A randomised controlled trial on beneficial effects of early feeding post-Caesarean delivery under regional anaesthesia

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ABSTRACT

Introduction: We prospectively investigated the incidence of ileus, nausea/vomiting, and hospital course of non-labouring women fed immediately after Caesarean delivery under regional anaesthesia.

Methods: 196 patients were randomised into either the early-fed group (250 ml clear fruit juice 30 minutes postoperatively, and unlimited solid food thereafter) or the control group (clear feeds allowed after two hours, advanced to solids as tolerated).

Results: Both groups had similar baseline demographics and operative characteristics. Bowel sounds were present immediately postoperatively in 90.8 percent (early group) versus 95.9 percent (control). The early-fed group had reduced time to first drink (0.86 +/- 0.6 hours versus 14.4 +/- 18.2 hours) and solid food intake (4.2 +/- 2.7 hours versus 20.0 +/- 6.8 hours), earlier passage of flatus (14.4 +/- 9.4 hours versus 21.0 +/- 10.4 hours) and first stool (44.4 +/- 18.7 hours versus 65.6 +/- 25.4 hours), shorter duration of intravenous hydration (12.8 +/- 7.5 hours versus 22.4 +/- 5.8 hours), and earlier removal of intravenous cannulae (20.5 +/- 6.7 hours versus 24.7 +/- 7.8 hours), with all p-values less than 0.001. Early-fed mothers also mobilised (23.1 +/- 6.8 hours versus 27.4 +/- 7.6 hours), commenced breastfeeding (26.5 +/- 14.1 hours versus 38.8 +/- 21.8 hours), and were ready for discharge earlier (44.3 +/- 10.4 hours versus 62.0 +/- 12.7 hours), compared to the control group, with all p-values less than 0.001. There was no difference in mild ileus symptoms (3.1 percent). Earlier solid intake resulted in more nausea (10.2 percent versus 2 percent, p-value is 0.033), which was self-limiting. Maternal satisfaction rated higher in the early-fed group (90 versus 60, on visual analogue scale score 0–100, p-value is less than 0.001).

Conclusion: This prospective randomised trial showed no increase in ileus with early feeding post-Caesarean delivery under spinal anaesthesia, with added benefits of earlier intravenous cannulae removal, ambulation, breastfeeding initiation and potential for shorter hospitalisation. Despite increased nausea in those taking solids earlier (but not feeds), maternal satisfaction rated higher in the early-fed group.

Keywords: Caesarean delivery, Caesarean section, early feeding, ileus, regional anaesthesia

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INTRODUCTION

Historically, patients were fasted following abdominal surgery until return of bowel sounds or passage of flatus. However, Caesarean sections are generally short operations involving minimal, if any, bowel manipulation in young healthy women. Practices vary among individual practitioners and different institutions worldwide regarding the post-partum dietary management and "safe" timing for re-introduction of solids. A Cochrane review found previous studies on early post-partum feeding to be small in number and heterogeneous in make-up.[1] We therefore undertook a larger prospective randomised controlled study to assess superiority of early feeding versus standard protocol, with regard to tolerability, incidence of nausea or vomiting, ileus and hospital course

of patients who were fed early. The primary hypothesis of the study was that the incidence of ileus would not be affected by early feeding. In addition, we also addressed the duration of intravenous (IV) hydration, maternal satisfaction, and breastfeeding initiation.

METHODS

We conducted a prospective randomised controlled trial involving 200 ASA I and II patients undergoing elective Caesarean delivery under spinal anaesthesia. Hospital ethics committee approval was obtained and all subjects gave prior written informed consent. As part of the informed consent process, patients were advised that they had equal chances of being randomised into two groups of either the early feeds or control group. How early the feeds were was not specified to keep patients blinded to their group allocation. If patients were told that they would be offered feeds within one hour post-surgery, then they would know they were in the early feeding arm of the study, and thus would not be blinded. We excluded patients opting for general anaesthesia, those in active labour, or in whom emergency Caesarean sections were performed for non-reassuring foetal status. We also excluded those with pre-existing gastrointestinal disorders, such as peptic ulcer, hiatus hernia, irritable bowel syndrome, or oesophagitis, and those with an intraoperative blood loss exceeding 800 ml.

