ORIGINAL ARTICLE

Comparative study between eras protocol and conventional perioperative care in elective cesarean section patients in a tertiary care centre of eastern India

Poreddy Sravani[1], Rachita Pravalina[1], Gitanjali Sahoo, [1] Basanta Kumar Pati[1]

[1]Department of Obstetrics and Gynecology, IMS & SUM Hospital, Siksha O Anusandhan (Deemed to be) University, Bhubaneswar, Odisha, India.

Corresponding Author: Basanta Kumar Pati **Email:** basantapati@soauniversity.ac.in

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ABSTRACT

Enhanced Recovery after Surgery (ERAS) was originally introduced in colorectal surgery. ERAS pathways have been extensively implemented in various surgical branches like orthopedics, urology, and gynecologic surgery. Commencement of these ERAS programs has consistently resulted in a decreased duration of hospital stay and enhanced patient comfort. We aim to implement the ERAS program successfully with the main objective of comparing the duration of hospital stay in both groups. A prospective comparative observational study was conducted at the Department of Obstetrics and Gynecology, in a tertiary care center of Bhubaneswar. Non-probability convenient sampling was done and consenting patients undergoing elective cesarean sections were included in the study conducted over 1.5 years. 200 pregnant women were included in the study. 100 were enrolled in the ERAS group and 100 in the conventional peri-operative hospital protocol group. None of the participants were lost to follow-up in either group. Post-operative outcomes in both groups were analyzed. In the study, there was a significant difference in the mean duration of 1st oral intake, 1st appearance of bowel sounds, first ambulation, catheter removal, 1st passage of flatus, bowel movements and postoperative length of stay between the two groups. The application of the ERAS protocol in our hospital led to a shorter duration of hospital stay postoperatively. Early allowance of oral diet reduced the duration of appearance of 1st bowel sounds, the first passage of flatus, and bowel movements. It also helped in ambulating the patients early, early catheter removal and faster resumption of regular normal diets. We recommend the application of the ERAS protocol to all uncomplicated cesarean sections. ERAS implementation challenges can be overcome by education of patients and care givers along with communication of economic benefits of ERAS to health care administrators.

Key words:
ERAS, pregnant women, cesarean delivery

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INTRODUCTION

A Cesarean section is the surgical delivery of the baby through a cut made on the abdominal and uterine walls after 28 weeks of pregnancy. It is the most common procedure done in obstetrics. Its evolution and utilization have rescued several uncountable lives of mothers and babies. In the last 2 decades, cesarean section rates have increased worldwide.[1] In India, cesarean section rates have increased slowly since the late 1980s.[2] According to World Health Organization (WHO), cesarean section rates have been increasing globally, accounting for 1 in 5(21%) of all childbirths. By 2030, this number will increase to 29%.[3]

A recent survey done by *National Family Health Survey* -5 (NFHS) from 2019-2021 showed the overall cesarean section rate is about 21.5%, which was 17.2% during NFHS-4.[4] Such high cesarean section rates will increase the burden on the health care system, which will lead to an increased bed occupancy rate. Women who deliver by Cesarean Section (C-section) need more care after surgery than those who deliver vaginally. Most of the women undergoing C-sections being young and healthy, can recover fast postoperatively.

Traditional peri-operative care includes prolonged fasting, mechanical bowel preparation, and gradual introduction of feeds. They will be allowed an oral diet, either fluid or solid food only after the appearance of bowel sounds, and passage of flatus/stool.[5] The reason behind this approach was to avoid nausea and vomiting post-operatively, abdominal distension, and other problems. However, delayed feeding can give rise to ileus symptoms that can increase the duration of stay in the hospital and cause monetary issues to the patient.[6] They will be ambulated first and catheter removal will be done 24 hours after surgery.

