ 4. Patient satisfaction regarding the perioperative experience was documented using a 5-point scale (1 = very good to 5 = very bad). Readiness for discharge was assessed using standard vital parameters e.g., pulse rate, NIBP, SpO_2 and total hospital stay duration was recorded.

STATISTICAL ANALYSIS

Data were analysed using SPSS version 22.0 and EpiInfo 7. Continuous variables were compared using the Student's t-test, and categorical variables using the Chi-square. A p-value <0.05 was considered statistically significant. Results were expressed as mean±standard deviation or in percentages.

RESULTS

Demographic parameters were comparable in both haemodynamics as shown in [Table/Fig-2].

Variables	Haemodynamic E	Haemodynamic T	p-value
ASA II/III	72/3	70/5	0.72
Age (years)	27.13±4.7	26.51±5.3	0.44
Weight (kgs)	72.35±10.85	71.98±13.84	0.83
Height (cm)	157.07±3.91	157.01±3.78	0.91
BMI (kg/m^2)	25.83±3.85	25.32±2.1	0.31

[Table/Fig-2]: Demographic difference between two haemodynamics. Values presented in Mean±SD

Comparison of perioperative variables between ERAC (haemodynamic E) and Traditional care (haemodynamic T) are illustrated in [Table/Fig-3]. Haemodynamic E had significantly fewer incidences of nausea and vomiting, hypotension, tachycardia and shivering compared to haemodynamic T. Haemodynamic E had earlier time for initiation of enteral nutrition, shorter time to first flatus, reduced time to mobilisation baby holding time.

Variables	Haemodynamic E	Haemodynamic T	p-value (t-test)[a]
Nausea and vomiting	21 (28%)	43 (57.3%)	p=0.0005*
Headache	12 (16%)	14 (18.6%)	p=0.8292
Hypotension	13 (17.3%)	28 (37.3%)	p<0.005*
Tachycardia	7 (9.3%)	27 (36%)	p=0.0002*
Shivering	21 (28%)	42 (56%)	p=0.0009*
Bradycardia	1 (1.3%)	4 (5.3%)	p=0.3630
Baby feeding			
<1 hour	74 (98.6%)	32 (42.7%)	p<0.0001*
>1 hour	1 (1.4%)	43 (57.3%)	
Baby holding time (Hours)	6.57±3	10.73±4.85	p<0.0001*
Time for removal of urine catheter (Hours)	19.23±9.6	20.95±14.11	p=0.39
Need for re-catheterisation (no. of patients)	1 (1.3%)	3 (4%)	0.257
Time for mobilisation (Hours)	11.32±2.45	24.02±4.13	p<0.0001*
Time to start enteral nutrition (Hours)	6.8±0.98	9.4±1.5	p=0.02*
Time for passing flatus (Hours)	3.79±1.57	9.08±3.23	p<0.0001*
Total hospital stay (Days)	4.04±1.07	4.15±1.05	p=0.5
Readiness to discharge (Days)	1.7±0.71	2.9±0.79	p<0.0001*

[Table/Fig-3]: Comparison of perioperative variables.
[a]student t-test; *p<0.05; statistically significant; Values presented in Mean±SD

Haemodynamic E had a significantly shorter time to readiness for discharge (p<0.0001), although the total hospital stay was comparable. Intraoperative pulse rates and blood pressure were more stable in haemodynamic E [Table/Fig-4,5].

Time	Haemodynamic E (mmHg) (Mean±SD)	Haemodynamic T (mmHg) (Mean±SD)	p-value (t-test)[a]
Induction	87.56±6.9	89.36±9.48	p=0.69
3 min	87.79±9.16	84.71±7.71	p=0.0274*
5 min	88.01±8.86	84.81±7.83	p=0.0203*
7 min	86.74±7.09	76.77±18.39	p<0.0001*
10 min	86.83±7.74	77.68±18.13	p=0.0001*
15 min	89.97±12.77	84.66±11.83	p=0.28
20 min	88.64±7.5	86.37±6.92	p=0.0565
30 min	86.05±9.91	84.35±8.09	p=0.2324
60 min	85.18±10.38	84.78±8.39	p=0.79

[Table/Fig-4]: Comparison of intraoperative mean blood pressure changes.
[a]student t-test; *p<0.05; statistically significant

Time	Haemodynamic E (Beats/min) (Mean±SD)	Haemodynamic T (Beats/min) (Mean±SD)	p-value (t-test)a
Induction	80.17±12.14	80.51±11.70	p=0.8643
3 min	80.91±12.11	81.26±12.18	p=0.8562
5 min	84.45±13.51	86.36±11.35	p=0.35
7 min	84.56±14.56	88.8±16.14	p=0.0933
10 min	83.92±15.18	89.39±15.98	p=0.0333*
15 min	83.47±15.3	89.2±13.6	p=0.0230*
20 min	79.42±11.68	82.73±10.36	p=0.073
30 min	83.7±15.3	89.2±13.6	p=0.16
60 min	79.56±13.56	81.93±12.11	p=0.2602

[Table/Fig-5]: Comparison of intraoperative mean heart rate changes.
[a]student t-test; *p<0.05; statistically significant

Postoperative VAS scores were consistently lower in haemodynamic E at all intervals (p<0.01), suggesting better analgesia [Table/Fig-6].

