

Effect of feeding time on women's satisfaction after caesarean section: a randomized control study.

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ABSTRACT

Trial design : A quazi randomized controlled trial

Methods Participants : A total of 226 parous women with singleton vaginal delivery at term pregnancy (37 to 42 weeks of gestation) with cephalic presentation. Study participants who had undergone the use of tocolytics drugs for delivery, or caesarian section performed under general anaesthesia were excluded from the study. Moreover, participants with intra-operative complications (bowel injury, bowel adhesions, post-partum haemorrhage and anaesthetic complications) and postoperative complications (post-partum haemorrhage, shock, fever, eclampsia, and use of MgSo₄) were excluded from the study. The participants with pre-existing medical conditions like hypertension, diabetes and gastrointestinal diseases were screened off and removed from the study. Additionally, obstructed labour and the use of butrophanone as labour analgesia or post-operative analgesia were excluded.

Intervention The study participants were divided into two groups based on the intervention considered. After the participants were selected as per inclusion criteria, an informed consent was taken from all the respondents. The early feeding group was allowed for intake of food after 6 hours of delivery starting with liquid diet followed by solid diet. Similarly delayed feeding group was allowed for intake

of food after complete reversal of anaesthesia i.e. 12 hours of delivery starting with liquid diet followed by solid diet.

Outcome : improved patient satisfaction in early feeding group.

Results : The total study participants was 226. The average level of satisfaction of patients in the early feeding group (7.31 ± 0.710) is more than the delayed feeding group (6.47 ± 0.695) with a p-value of <0.001 which is statistically significant.

Keywords : Caesarean section, Satisfaction, Gastrointestinal, Feeding

INTRODUCTION

Post-operative ileus is a common complication arising after abdominal surgery. After a Cesarean section, it affects about 26-31% of patients.¹ Such problems can delay post-operative recovery, extend hospitalizations, raise costs and increase the discomfort of the patients.¹ Caesarian sections are usually small operations involving minimal bowel manipulation in young healthy women but bowel damages occurs with 1 in 1000 caesarean deliveries. Some degree of adynamic ileus follows virtually every abdominal operation.^{2,3} Despite the studies that have shown that post-operative early feeding reduces post-operative ileus, many hospitals and different practitioners still stick to their traditional approach.^{3,4} Many researchers believe, that after a non-eventful caesarean section, oral fluids can be initiated after the recovery from anaesthesia followed by a solid diet immediately. This causes the belching by which flatulence and abdominal distension are relieved and faster peristaltic motion in the intestines.^{5,6} In this study we aimed to understand woman's satisfaction and the reduction in post-operative pain after early feeding following the delivery. We also aimed to study the self rated abdominal pain, flatulence, time of passage of flatus, duration of abdominal distension, nausea/ vomiting within 24 hours of surgery and time to first passage of stool of both the study groups.

MATERIAL AND METHODS

Ethical Consideration

This research was conducted after the approval of research from the Institutional Review Committee of B.P. Koirala Institute of Health Science with code no IRC/1352/018 and is in line with CONSORT 2010 guidelines.⁶

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Informed Consent

The study was conducted after the approval from the ethics committee. Informed written consent is obtained from the research participants after properly explaining the procedure. No personal details of patients are revealed in this study.

Trail Design

This is a prospective, randomized control trial conducted to determine the effect of early versus delayed feeding after a caesarian section on women's satisfaction.

In this study, we have included 484 women who had a singleton, emergency or elective caesarian section at term pregnancy (37 to 42 weeks of gestation) conducted under general anaesthesia. After the exclusion of participants, as per exclusion criteria, informed consent was taken from the patient.