Enhanced Recovery after Surgery (ERAS)/ Fast Track Surgery was originally introduced by Professor Henrik Kehlet in the 1990s in colorectal surgery.[7] ERAS is a multifaceted, global, non-profitable, evidence-based proposal that involves multiple changes in perioperative care which aim to systematize postoperative patient care, reduce surgical stress, enhance patient outcomes and decrease the duration of hospital stay postoperatively.[8,9] ERAS pathways have been extensively implemented in various surgical branches, such as orthopedics, urology, and gynecologic surgery. Commencement of these ERAS programs has persistently resulted in a decreased duration of hospital stay and enhanced patient comfort.[10] There is a broad difference in the elements of ERAS pathways among various surgical specialties but the proposition behind it is the same.[11-13] Currently, the ERAS protocol has been implemented for Gynecologic Oncology surgery patients to decrease the length of stay, complications and financial burden without any rise in readmission or mortality. This will lead to ERAS protocol implementation as the standard of care for post-operative patients with added advantages.[14,15]

The various elements of the ERAS pathway include counseling the mothers before admission, ensuring a good perioperative diet and hydration, preventing hypothermia intra-operatively, promoting early oral feeding, providing appropriate postoperative pain relief, encouraging early ambulation, early catheter removal, and facilitating early discharge.[16] All these components together help in stress reduction, cytokine level reduction, improve tissue repair and decrease complications.[17,18] ERAS society advocates applying specific recommendations during cesarean section in the perioperative period for better

maternal and fetal outcomes postoperatively.[19,20]

There is an immense discrepancy between institutional and personal practices ranging from an early allowance of diet to delayed feeding after 24 hours or more. This variation will raise concerns about the foundation of different practices. During an unproblematic cesarean section, there will be no or very minimal bowel handling. So, there will be no disturbance to bowel function. Considering this, early oral feeding can be allowed postoperatively.[21] Usually, in our hospital, the traditional protocol will be followed. As per hospital protocol, patients will be usually discharged 72 hours after surgery.

In our hospital, the adoption of ERAS protocol in perioperative care remains to be a novel and unexplored idea in any surgical field. By endorsing this time-tested ERAS pathway in our branch, we aim to implement the ERAS program successfully with the main objective of comparing the duration of hospital stay in both groups.

METHODS

A prospective comparative observational study was conducted at the Department of Obstetrics and Gynecology, IMS & SUM Hospital, Bhubaneswar. This study protocol was approved by the Ethical Committee and Review Board of the institution for the rights and safety of the research subjects. Written informed consent was taken from all the study participants. Women with uncomplicated pregnancies who underwent cesarean section at IMS and SUM Hospital, Bhubaneswar, and who gave consent were enrolled in the study. Non-probability convenient sampling was done and consenting patients undergoing elective cesarean sections were included in the study conducted over 1.5 years.

The Inclusion criteria are:

1. Primigravida with malpresentations, 2. Patient with previous Lower Segment Cesarean Section (LSCS) [refusing for Vaginal Birth After Cesarean Section (VBAC) or where contraindicated], 3. Patients with contracted pelvis/ CPD, 4. Severe oligohydramnios, 5. Pregnancy with Inter Uterine Growth Restriction (IUGR) (± Doppler changes), 6. Uncomplicated twin pregnancies, 6. Pregnancies following infertility treatment requesting c-sections.

The Exclusion criteria are:

1. Gestational diabetes mellitus, 2. Overt diabetes mellitus, 3. Chronic hypertension, 4. Hypertensive disorders in pregnancy, 5. Cardiac diseases, 6. Liver disorders during pregnancy, 7. Bronchial Asthma, 8. Chronic kidney disease, 9. Hemoglobinopathies, 10. Obstructed labor, 11. Prolonged Labour, 12. Emergency LSCS, 13. Antepartum hemorrhage, 14. Postpartum hemorrhage 15. Urinary Tract Infection (UTI)/Sepsis

After implementing the informed consent process, a detailed patient history and examination were done.

All patients are subjected to thorough clinical evaluation with emphasis on full medical and surgical history from the patient with special emphasis on the obstetric and gynecological history. General clinical examination, laboratory investigations; complete blood count (CBC); liver function tests (LFT); viral markers (HIV (human immunodeficiency virus), HBsAg (Hepatitis B surface antigen), HCV (hepatitis C virus)); blood grouping and Rh typing; radiological studies; and confirmation of gestational age by dating scan are done.

