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Randomized Clinical trial Comparing Postoperative Outcomes of early versus late oral Feeding after Cesarean Section

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Abstract
Background: *Cesarean section is the most common major surgical procedure performed in the world with a low chance of mortality for mother and child.*
Aim of the Work: *to compare between the outcomes of early and late oral feeding after cesarean section under regional anesthesia.*
Patients and Methods: *300 women were included in this study. They were divided into two equal groups:* ***Group A:*** *composed of 150 patients who were encouraged to oral fluid (semi solid and solid) starting 2 h after C- section.* ***Group B:*** *composed of 150 patients who received oral fluid at 8 h following surgery.*
Result: *there were no significant differences between the 2 groups in mean maternal age, BMI and parity. Women in the two groups had similar operative and postoperative characteristics. In this study it was found that women in the early oral feeding group had a highly significant shorter hospital staying time than the late oral feeding group (25 (23 – 28) hours versus 27 (24 – 29.5) hours P value 0.001), and a highly significant satisfaction level among early oral feeding group (132 (88.0%) versus 47 (31.3%) P value 0.000). A significantly shorter time to ambulation in early oral feeding group (6 (4.5 – 8.5) hours versus, 6.5 (5 – 9.5) hours P value 0.014), and a significantly higher rate of occurrence of distention among the late oral feeding group (27 (18.0%) versus 15 (10.0%) P value 0.045). No significant differences were identified with respect to nausea, vomiting, time to 1st passing flatus, and time to defecation. Results were the same as regard rehospitalization, and wound infections.*
Conclusion: *Women who underwent cesarean births under regional anesthesia, and started early oral feeding had better post cesarean outcomes like those who receive routine hospital care for the same type of anesthesia as regard GIT functions and complications except the abdominal distension that showed a lower rate in the early feeding group. Also showed no difference as regard rate of wound infection and rehospitalization.*
Key words: *postoperative outcomes, early, late oral feeding, Cesarean Section, regional anesthesia*

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I. Introduction

Cesarean section is one of the commonly performed surgical procedures in obstetrics and is certainly one of the oldest operations in surgery. One of the most dramatic features of modern obstetrics is the increase in the cesarean section rate **(1).**

In recent years, the cesarean section rate has increased in different parts of the world, both in developed and developing countries. There is an increase in trend in both primary and repeat cesarean rates. The reasons for the increase are multifaceted. Fetal distress, especially its detection by continuous electronic fetal monitoring, more liberal use of cesarean section for breech presentation, abdominal delivery of growth-retarded infant, delayed childbearing, increasing maternal body mass, multiple gestation, prematurity and improved safety of cesarean section are commonly cited causes **(1).**

Traditionally, patients are not given fluid or food until clinical signs of normal intestinal function return, which is most commonly the presence of bowel sound, a passing of flatus or stool and the feeling of hunger. The rationale of this practice is to prevent postoperative nausea and vomiting, distention and other complications. However, withholding oral feedings may lead to intestinal ileus, which can prolong the length of hospital stay (LOS) and increase the financial burden **(2).**

It has been suggested that, even following bowel surgery, bowel sounds change in character but bowel function continues uninterrupted. One study suggested that perioperative nutritional status is of more importance to wound healing than the overall nutritional status (Burrows 1995). In spite of these reports, the tradition of withholding or delaying the intake of fluids immediately postoperatively has been practiced without supportive evidence (Guedj 1991). Ingam et al and Ryan et al., quoted in Guedj 1991, report that gastro-intestinal function returns soon after abdominal surgery **(3).**

With changing surgical attitudes, however, the benefits of early oral feeding, especially after cesarean section, are being reconsidered. Early feeding can reduce the rate of body protein depletion, improve wound healing, impact positively on psychological status and reduce the incidence of nosocomial infections; length of hospital stay and treatment costs [(4)].