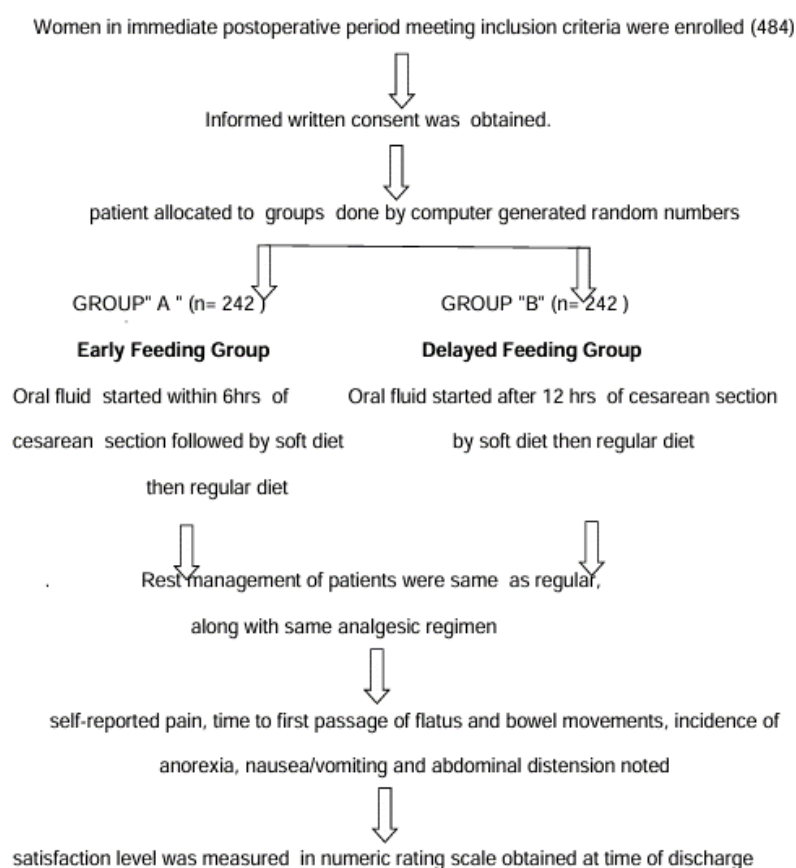
The primary outcome was patient satisfaction before discharge from the hospital, measured using a numeric rating scale. A 100mm long scale will be used, with adjectival descriptions at the end. Participants were provided with a questionnaire containing the numeric rating scale, which was presented with a statement explaining what it intended to measure.

Participants

We conducted a randomized analysis of 226 individuals who fit the inclusion criteria, after ensuring appropriate consent and privacy of patients. We have included all the parous women who had singleton vaginal delivery at term pregnancy (37 to 42 weeks of gestation) with cephalic presentation.

Study participants who had undergone the use of tocolytics drugs for delivery, or caesarian section performed under general anaesthesia were excluded from the study. Moreover, participants with intra-operative complications (bowel injury, bowel adhesions, post-partum haemorrhage and anaesthetic complications) and postoperative complications (post-partum haemorrhage, shock, fever, eclampsia, and use of MgSo₄) were excluded from the study. The participants with pre-existing medical conditions like hypertension, diabetes and gastrointestinal diseases were screened off and removed from the study. Additionally, obstructed labour and the use of butrophanone as labour analgesia or post-operative analgesia were excluded. Such selection criteria help to ensure the appropriate study sample is selected for the study and these factors will not confound the results obtained. This study took place in the Department of Obstetrics and Gynaecology of BPKIHS from January 2019 to December 2019.

Fig: Consort Flow Chart



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Interventions

For the study, the study participants were randomly allocated into two groups using the computer-generated random table. In this study, we have considered 484 women who were in the immediate postoperative period after going through the eligibility criteria. An informed written consent was obtained from all the study respondents. After the delivery, the early feeding group was allowed to intake of food after 6 hrs of delivery initiating with liquid diet followed by solid diet of patients choice. For the delayed feeding group, the process for diet initiation is same as early except for the time of initiation of diet which is 12 hrs following the delivery.

Outcomes

The study was focused on determining the satisfaction in females following the early oral feed and delayed oral feed along with gastrointestinal complaints faced after the caesarean section.