The women with uncomplicated pregnancies who underwent cesarean section and gave consent for the study are divided into two groups.

After fulfillment of the above criteria and prerequisites, each eligible patient is included in the study as per the ERAS group or conventional peri-operative

care group. ERAS protocol patients are allotted to group A.

Pre-operative care for group a-

1) The patient was kept NPO, 6 hours for solids and 2 hours for clear liquids before cesarean section.
2) Betadine vaginal pessary was given before surgery.
3) Prophylactic antibiotics were given to patients 30-60 minutes before skin incisions.

Intra-operative care-

1) Active warming by giving warm intravenous fluids to prevent hypothermia.

Post-operative care-

1) The patient was allowed to chew gum every 8 hours for 24 hours.
2) Early oral nutrition- allowing liquid diet within 2 hours of C-section, diet after 6 hours of surgery.
3) The patient was ambulated 8 hours after the C-section.
4) Catheter removal was done 8 hours after surgery.

Conventional peri-operative hospital protocol patients were allotted to group B.

Pre-operative care for group a-

1) Nil per oral for 8 hours before surgery.
2) No betadine vaginal pessary
3) Prophylactic antibiotics were given 30-60 minutes before the skin incision.

Intra-operative care- no specific intervention was done.

Post-operative care-

1) Allowed sips of water after the appearance of bowel sounds.
2) Patients used to ambulate 24 hours after surgery.
3) Catheter removal used to be done 24 hours after surgery.
4) Women will be discharged on the fourth day in stable clinical condition.

The two groups were compared concerning various parameters like post-operative duration of hospital stay, time of first passage of flatus, time for ambulation, time for catheter removal, and pain score using a visual analog scale.

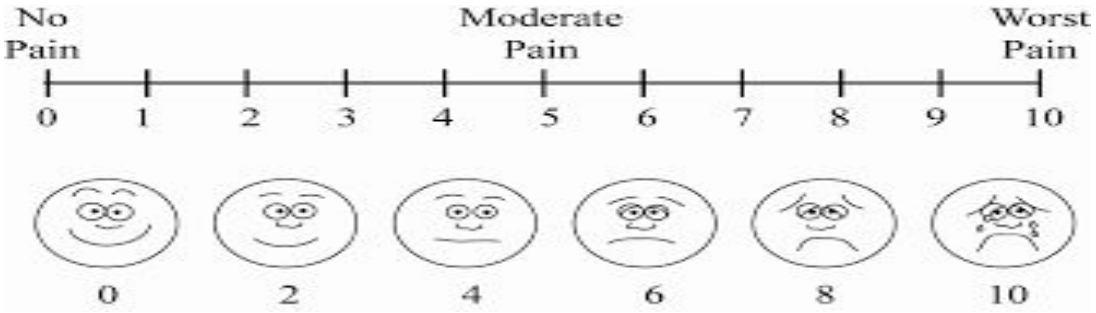

Figure 3. Visual analogue scale

Statistical Analysis

The data obtained were tabulated in Microsoft Excel version 16. The statistical analysis was performed using the statistical software SPSS version 20.0. The continuous variables were expressed in mean and standard deviation and these variables between the two groups were compared using the student's t-test. The categorical data were expressed in frequencies and percentages. The level of statistical significance was assumed to be p-value <0.05. The graphs were made using both Microsoft Excel and SPSS software.

RESULTS

A total of 200 pregnant women were included in the study. 100 women were enrolled in the ERAS group and remaining 100 were included in the conventional peri-operative hospital protocol group. None of them were lost to follow-up in the groups. Post-operative outcomes in both groups were analyzed.