All patients received a spinal anaesthetic comprising intrathecal 10 mg hyperbaric bupivacaine (2 ml of 0.5% bupivacaine with 8% glucose, AstraZeneca, Sweden) and 100 mcg Morphine (Mayne Pharma, Victoria, Australia). Caesarean deliveries were performed via a low segment transverse cervical incision. Anti-emetic prophylaxis (IV Metoclopramide 10 mg [Yung Shin Pharmaceutical, Taiwan], Ondansetron 4 mg [GlaxoSmithKline, Victoria, Australia] plus Dexamethasone 4 mg [Mayne Pharma, Victoria, Australia]) was administered after delivery of the baby, in keeping with our standard hospital practice. At the end of surgery, all patients received 100 mg rectal diclofenac sodium [Farmaceutici Ecobi, Ronco Scrivia Genova, Italy], and were prescribed oral mefenamic acid [YSP, Malaysia] 500 mg eight-hourly to be administered after return to the ward as required (prn) for pain. Patients who were allergic to non-steroidal anti-inflammatory drugs received 975 mg rectal paracetamol (Pharmascience, Montreal, Canada), and were prescribed oral paracetamol 1 g eight-hourly prn. As standard hospital policy, patients who had received intrathecal opiates were not allowed to receive systemic opiates for 24 hours.

Immediately after surgery, patients were randomised into two groups: the early-fed (E) group and the control (C) group. Randomisation was achieved by a computer-generated random number list, with subsequent placement into sealed opaque envelopes. The investigator who enrolled the patient into the trial would then administer the prescribed intervention according to group assignment. This investigator subsequently had no role in that patient's assessment and data collection. The obstetricians involved in the intraoperative care of the patient were also blinded to the assigned group. Group E patients were given a 250 ml pack of clear fruit juice after a 30-minute uneventful observation period in the recovery area (the first drink), while Group C patients were kept nil by mouth during this 30-minute observation period. All subsequent management of patients in both groups was similar. 10 mg of metoclopramide was to be administered intravenously eight-hourly on an "as required" basis for vomiting. No anti-emetics were prescribed for nausea. In keeping with standard ward practice, patients would be reviewed by an obstetric resident on the ward two hours postoperatively, and feeding was advanced to fluids or solids as tolerated. Meals were made available and served to the patients regardless of whether they experienced nausea or vomiting, but patients could choose not to eat if they so desired. The standard first fluid was chocolate milk, and the first solid was a bowl of porridge (congee). We did not document the actual quantity of food or drink ingested, but only meals that were completely consumed constituted the "first solid".

IV hydration was to be discontinued when patients successfully completed a meal without nausea or vomiting. The IV cannula was removed upon completion of three doses of IV antibiotic or hydration, whichever was later. Patients received IV Cefazolin 1 g eight-hourly, with the first dose administered intraoperatively after delivery of the baby. Early breast feeding and ambulation was encouraged in both groups. Commencing from the immediate postoperative period, all caregivers would remind the patients that they could ask for their baby (to breastfeed and for other purposes such as bonding) and urged to mobilise early. Baseline demographical and operative characteristics were obtained, including the presence of bowel sounds in the immediate postoperative period. The duration of surgery was defined as the time from the onset of surgery to skin closure. All other durations (first drink/solid food, passage of flatus and first bowel action, commencement of breastfeeding, ambulation, cessation of IV hydration and removal of IV cannulae) were recorded in hours from the completion of surgery. We defined mild ileus as anorexia, abdominal cramps, non-persistent nausea or vomiting; and severe ileus as abdominal distension, more than four episodes of vomiting in 24 hours, intolerance to oral fluids, a need for abdominal radiographs or nasogastric decompression.[2]

A dedicated research nurse, who was independent of the managing obstetric team, and blinded to patient group allocation, reviewed the patient twice daily to assess the

Table I. Patient demographics.

	Early group (n= 98)	Control group (n= 98)
Age (years)	32.8 (4.3)	31.8 (4.1)
Weight (kg)	68.6 (10.6)	71.5 (10.4)
Height (cm)	157.8 (5.7)	159.3 (5.7)
Gravidity	2 (2–3)	2 (2–3)
Parity	1 (1–2)	1 (1–2)
Gestation (weeks)	38 (37–38)	38 (37–38)
Prior Caesarean delivery	71 (72.4%)	69 (70.4%)

Data are expressed as mean (standard deviation), median (interquartile range), or number (percentage). No comparisons were statistically significant (all p-values > 0.05).