Sample size

According to the annual report of 2016/17 of the institution, total number caesarean section was 296, out of a total of 10,669 deliveries. As reported by GH Izbizky et al⁷ mean $\pm$ SD for both early feeding group is ± 13 and delayed feeding group is ± 17 . The sample size for the study group was 77 and the delayed group was 73, the calculated sample size is Where,

$$Z_{\alpha} \text{ at } 5\% = 1.96, Z_{\beta} \text{ at } 20\% = 0.84$$

$$X_1 = 73, X_2 = 77$$

$$S_1 = 17, S_2 = 13$$

So,

$$n = 2 (1.96 + 0.84)^2 (15)^2 / (4)^2 = 220 = 220 \text{ (in each group)}$$

Adding 10% to each group for error in the study

A final sample size of 242 in each group

Control Group: 80 pregnant women planned for elective CS and meeting inclusion criteria

Randomization

A total of 484 participants participated in this study. These participants were at term pregnancy (37 to 42 weeks of gestation) undergoing elective or emergency caesarian section under regional or general anaesthesia. The participants were divided into two groups based on the intervention considered. The randomization was done by the computer-generated random number table and it was maintained throughout the study.

Blinding

No blinding was done for the study.

Statistical Methods

The data were collected using the performa prepared by the authors. Later these data were entered in Microsoft Excel

2010 and followed by Statistical Package for Social Science (SPSS) version 20 for statistical analysis. For descriptive statistics: percentage, proportion, mean and Standard Deviation tabular presentation. For inferential statistics: Chi-square, independent T-test, Mann-Whitney U-test applied to find out the significant differences between the groups and other related variable at 95% Confidence Interval (CI) where level of significance = 0.05.

RESULTS

A total of 484 pregnant females enrolled in this study as per the inclusion criteria. The study groups were divided as mentioned above in the methodology. The sociodemographic details of patients are mentioned in Table 1

Table 1: Age distribution of patients in the study.

Age groups in years	No of Participant	Percentage (%)
≤ 20	45	9.3
21 – 25	193	39.9
26 – 30	160	33.1
31 – 35	71	14.7
≥ 36	15	3.1
Total	484	100.0
Parity	No of Participant	Percentage (%)
Nullipara	244	50.4
Primipara	177	36.6
Multipara	63	13
Total	484	100.0
Period of gestations in weeks	No of Participant	Percentage (%)
37	54	11.1
38	84	17.3
39	131	27.0
≥ 40	215	44.4
Total	484	100.0
Indication for present section	No of Participant	Percentage (%)
Previous LSCS	130	26.8
Breech	44	9.0
Failed Induction	62	12.8
NRNST	109	22.5
Arrest disorders	24	4.9
Others	115	24
Total	484	100.0

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Most of the participants in this study were from the age group of 21-25 years (39.9%) and the majority were nulliparous (50.4%). Previous LSCS (26.9%) was the most common cause for the current CS delivery. The study was divided into 2 groups as per indications of the Caesarian Section and age group.

Table 2 : Distribution of the study groups and association

Character	Category	Group and (%)		P value	Remarks
		Earlyfeeding group	Delayed feeding group		
Age group	≤20	23 (51.1)	22 (48.8)	0.298	Not Significant
	21 – 25	89(46.1)	104(53.8)		
	26 – 30	89(55.6)	71(44.3)		
	31 – 35	36(50.7)	35(49.2)		
	≥36	5(33.3)	10(66.6)		
Character	Category	Group and (%)		P value	Remarks
		Early feeding group	Delayed feeding group		
Period of gestation group (in weeks)	37	27(50)	27(50)	0.682	Not Significant
	38	52(61.9)	32(38)		
	39	67(51.1)	64(48.8)		
	≥40	96(44.6)	119(55.3)		
	Character	Mean ± SD		P value	Remarks
		Early feeding group	Delayed feeding group		
	Level of satisfaction	7.31 ± 0.710	6.47 ± 0.695	<0.001	Significant

There was no significant association of patient age with satisfaction for both the groups (study and control group). Similar findings were also noted with no association between the period of gestation and patient satisfaction as shown in Table 2. However, the average level of satisfaction of patients in the early feeding group (7.31 ± 0.710) is more than the delayed feeding group (6.47 ± 0.695) with a p-value of <0.001 which is statistically significant.