Table 1. Demographic characteristics

Demographic characteristics	Group A	Group B	P value
Age (years)	28.79±4.053	28.08±3.897	0.028
Gestational age (weeks)	38.175 ±1.040	37.903±1.024	0.064
Gravidity (n,%)			
Primigravida	51 (51%)	56 (56%)	
Multigravida	49 (49%)	44 (44%)	

Data represented as mean±standard deviation (SD), p >0.05- Nonsignificant

Both groups did not differ significantly in mean maternal age or gestational age. 107 women out of 200 are primigravida, of which 51 are in group A, and 56 are in group B. Additionally, 93 women out of 200 are multi gravida, of which 49 are included in group A and 44 are in group B.

Table 2. Post-operative outcomes

Criteria	Group A(n=100)	Group B (n=100)	P value
Time of ambulation (h)	11.19±1.716	24.02±1.318	<0.001
Catheter removal (h)	13.28±1.491	25.42±1.736	<0.001
Duration of iv fluids (h)	20.3±1.039	25.94±1.003	<0.001
Post-operative duration of hospital stay (h)	54.00±10.445	74.40±13.430	<0.001

Data represented as mean±standard deviation (SD), p <0.05- Significant

In Table 2 it shows postoperative outcomes in both groups. Time of ambulation and catheter removal were found to be significantly earlier in the ERAS group with a p-value <0.001. There is a statistically significant decrease in the duration of intravenous fluids in group A (20.3±1.039) compared to group B (25.94±1.003) with a p-value (<0.001). Furthermore, there is a statistically significant reduction in post-operative hospital stay in group A (54.00±10.445) when compared to group B (74.40±13.430) with a p-value (<0.001).

Table 3. Gastrointestinal parameters

	Group A(n=100)	Group B (n=100)	P value
Allowance of 1st oral intake	2.42±0.806	6.54±1.20	<0.001
Appearance of 1st bowel sound (h)	5.88±1.805	7.83±1.995	<0.001
Passage of flatus (h)	16.39±1.803	23.12±2.548	<0.001
Bowel movements (h)	35.62±7.514	53.56±7.588	<0.001
Post-operative nausea (%)	7 (7%)	7 (7%)	

Data represented as mean±standard deviation (SD), p <0.05- Significant

In Table 3, we compared the ERAS group with the standard hospital protocol group, and the result showed that women in the ERAS group had a significant decrease in the duration of appearance of 1st bowel sound (5.88±1.805 vs 7.83±1.99), the passage of flatus (16.39±1.803 vs 23.12±2.548), bowel movements (35.62±7.514 vs 53.56±7.588) with a p-value < 0.001.

Table 4. Pain score

Pain score after surgery (hours), mean ±SD	GROUP A	GROUP B	P Value
6	2.68±.695	3.41±.637	<0.001
12	2.13±.677	2.71±.677	<0.001
24	1.61±.601	2.08±.598	<0.001
48	1.01±.541	1.41±.514	<0.001

We measured pain scores at 6, 12, 24 and 48 hours after cesarean section using a visual analog scale (VAS) (Table 4). Our result showed a statistically significant difference in pain score, where the ERAS group perceived less pain compared to the conventional peri-operative hospital protocol group with a p-value <0.001.

DISCUSSION

Enhanced Recovery after Surgery is an approach that reinforces distinct data-based means of operative care to fasten patient recovery. As a tradition, patients will be kept nil per oral for overnight before C-section to decrease the chances of aspiration. Patients will be allowed an oral diet after the appearance of bowel sounds/ after the passage of flatus. Studies that have been done recently in patients undergoing cesarean delivery have refused this myth and demonstrated that starting an oral diet early is well accepted and a boon to the patient.[22-25] It also promotes enhanced gastrointestinal function and enhanced mobilization, reduces the rate of sepsis, and decreases the length of hospital stay.[26-28]

The main purpose of implementing the ERAS program was to promote early mobility and function, and to decrease the duration of hospital stays. In our study among 200 women undergoing elective cesarean section, 100 were allotted to group A which followed ERAS protocol and 100 women were allotted to group B which

followed conventional hospital protocol. The age group of study subjects in both groups was found to be similar and it was comparable to the study findings of Sara Taha Mostafa which is also the most common childbearing age group in the Indian population.[29] Prophylactic antibiotics were given in both groups to prevent infections as studies done by Smaill et al. 2014 and Saeed et al. 2017.[30,31]

Our study shows there is a statistically significant difference in the time taken for the first mobilization in the ERAS group (11.19±1.716) when compared with the conventional group (24.02±1.318) with a p-value (<.001). The advantage of early mobilization is to prevent thromboembolism. Early ambulation can help in preventing adhesions.