In haemodynamic E, six patients had very good satisfaction score and 36 patients had good satisfaction score [Table/Fig-7].

VAS score for pain	Haemodynamic E (Mean±SD)	Haemodynamic T (Mean±SD)	p-value (Chi square test)[b]
After 60 min	1.67±0.52	2.04±0.64	p<0.01*
After 90 min	2.12±0.63	2.67±0.74	p<0.01*
After 120 min	2.91±0.85	3.39±0.8	p<0.01*
After 180 min	3.81±0.83	4.25±0.87	p<0.01*
After 240 min	5.17±0.91	5.99±0.9	p<0.01*

[Table/Fig-6]: Comparison of postoperative VAS score for pain between two haemodynamics.
[b]Chi-square test; *p<0.05; statistically significant

Patient satisfactory score	Haemodynamic E n (%)	Haemodynamic T n (%)	p-value (Chi-square test)[b]
Grade-1 (Very good)	5 (6.7%)	1 (1.3%)	p=0.20
Grade-2 (Good)	36 (48.0%)	21 (28.0%)	p=0.02*
Grade-3 (Neither good nor bad)	29 (38.7%)	39 (52.0%)	p=0.14
Grade-4 (Bad)	5 (6.7%)	14 (18.7%)	p=0.04*
Grade-5 (Very bad)	0	0	

[Table/Fig-7]: Comparison of postoperative patient satisfactory score between two haemodynamics.
[b]Chi-square test; *p<0.05; statistically significant

In haemodynamic T one patient had very good satisfaction score and 21 patients had good satisfaction score. So patient in haemodynamic E had better satisfaction scores, reflecting a more favourable postoperative experience and difference was statistically significant (Chi-square for trend= 12.348, p=0.0063).

DISCUSSION

The ERAS refers to patient-centred, evidence-based, multidisciplinary team developed pathways for a surgical care to improve recovery. Traditionally, patients are instructed to abstain from oral intake overnight before a C-section to minimise the risk of aspiration and are only allowed food once bowel sounds are audible or flatus is passed. However, various studies have discredited this belief and shown that early initiation of oral feeding is beneficial, well-tolerated. Early feeding improves gastrointestinal function, enhances mobility, reduces sepsis risk, and shortens hospital stays [2]. The primary goal of the ERAC protocol is to promote early mobilisation and enhance functionality while reducing hospitalisation duration.

Better intraoperative haemodynamic stability in the ERAC haemodynamic was due to optimised oxytocin administration and prophylactic phenylephrine infusion. The control haemodynamic (Haemodynamic T) received a 5 IU bolus of oxytocin, the ERAC haemodynamic (Haemodynamic E) received a lower dose infusion (0.125-0.250 IU/ml), reducing tachycardia and hypotension. The present study finding suggests that the incidence of tachycardia was notably higher in haemodynamic T than in haemodynamic E, yielding a statistically significant difference. Mean blood pressure (mmHg) was significantly lower at 3, 5, 7 and at 10 minutes. After 15 minutes, difference in blood pressure was not statistically significant which aligns with Gupta S et al., who reported fewer hypotensive episodes in the ERAC haemodynamic, attributing this to the prophylactic use of phenylephrine infusion exclusively in the study haemodynamic [6]. In contrast, Pan J et al., found no significant difference in hypotension incidence between the ERAC and the control haemodynamics, despite using intravenous crystalloid and phenylephrine infusion as needed in both haemodynamics [7]. Emelinda BN et al., also reported a higher incidence of perioperative hypotension in the control haemodynamic compared to the study haemodynamic which was not significant [8].

Postoperative VAS was significantly lower in haemodynamic E during the first four hours due to multiple analgesics (i.v. paracetamol and diclofenac), while haemodynamic T received no

immediate i.v. analgesia. Gupta S et al., found that average VAS in ERAC haemodynamic was significantly lower upto eight hours postoperatively [6]. Studies by Mundhra R et al., found that women in ERAC had better pain score at rest and during ambulation [9]. Divya K et al., studied that VAS score at 12 hour and at 24 hour was significantly lower in ERAC haemodynamic [10]. Similar results were observed by Pan J et al., Sravani P et al., and Christensen N et al., who reported significant pain reduction up to 48 hours postsurgery [7,11,12]. Kanniga R et al., had given Transversus Abdominis Plane (TAP) block and Pujic B et al., had given bilateral quadratus lumborum block in study haemodynamic and found significantly reduced pain scores in study haemodynamic [13,14].