Table II. Operative characteristics.

	Early group (n= 98)	Control group (n= 98)
Adhesions found	13 (13.3%)	16 (16.3%)
Estimated blood loss (ml)	321 (157.8)	297 (152.9)
Duration of surgery (min)	40.1 (13.1)	37.8 (12.3)
Urine output (ml)	132 (67.3)	126 (85)
Fluids infused (ml)	1598 (355)	1571 (325)
Intraoperative nausea	7 (7.1%)	6 (6.1%)
Intraoperative vomiting	2 (2%)	1 (1%)

Data are expressed as mean (standard deviation), median (interquartile range), or number (percentage). No comparisons were statistically significant (all p-values > 0.05).

patient for ileus symptoms and to specifically collect data. The data was verified by one of the investigators blinded to the allocation group, by checking the medical records and by a daily phone interview with each patient at the end of each workday. Phone interviews were conducted daily for each patient, even during their hospitalisation, to ensure accurate recall of symptoms of ileus and times of first meal, flatus, and cannulae removal. This was to further verify the accuracy of data collected by the research nurse. Patients were contacted via their personal cellular mobile phone, bedside or ward phone, interviewed and followed up daily till discharge or bowel action, whichever was the later. On the first postoperative day, maternal satisfaction pertaining to the feeding regimen was recorded on a 0-100 mm visual analogue scale (VAS), with 0 meaning not satisfied to 100 being most satisfied. They were asked "On a scale of 0–100, how satisfied were you with the timing of feeding after your surgery? (0 meaning not satisfied to 100 being most satisfied)". Patients were considered ready for discharge if they were tolerating solid food without emesis, ambulating, afebrile, with minimal postoperative pain that was easily controlled with oral analgesics. If actual hospital discharge time exceeded the fitness for discharge time, the reasons for this were documented.

A previous study found a 26% rate of ileus symptoms post-Caesarean delivery in a population of patients that received both general and regional anaesthesia, and included patients who were in labour.[2] There was no published local data on ileus rates post-Caesarean delivery in a population of patients not in labour and receiving only regional anaesthesia. We chose a total (mild or severe) ileus rate of 10% based on our clinical observations and determined by prospective power analysis that a sample size of 90 in each group would be required to detect an increase in ileus to 26% with an alpha error of 0.05 and a power of 0.80. For parametric data, Student's t-test was used to compare the data between the two groups. Wilcoxon rank-sum test (Mann-Whitney) was used for non-parametric data. Fisher's exact test was used to compare the incidence of side effects. Statistical analysis was performed using the Statistical Package for Social Sciences version 10.0 for Windows (SPSS Inc, Chicago, IL, USA). A p-value < 0.05 was considered significant.

RESULTS

200 patients were recruited over a three-month period. Data was only available for 196 patients, 98 in each group. One patient refused to participate after delivery of her baby, and three patients had incomplete data. Both groups were comparable in terms of baseline demographics (Table I). The operative characteristics of both groups were also comparable, with no difference in adhesion rates, surgical duration, blood loss, urine output and fluids infused (Table II). Although an intraoperative estimated blood loss of 800 ml was an exclusion criterion, no patients were excluded for this reason.

All patients in Group E consumed the entire contents of their 250 ml clear fruit juice pack. Patients in Group E had reduced time to first drink (0.86 ± 0.6 hours versus 14.4 ± 18.2 hours) and solid food intake (4.2 ± 2.7 hours versus 20.0 ± 6.8 hours). Group E patients had a shorter duration of IV hydration (12.8 ± 7.5 hours versus 22.4 ± 5.8 hours), earlier IV cannulae removal (20.5 ± 6.7 hours versus 24.7 ± 7.8 hours), earlier ambulation (23.1 ± 6.8 hours versus 27.4 ± 7.6 hours), earlier commencement of breastfeeding (26.5 ± 14.1 hours versus 38.8 ± 21.8 hours), and were also ready for discharge earlier (44.3 ± 10.4 hours versus 62.0 ± 12.7 hours), compared to Group C. All these comparisons were significantly different, with $p < 0.001$ (Fig. 1). Actual length of hospital stay was not statistically different (68.0 hours versus 69.4 hours, $p > 0.05$). The incidence of breastfeeding did not differ up till the end of the follow-up period (Group E 78% versus Group C 76%, $p > 0.05$).