Table 3: Relationship between two variables in the two study groups

Character	Mean ± SD		P value	Remarks
	Early feeding group	Delayed feeding group		
Pain (in VAS)	6.464 ± 0.598	6.782 ± 0.649	<0.001	Significant
Abdominal distension	5(2.1%)	3(1.2%)	0.476	Not significant
Nausea/Vomiting	23(9.5%)	17(7%)	0.322	Not significant
Time of passage of flatus (in hrs)	13.30 ± 3.591	14.73 ± 2.710	<0.001	Significant
Time of bowel movements (in hrs)	23.02 ± 3.555	26.24 ± 4.673	<0.001	Significant
Duration of hospital stay in days(mean rank)	2.07 ± 0.249 (228.40)	2.21 ± 0.489 (256.60)	<0.001	Significant

Several characteristics of abdominal complaints are noted in Table 3. The mean post-operative pain value recorded in VAS in the case group was 6.464 ± 0.598 as compared to that in the control group which was 6.782 ± 0.649 . The comparison was significant statistically (P value = <0.001).

The mean time for the passage for flatus after cesarean section in the case group was recorded to be 13.30 ± 3.591 hrs while that in the control group was 14.73 ± 2.710 hrs. This analysis was found to be significant statistically with a P value of <0.001. Also, the mean time for first bowel movements after cesarean section among the case group and control group was calculated, which was 23.02 ± 3.55 hrs and 26.24 ± 4.673 hrs respectively. This interpretation was also found to be significant statistically.

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with a P value of <0.001 .

In this study among the case group 5(2.1%) had abdominal distension while 3(1.2%) in the control group had abdominal distension which was not statistically significant ($p=0.476$). In the case 23(9.5%) patients had nausea and vomiting while 17(7%) in the control group had nausea and vomiting which was also not significant ($p=0.322$).

In this study, none of the individuals either in the case or control group needed admission to ICU and none of the patients had any other complications.

DISCUSSION

Over the recent decades, caesarean section rates have been rising progressively all over the world. Many causes are there for such a rise including women's choice. This has turned the facilities providing the health care for pregnancy and perinatal care in an increase. It is vital for all obstetricians to reduce morbidity and increase satisfaction rates from this procedure.⁷

Conventionally, oral feeding was held during the post-operative period until the resolution of post-operative ileus, demonstrated by the return of bowel sound and passage of flatus. However in recent studies, this historical dictum has been refuted as early initiation of oral feeding is well tolerated and beneficial to the patient. Such studies have been performed in developed countries and under regional anaesthesia.

In the present study, all the socio-demographic characteristics of all the patients in both the case and control groups were comparable. The early and delayed feeding group was allowed to feed orally at 6 and 12 hrs respectively with a liquid diet followed by a soft diet to regular diet as tolerated.

In our study the overall satisfaction level measured on a numeric rating scale at the time of discharge from the hospital in the case and control group were 7.31 ± 0.710 and 6.47 ± 0.695 respectively and was significant ($p < 0.001$). The findings are consistent to the study conducted by Teoh et al where study the mean satisfaction level in early and delayed feeding group were 90 (80-100) and 60(40-80) with $p < 0.001$.³ While Guy Bar et al calculated no of patients satisfied by the treatment protocol and found that in early and delayed feeding group 68/72(94.4%) and 40/51(78.4%) were satisfied with the treatment and the mean satisfaction level in early feeding group was 96.4 ± 4.9 and in delayed feeding group was 90.7 ± 1.6 with $p < 0.001$.⁸