ERAC protocols significantly reduced IONV due to preoperative carbohydrate loading, and optimised oxytocin infusion. Our findings align with Ituk U et al., Emelinda BN et al., and Divya K et al., who reported a notable decrease in IONV in the ERAC haemodynamic [3,8,10] Pan J et al., observed a significant reduction in nausea in the ERAC haemodynamic compared to the control haemodynamic, and a decrease in vomiting, though not statistically significant [7]. They had given Tropisetron 5 mg used with other antiemetic in ERAC haemodynamic while only tropisetron in control haemodynamic. Additionally, intraoperative shivering was significantly lower in haemodynamic E, likely due to active warming techniques consistent with studies by Emelinda BN et al., and Jakhetiya B et al., [8,15].

Early breastfeeding leads to increase maternal-newborn bonding. In our study, ERAC facilitated significantly earlier baby holding and breastfeeding initiation within one hour. Preoperative carbohydrate loading, effective analgesia, and reduced nausea contributed to this improvement. Jakhetiya B et al., similarly reported significantly earlier breastfeeding initiation in ERAC haemodynamics [15].

Although early urinary catheter removal in haemodynamic E did not significantly increase re-catheterisation rates, it promoted early mobilisation. Haemodynamic E mobilised significantly earlier than haemodynamic T, supporting findings by Sravani P et al., and Lester SA et al., who observed significantly reduced postoperative ambulation times in ERAC haemodynamics [11,16]. These improvements are attributed to factors such as better pain management and reduced intraoperative complications in the ERAC haemodynamics.

Patients in haemodynamic E resumed enteral nutrition earlier than haemodynamic T, with no increase in gastrointestinal complications. Lester SA et al., also observed significantly faster times to first oral intake in the ERAC haemodynamic [16]. Faster return of bowel function was evident as ERAC patients passed flatus significantly earlier. Similar findings were reported by Sravani P et al., Mundhra R et al., and Manoghna G et al., who demonstrated that preoperative carbohydrate loading is associated with increased gastric emptying time, reduces the hunger, thirst, urinary ketones levels, reduced bowel irritability and allows the patient to start enteral nutrition earlier [9,11,17]. Early gastric emptying and improves blood glucose levels in ERAC haemodynamic after preoperative non particulate carbohydrate loading result in early passing of flatus. Contrary to this finding, Lestari MI et al., found that first bowel movement was only variable which was not affected by ERAC protocol [18]. These outcomes are linked to better control of nausea, vomiting, pain, and minimal bowel handling during surgery in the ERAC protocols.

In the current study, haemodynamic E had a significantly shorter readiness for discharge than haemodynamic T, driven by early mobilisation, prompt initiation of enteral nutrition, timely passage of flatus, superior analgesia, fewer perioperative complications early breastfeeding support, and improved mother-newborn bonding. The benefits of ERAC protocols in reducing readiness for discharge times enhances overall maternal outcomes. Gupta S et al., and Mundhra R et al., both reported a significantly shorter readiness for discharge in ERAC haemodynamic [6,9]. Both studies assessed factors like haemodynamic, early ambulation, pain control, oral intake, and urinary catheter removal as discharge criteria.

In the present study, duration of hospital stay was similar in both haemodynamics. Readiness for discharge was prioritised, as actual discharge depends on factors such as neonatal health institutional policies, and patient preferences. Similarly, Mundhra R et al., reported a shorter but statistically insignificant hospital stay in the ERAC haemodynamic vs. the conventional haemodynamic [9]. Pan J et al., also found no significant difference, attributing this to insurance constraints [7]. Conversely, studies by Sravani P et al., Choudhary S et al., and Tewary K et al., found a significantly shorter hospital stay in the ERAC haemodynamics [11,16,19]. Sultan P et al., and Baluku M et al., also reported significantly reduced hospital stay across multiple studies [20,21]. Meta-analysis conducted by Lestari M et al., also found that postoperative hospital stay was shorter in ERAC haemodynamic [18].

In the current study, better patient satisfaction scores in ERAC haemodynamic were found and the difference is statistically significant. Similar to the present study finding, Kanniga R et al., and Manoghna G et al., found significantly greater levels of satisfaction and overall wellness in ERAC haemodynamic [13,17]. Darwish A et al., also found a better satisfaction score in patients with ERAC protocol as compared to control [22]. In support of this finding, Jakhetiya B et al., studied satisfaction score (rated between 1-10) 24 hours after the surgery which was greater in ERAC haemodynamic than control haemodynamic [15].

Limitation(s)

A major limitation of the present study is that it was a single centre study and hence, the universality of the findings to other healthcare settings might be limited, requiring the need for large scale multi-centric studies to validate the results. Blinding of participants was not possible. Institutional discharge policies will affect the overall length of stay. The healthcare workers unwillingness to follow new protocols and adherence to protocol, limited resources and staff training, patient education, lack of man power, lack of cooperation from the staff are all potential limitations to the successful implementation of an ERAS protocol for caesarean delivery.

CONCLUSION(S)

The present study demonstrates that the ERAC protocol is more effective than the traditional approach in promoting early oral intake, improving pain control and enhancing newborn care, all while reducing complications. Additionally, patients managed with the ERAC protocol reported higher satisfaction with their perioperative experience. Given these benefits, it concluded that the ERAC protocol is a superior approach and should be widely implemented to optimise maternal recovery and neonatal care following caesarean delivery.

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