Because the majority of cesarean surgery is performed under regional anesthesia with low intestinal manipulation and patients are mostly young, some researchers believe that these women can receive their usual diet as early as 4–8 h after surgery. There are even some studies which suggest that oral intake can be commenced within the first few hours after cesarean section [(5)].

One of the main concerns of any surgeon is the earlier return of the patients to normal feeding habits after caesarian section. This study was designed to evaluate the effect of early versus delayed postcaesarean feeding on gastrointestinal function and patient postoperative satisfaction after discharge.

Aim of the Work

This study aims to compare between the outcomes of early and late oral feeding after cesarean section under regional anesthesia.

Patients and Methods

The study is a randomized controlled trial that was done in Ain Shams University Maternity Hospital, in the Department of Obstetrics and Gynecology between November, 2016 and December 31, 2017. Women selected for this study fulfilled the following inclusion and exclusion criteria:

Inclusion criteria:

Singleton pregnant women undergoing elective C-section under spinal anesthesia with a body mass index (18-32) Kg/m^2.

Exclusion criteria:

1-Maternal criteria of exclusion:

- Medical:

Such as Hypertension, DM, Cardiac diseases, Hepatic diseases …..etc.

Or presence of any intestinal disease e.g. inflammatory bowel diseases.

- Surgical:
  - History of intestinal or bowel surgery or adhesions.
  - Presence of severe adhesions.
  - Surgical complications during or immediately after the section e.g. major blood loss, intestinal or bladder injury ….etc.
- Obstetrics complications such as:
  - Fatty liver in pregnancy
  - Preeclampsia or pregnancy induced hypertension.
  - Placental abruption.
  - Gestational diabetes.
  - User of the tocolytic drugs.
  - Premature rupture of membranes and chorioanmionitis.

2-Fetal criteria of exclusion:

- Multiple pregnancy.
- Fetal distress.

The selected women were subjected to the following:

1. History: proper full history was taken including.

- **Personal history:** -maternal age
- **Obstetric history:** -gravidity -parity.
- **Menstrual history:** -last menstrual period.
- **Maternal medical history:** -DM. -Hypertension. -Pervious abdominal surgery.

2. Examination

General examination

Full general examination was done with special concern to:

Vital signs: blood pressure (is measured on all participants using a single calibrated sphygmomanometer), pulse, temperature, heart rate and respiratory rate.

Chest and heart examination.

Abdominal examination: For assessment of gestation age, fetal weight, amount of liquor, fetal lie and presentation, fetal heart sounds, uterine contractions and any scars.

Trans-abdominal ultrasound: For assessment of gestational age, placental site and fetal weight.

300 patients were randomly assigned to either one of two groups:

- Group A: composed of 150 patients who were encouraged to oral fluid (then semi solid and solid) starting 2 h after C- section was performed.
- Group B: composed of 150 patients who received oral fluid starting 8 h following surgery.
- **Allocation and concealment:**

Three hundred opaque envelopes were numbered serially and in each envelope the corresponding letter which donated the allocated group was put according to randomization table then all envelopes were closed and put in one box. When the first patient arrived the first envelope was opened and the patient was allocated according to the letter inside.

Type of anesthesia:

All women were under spinal anesthesia.

Post-operative care:

All patients were observed every hour in the first 4 hours then every 4 hours till discharge for any post-partum complication or any adverse effect like fever, nausea, vomiting or diarrhea.

1- Both groups were compared to outcomes:

1ry outcome:

- Length of hospital stay.

2ry outcome:

1- Gastrointestinal function:

- Time of first passage of flatus,
- Time of first defecation,

2- Gastrointestinal complications

- Nausea, vomiting and abdominal distention

3 - Time to ambulation.

4- Level of maternal satisfaction and this was graded as (satisfied and not satisfied).

Patients were given appointment in the outpatient clinic for wound dressing and follow up for any further complications as:

- Wound infection
- Rehospitalization for any other reason

Data were prospectively collected using a sheet which was attached to the patient's obstetric chart and completed at the operative room and at maternity ward. The information gathered in data sheets were then fed into computerized database.