Compared with another study by Pravina et al. found that there is a statistically significant decrease in the time for first mobilization which is earlier in the ERAS group (41.66%) in comparison to standard hospital care protocol (12.5%) with a p-value of 0.0003.[32] Lester et al. also concluded that mean post-operative ambulation time as 9.6 hrs vs 32.89 hrs in ERAS and pre-ERAS groups respectively. (p<0.001).[33]

Aluri and Wrench conducted a study, in which 72% of the patients were mobilized within 12 hours of surgery in the ERAS group which is in comparison with our study where the mean duration of ambulation was shorter in the ERAS group.[34]

Our result showed that there is a statistically significant difference in catheter removal time which is earlier in the ERAS group (13.38±1.491) compared to the conventional group (25.42±1.736) with a p-value (<0.001). These results are consistent with Kovavisarach and Atthakorn's study where the time for catheter removal was decreased in the early oral feeding group compared to the traditional feeding group (20.43±3.21 vs 24.21±1.54) with a p-value <0.05.[35] Another study conducted by Anne Laronche et al. also shows decreased time in the removal of the catheter in ERAS group with a p-value < 0.05.[36]

Our results showed a statistically significant decrease in the duration of intravenous fluids in the ERAS group (20.3±1.039) compared to the conventional group (25.94±1.003) with a p-value (<0.001). These results are consistent with E. Kovavisarach and M. Atthakorn's study where the duration of IV fluid was decreased in the early oral feeding group compared to the traditional feeding group (19.96±3.08 vs 24.11±1.55) with a p-value <0.05.[35]

Our main outcome is to observe the duration of hospital stays postoperatively. The result shows that there is a statistically significant reduction in hospital stay in the ERAS group (54.00±10.445) when compared to the conventional group (74.40±13.430) with a p-value (<0.001).

The results were consistent with the study conducted by Pilkington et al. 2016, where their results showed a reduction in the duration of hospital stays from 3 to 6 days before the implementation of ERAS protocol to 1 to 5 days after implementation of ERAS protocol, with an average reduction of 2.5 days.[37] Wrench et al. 2015 conducted a study where results showed that the number of patients who were discharged on day 1 after a cesarean section increased from 1.6% to 25.2% in 2014.[38]

Baluku et al. showed a statistically significant decrease in the duration of hospital stay when compared with standard hospital care in emergency cesarean delivery cases with a disparity of 18.5 hours (p-value, 0.001).[39] Sharma et al. conducted a study where results showed a significant decrease in the duration of hospital stay in the ERAS group (2.85±0.5 vs 5.25± 0.61 days, p <0.0001) compared to the standard hospital protocol group.[40] Our study showed that the ERAS group has better outcomes compared to the conventional

hospital protocol group as per the following observations. In our study, we have allowed early oral feeding for the ERAS group (2.42±0.806) compared to the conventional peri-operative protocol group (6.54±1.20) with a p-value (<0.001) which is statistically significant. Our study shows similar rates of postoperative nausea which is 7% in both groups. Our study has also shown that women in the ERAS group had significantly faster resumption of normal diets than the standard hospital protocol group.