The mean level of pain measured in this study in the early feeding group was 6.464 ± 0.598 and in the delayed feeding group was 6.782 ± 0.649 with $p < 0.001$. Pain was measured as a separate variable in a study conducted by Izbizky et al In that study, the mean pain level in the early group was 29 ± 13

and in the delayed group was 24 ± 11 with $p = 0.008$.⁷

The mean duration of passage of flatus was 13.30 ± 3.591 in the early feeding group while it was 14.73 ± 2.710 hrs in delayed feeding group. The mean time for first bowel movement were 23.02 ± 3.55 hrs and 26.24 ± 4.673 hrs in early and delayed feeding groups respectively. Both were significant with $p < 0.001$. Similar findings were observed in the study conducted by Izbizky et al where the mean time for passage of flatus in early and delayed feeding group were 12 ± 11 hrs and 15 ± 11 hrs respectively.⁷ Findings by Teoh et al showed the mean time for passage for flatus in early and delayed feeding group to be 14.4 ± 9.4 hrs and 21 ± 10.4 hrs respectively and mean time for first bowel movements in both groups were 44.4 ± 18.7 hrs and 65.6 ± 25.4 hrs respectively. The findings were in consistent with our study and significant with $p < 0.005$.³

The result of present study showed no significant difference in the symptoms of mild post operative ileus, these included incidence of nausea, vomiting and abdominal distension. In this study the incidence of abdominal distension in the case and control group were 5(2.1%) and 3(1.2%) respectively. While incidence of nausea/vomiting were 23(9.5%) in case and 17(7%) in control group. Both of these findings are not significant ($p = 0.476$ and 0.322). None of the cases in both group had symptoms of severe post operative ileus requiring intervention including nasogastric decompression and abdominal radiographs. The findings of the study is almost consistent with the findings of the study conducted by Izbizky et al where the incidence of mild ileus in early and delayed feeding group was 17% and 16% respectively and was not significant in the study.⁷

The women who fed early made more rapid recovery and expressed their interest in early discharge. The women on early feeding group had a shorter hospital stay compared to women in the routine group. In our study the mean duration of hospital stay in early and delayed feeding groups were 2.07 ± 0.249 days vs 2.21 ± 4.673 days respectively ($p < 0.001$). This finding was supported by other studies. Göçmen et al reported that women who were given food shortly after caesarean delivery had a shorter hospital stay than those given food in the traditional post-operative times, 26.7 ± 5.2 hours versus 43.9 ± 8.1 hours ($p < 0.001$).⁹ However, Adupa et al reported that there was no significant difference in length of hospital stay between early feeding group and traditional feeding group, 5.5 ± 3.0 days versus 6.0 ± 3.8 days ($p = NS$).⁴ Guy bar et al reported no significant difference in mean duration of hospital stay. It was 5.1 ± 1.48 days and 5.5 ± 1.6 day ($p = 0.107$) respectively in both groups.⁸ Although the duration of hospital stay and time for discharge is also affected by the hospital protocol but in most of the studies it is seen that the difference between the study and control groups are significant.

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Advantage of early mobilization is that it prevents thromboembolism. Benefits of early initiation of oral feeding after cesarean section include shorter hospital stay, early resumption of normal diet and fewer numbers of intravenous fluid consumption. In conclusion, early initiation of oral feeding after cesarean section is safe and well tolerated by patient. Benefits are shorter hospital stay, early resumption of normal diet, early mobilisation and reduction cost of hospital bills. There is no increase in incidence of post-operative paralytic ileus. In addition to this other important benefit observed was with early resumption of feeding and mobilization lead to early breastfeeding and care of newborn.

CONCLUSION

Early feeding after uncomplicated caesarean in low-risk women is equivalent in terms of the woman's satisfaction and the reduced perceived pain. In a developing country like ours where the trend of cesarean section is increasing, ways to reduce hospital costs, effective utilization of human resources along increased satisfaction to the patient seem justifiable.

Author Contributions

SS- Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, visualization, Writing – Original Draft Preparation, Writing – Review & Editing

SU- Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, visualization, Writing – Original Draft Preparation, Writing – Review & Editing

BK- Data Curation, Formal Analysis, Investigation, Methodology, Validation, visualization, Writing – Original Draft Preparation, Writing – Review & Editing

Ethics statement

Prior approval was obtained from the Institutional Review Committee for the study purposes. All the personal details of patients are kept confidential and no information which reveals patient identity is disclosed in the article.

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Conflict of interest: Authors declare no conflict of interest.

Data availability statement: The author of this article Sajana Shrestha affirms for honest, accurate and transparent account of study being reported, no additional or supporting information has been omitted and the discrepancy of the article is explained.

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