Statistical methods

All results were arranged, tabulated and statistically analyzed by the appropriate methods. It was done using SPSS (Statistical Program for Social Science) 16 statistical software as follows:

Description of quantitative variable as mean, SD, median and range. Description of qualitative variable as number and percentage. Chi-square test was used to compare qualitative variables. Mann-Whitney test was used to compare two groups as regard a quantitative variable.

ANOVA test was used to compare multiple variables. Spearman correlation between two variables which either positive correlation or negative correlation. Significance level was set at 0.05.

II. Results

Table (1): Demographic data of both groups.

		Group A No. = 150	Group B No. = 150
Age	Mean±SD Range	28.64 ± 4.30 20 – 38	28.97 ± 4.13 21 – 38
Parity	Median(IQR) Range	2.00 (1 – 3) 0 – 4	2.00 (1 – 3) 0 – 5
BMI	Mean±SD Range	30.13 ± 1.66 26.24 – 34.8	30.24 ± 1.23 26.4 – 32.79
CS duration (hours)	Mean±SD Range	1.02 ± 0.13 0.75 – 1.5	1.01 ± 0.14 0.75 – 1.5

This table shows no statistical difference between the two groups as regard age, parity, body mass index & duration of CS.

Table (2): Comparison between the studied group (A) & the control group (B) as regard GIT complications (nausea, vomiting & distention)

GIT complications		Group A No. = 150	Group B No. = 150	Test value	P-value	Sig.
Nausea	No Yes	116 (77.3%) 34 (22.7%)	120 (80.0%) 30 (20.0%)	0.318*	0.573	NS
Vomiting	No Yes	140 (93.3%) 10 (6.7%)	140 (93.3%) 10 (6.7%)	0.000*	1.000	NS
Distention	No Yes	135 (90.0%) 15 (10.0%)	123 (82.0%) 27 (18.0%)	3.987 *	0.045	S

*:Chi-square test

This table shows no statistically significant difference between the two groups as regard nausea & vomiting but shows that more patients in group (B) had distention with statistically significant difference (P value < 0.05) between the two groups using Chi-square test.

Table (3): Comparison between studied group (A) & control group (B) as regard GIT functions (1st passage of flatus, 1st defecation)

GIT functions		Group A No. = 150	Group B No. = 150	Test value	P-value	Sig.
1st flatus (hours)	Median (IQR) Range	12 (9 – 15.5) 7 – 20	13 (10 – 16) 7 – 21	1.431	0.153	NS
1st defecation	Median (IQR) Range	22 (17 – 26) 11.5 – 30.5	23 (19.25 – 26.0) 8 – 32	1.635	0.102	NS

NS: Non significant; S: Significant; HS: Highly significant
•: Mann-Whitney test

This table shows no statistically significant difference between the two groups as regard GIT functions (1st passage of flatus & 1st defecation) by using Mann-Whitney test.

Table (4): Comparison between studied group (A) & control group (B) as regard ambulation, satisfaction and duration of hospitalization

		Group A No. = 150	Group B No. = 150	Test value	P-value	Sig.
Ambulation	Median (IQR) Range	6 (4.5 – 8.5) 3 – 16	6.5 (5 – 9.5) 3.5 – 13.0	-2.451•	0.014	S
Satisfaction	No Yes	18 (12.0%) 132 (88.0%)	103 (68.7%) 47 (31.3%)	100.074*	0.000	HS
Duration of hospitalization	Median (IQR) Range	25 (23 – 28) 18 – 31.5	27 (24 – 29.5) 21 – 33	-3.449•	0.001	HS

NS: Non significant; S: Significant; HS: Highly significant
*:Chi-square test; •: Mann-Whitney test

This table shows that group A has a shorter time to ambulation, more satisfaction and shorter duration of hospitalization than group B with statistically significant difference as regard ambulation (P value < 0.05) and statistically highly significant difference as regard satisfaction and duration of hospitalization (P value < 0.001); using Chi square test, for satisfaction & Mann-Whitney test for Ambulation & duration of hospitalization.