Our study findings were found to be significant in comparison to the study conducted by Lee et al. where they showed that early intake of oral feeding increased from 17% to 57% (p=0.001) after implementation of the ERAS protocol without any abnormal outcomes.[41]

Our results showed that study group patients tolerated our ERAS protocol well, with a significantly faster resumption in intestinal function represented as reduced time for 1st audible bowel sounds, decreased time for ambulation, decreased time taken for passage of flatus, and decreased time for passage of bowel movements. Our study demonstrated the early appearance of 1st bowel sound in the ERAS group (5.88±1.805) when compared with the conventional group (7.83±1.995) with a p-value (<0.001). Our results are similar to the study conducted by Orji et al., where their results showed that the early feeding group had a statistically significant decrease in the meantime for the appearance of bowel sounds (18.90±4.17 vs 36.21±3.52 hr, P <0.001).**[42]** A study done by Adupa et al. showed a significant difference in mean postoperative time intervals to bowel sounds (24.2hrs vs 34.2hrs).[43]

However, a study conducted by Barat et al. shows no significant difference in the time taken for the appearance of bowel sounds in the early feeding group compared to the delayed feeding group with (p value=1).[44]

Our results showed a statistically significant difference in the passage of flatus which is earlier in the ERAS group (16.39±1.803) compared to the conventional group (23.12±2.548) with a p-value (<0.001). A randomized controlled study conducted by Sahin and Terzioglu showed that passage of flatus (15.13±1.70 vs 29.01±4.44 h) was significantly earlier in the ERAS protocol group (p<0.05).[45] Another randomized clinical trial conducted by Nasrin Jalilian and Mohammad Rasoul Ghadami showed that there is no significant discrepancy in the passage of flatus between both groups.[46]

Our results showed a statistically significant decrease in time taken for the passage of bowel movement in the ERAS group (35.62±7.514) compared to the conventional group (53.56±7.588) with a p-value (<0.001). These results are similar to the study conducted by Ernest O. Orji et al. where the results showed that the early feeding group had a statistically significant decrease in the meantime for a bowel movement (58.30±5.91 vs 72.76±4.25 hr, P <0.001).[43]

Our result shows conventional group required more post-operative laxatives (40%) compared to the ERAS group (26%). Results are consistent with a study conducted by Junaidi et al., where results showed in the ERAS group, none of the participants required postoperative laxatives, whereas in the Non-ERAS group, 20% required post-op laxatives.[47]

Our result showed a statistically significant difference in pain score where the ERAS group perceived less pain compared to the conventional group. Kleiman et al. conducted a study where they showed decreased pain scores in the ERAS group compared to the non-ERAS group (p =0.007).[48] Xue et al. conducted a study where the results showed VAS scores

in the ERAS group at each time point after surgery were lower than those of the non-ERAS group (p-value <0.05).[49]

Pan J. et al. study showed that the ERAS group had significantly fewer patients with a pain score of more than 3 according to VAS till 48 hours of surgery.[50] We recommend the application of the ERAS protocol to all uncomplicated cesarean sections. ERAS implementation challenges can be overcome by education of patients and care givers along with communication of economic benefits of ERAS to health care administrators.[51,14]

LIMITATIONS

We have applied the ERAS protocol only in elective cesarean sections. Further studies are needed which include emergency cesarean sections as well. Compliance could have been affected, as both the groups stayed in the same ward. This situation could have been confounded by the caregivers (staff nurse/ patient attendants) who could have influenced patients in both groups, particularly in the starting phase of the program. This study only analyzes the length of hospital stay of the mothers post-operatively, irrespective of babies' stay. The discharge criteria were created for mothers alone, whereas few neonates were admitted to Neonatal Intensive Care Unit (NICU) which had prolonged their hospital stays. Our study does not describe this in the exclusion criteria.

RECOMMENDATION

This study recommends that the application of ERAS protocol in our hospital led to a shorter duration of hospital stays postoperatively. Early allowance of oral diet reduced the duration of appearance of 1st bowel sounds, the first passage of flatus and bowel movements. It also helped in ambulating the patients early, early catheter removal, and faster resumption of regular normal diets. Application of ERAS protocol has shown decreased pain scores using VAS. Early ambulation and early peristalsis can be contributing factors to decreasing intra-peritoneal adhesions. We recommend the application of the ERAS protocol to all uncomplicated cesarean sections. It is evident that compliance with our protocol guidelines was strictly enforced by the operating surgeon, nursing staff and anesthesia team. Although it appears to increase the workload of nursing staff to adhere to many elements of ERAS care, the overall workload is substantially lower due to shorter hospital stays.

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