Table (5): Comparison between studied group (A) and control group (B) as regard wound infections and rehospitalization

		Group A		Group B	
		No.	%	No.	%
Wound inf.	No	150	100.0%	150	100.0%
Rehospitalization	No	150	100.0%	150	100.0%

This table shows that there is not difference between the two groups as regard wound infection and rehospitalizaiton.

III. Discussion

The postoperative ileus (POI) is, unfortunately, very common after major abdominal surgery (but even in other or minor surgical procedures).

There are clear implications of an abnormal postoperative ileus on the poor quality of hospital stay for the patient, the increase in costs and occupation of beds in acute care areas due to increase of length of stay(LOS). In a recent review of patients undergoing colectomy, a postoperative ileus lengthened hospital stay of 8 days on average, with an additional cost of approximately $15,000 per patient.

The etiology is certainly multifactorial, with different mechanisms working together or at different times: sympathetic inhibitory input, secretion of hormones and neurotransmitters, inflammatory reaction, effects of opiates, or other drugs.

Many different approaches have been used to reduce the impact of postoperative ileus and clinical problems arising therefrom, with variable outcomes.

So far, the best suggestion is to minimize the impact of the factors underlying the phenomenon. Among these, the reduction of opioids and the use of alternative NSAIDs, acetaminophen, and local anesthetics in epidural analgesia. The selective use of nasogastric decompression, the correction of electrolyte imbalance, and a cautious policy of restriction of perioperative fluids all play an important role in multimodal management of the ileum.

Early enteral feeding has been promoted as a possible way to decrease duration of postoperative ileus (poi), in part by eliciting a contractile response in the GI tract.

In this study we compare between early oral feeding and late oral feeding after cesarean section as regard GIT functions, GIT complications, patient's ambulation, patient's satisfaction, length of hospital stay, wound infection, and rehospitalizaion.

All 300 patients were admitted to Ain shams university maternity hospital to have elective cesarean delivery. All patients received regional anesthesia.

Patients then were divided into two groups:

- ***Group A:*** composed of 150 patients who were encouraged to oral fluid (then semi solid and solid) starting 2 h after C- section was performed.
- ***Group B:*** composed of 150 patients who received oral fluid starting 8 h following surgery.

It was found that women in the early oral feeding group had a highly significant shorter hospital staying time than the late oral feeding group (25 (23 – 28) hours versus 27 (24 – 29.5) hours P value 0.001), and a highly significant satisfaction level among early oral feeding group (132 (88.0%) versus 47 (31.3%) P value 0.000). A significantly shorter time to ambulation in early oral feeding group (6 (4.5 – 8.5) hours versus, 6.5 (5 – 9.5) hours P value 0.014), and a significantly higher rate of occurrence of distention among the late oral feeding group (27 (18.0%) versus 15 (10.0%) P value 0.045). No significant differences were identified with respect to nausea, vomiting, time to 1st passing flatus,and time to 1st defecation. Results were the same as regard rehospitalization, and wound infections.

In 2014, ***Jalilian and Gandami*** [(5)]***,*** published a clinical trial that included 140 patients and compared the postoperative variables of women in the early feeding group versus the late feeding group the results were as the following, time to return of bowel movement (7.8 ± 2.9 vs 11.7 ± 5 h, $P < 0.0001$) and time to mobilization (10.7 ± 7.7 vs 13.5 ± 5.9 h, P: 0.015) occurred significantly earlier in the early feeding than in the late feeding group. The mean duration of passage of flatus appeared to be shorter in the early feeding group (13.6 ± 6.8 vs 15.4 ± 5.8 h). This difference, however, was not statistically significant ($P = 0.1$).

Jalilian and Gandami [(5)]***,*** also found that except for abdominal distention, there were no significant differences between groups with respect to postoperative gastrointestinal complications. The incidence of abdominal distention was significantly lower in the early feeding than in the late feeding group ($P = 0.008$). The incidences of fever, infections and rehospitalization were similar between groups. This study didn't compare between the two groups as regard the patients' satisfaction [(5)]***.***

Interestingly, in recent meta-analysis by ***Guo et al.*** [(6)]***,*** included 20 eligible studies, including a total of 4584 who had undergone cesarean in this meta-analysis, appearance of intestinal sound was shorter in EOF than DOF by 8 hours nearly (14.22 versus 22.15 hours), the first passage of flatus (28.84 versus 37.22 hours) and

length of hospital stay was found to be more than 15 hours shorter in the EOF group versus DOF (76.15 versus 91.76 hours). This reduction would have a large economic impact. Faster return of gastrointestinal tract function may explain this observation. Results in this meta-analysis are same as our study except for the time of first passage of flatus that showed no significance in ours [(6)].

Another systemic review by ***Mangesi and Hofmeyr*** [(3)] also showed similar results where the early oral fluids or food were associated with: reduced time to first food intake (one study, 118 women; the intervention was a slush diet and food was introduced according to clinical parameters; weighted mean difference -7.20 hours, 95% confidence interval -13.26 to -1.14); reduced time to return of bowel sounds (one study, 118 women; -4.30 hours, -6.78 to -1.82); reduced postoperative hospital stay following surgery under regional analgesia (two studies, 220 women; -0.75 days, -1.37 to -0.12 - random effects model); and a trend to reduced abdominal distension (three studies, 369 women; relative risk 0.78, 95% confidence interval 0.55 to 1.11). No significant differences were identified with respect to nausea, vomiting, time to bowel action/ passing flatus, paralytic ileus and number of analgesic doses [(3)].

Another recent meta-analysis by ***Huang et al***. [(2)], that included 11 studies, the results were different as the potential effects of EOF on gastrointestinal bowel motility compared with DOF showed that the time to passing flatus occurred significantly earlier by 7.3 h (95% CI, _12.80 to _1.80), bowel movement occurred 6.27 h sooner (95% CI, _10.97 to _1.57), and bowel sounds returned 8.75 h earlier (95% CI, _17.07 to _0.42) in the EOF group compared with that in the DOF group.

Huang et al. [(2)] also found that the effects of EOF on postoperative gastrointestinal complications including nausea, abdominal distension, diarrhea, mild ileus symptoms and vomiting showed no significant statistical difference compared with the DOF group, EOF was not associated with increases in nausea, abdominal distension, diarrhea, and mild ileus symptoms and vomiting. All these results were similar to our study except the abdominal distension rate which was significantly higher in the EOF group of our study.

In ***Huang et al.*** [(2)]**,** meta-analysis length of hospital stay was reduced for the EOF group. Only two studies reported the patients' satisfaction level. One study reported that patients in the early feeding group were satisfied with the timing of the start of the diet, duration of hospital stay, and ability to ambulate after surgery. The other one reported that compared with DOF, EOF was associated with increased in satisfaction. Also these results were similar to our study [(2)].

On the other hand ***Barat et al.*** [(7)], in a clinical trial that included 200 pregnant women, they had different results from our study. They found that The mean time of the first passage of flatus was 10.2±1.7 hours for the early oral feeding group versus 10.7±1.6 hours for the delayed feeding group and the difference was significant (P=0.03).

Barat et al. [(7)]**,** also found that length of hospital stay as well as patient satisfaction level did not differ significantly between the two groups, which was different from what we found in our study [(7)].

IV. Conclusion

Women who underwent cesarean births under regional anesthesia (spinal-epidural anesthesia) and started early oral feeding had similar post cesarean outcomes like those who receive routine hospital care for the same type of anesthesia as regard GIT functions and complications except the abdominal distension that showed a lower rate in the early feeding group. Also showed no difference as regard rate of wound infection and rehospitalization.

Also early oral feeding group showed a shorter duration of hospital stay, an earlier time to ambulation, and a higher level of satisfaction than the late feeding group.

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