There was no difference in the presence of bowel sounds immediately postoperatively: 90.8% in Group E versus 95.9% in Group C. Both groups displayed no

difference in mild ileus symptoms (3.1%), and no patients had severe ileus. Five patients in Group E vomited after the first drink, but none in Group C, a difference that did not achieve statistical significance. Although earlier solid intake resulted in more nausea (10.2% versus 2.0%, $p = 0.033$) and vomiting (7% versus 0%, $p < 0.05$) in Group E patients, it was self-limiting, since the time to subsequent solid intake in those with emesis was comparable in both groups (9.43 ± 5.87 hours versus 8.0 ± 8.49 hours, $p > 0.05$). All patients who vomited only did so once, except for one patient in Group E who vomited three times. Group E patients had earlier passage of flatus (14.4 ± 9.4 hours versus 21.0 ± 10.4 hours, $p < 0.05$) and first stool (44.4 ± 18.7 hours versus 65.6 ± 25.4 hours, $p < 0.05$) (Table III). No patients in either group received postoperative opiates. Maternal satisfaction rated higher in the early-fed group (median 90, interquartile range 80–100) versus the control group (median, 60; interquartile range, 40–80), on VAS score 0–100 ($p < 0.001$).

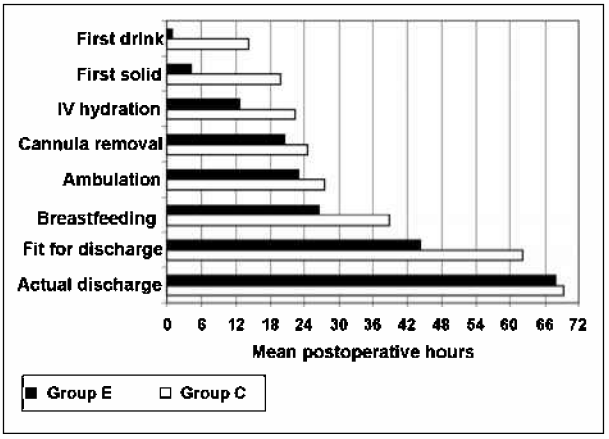

Fig. 1 Bar chart shows postoperative durations for both groups. All comparisons were $p < 0.001$, except actual time to discharge, which was not significant.

DISCUSSION

The traditional approach where patients receive nothing orally till return of bowel function (passage of flatus or bowel motion), followed by slow advancement of feeds to a solid diet postoperatively is now challenged. Although somewhat controversial, there is increasing evidence demonstrating the safety of early feeding after major gynaecological surgery,[3–6] bowel resections,[7–12] and intestinal perforation and peritonitis.[13] These prospective randomised trials indicated no increased aspiration pneumonia, wound dehiscence or anastomotic leaks, with some showing a reduction in hospital stay. Although clear liquids are accepted as the standard first postoperative meal, retrospective studies and anecdotal reports have suggested that a "regular" diet as the first postoperative meal is also tolerated,[14,15] although this is not standard practice.

Our study was confined to non-labouring patients presenting for elective Caesarean delivery under regional anaesthesia in order to maintain a homogeneous study population, thus avoiding the heterogeneity that was criticised in previous studies. Our study is the largest randomised controlled trial conducted to date in this population. The limitation of this approach is that the benefits of immediate oral feeds and diet resumption may not be readily extrapolated to other patient populations, for example, the situation of immediate oral feeding after Caesarean delivery under general anaesthesia.

Although Gocmen et al[16] found earlier development of bowel sounds and a shorter hospital stay in patients fed early after Caesarean sections performed under general anaesthesia, their "early group" comprised those fed a low residue diet only after a delay of six hours postoperatively. In contrast, our early-fed patients were given their first drink 30 minutes after an uneventful period in the recovery area. Given that patients with high

Table III. Gastrointestinal outcomes and satisfaction.

	Early group (n= 98)	Control group (n= 98)
Bowel sounds immediately postoperatively	94 (95.9%)	89 (90.8%)
Nausea after 1st drink	5 (5.1%)	4 (4.1%)
Anti-emetic after 1st drink	5 (5.1%)	0 (0%)
Nausea after 1st solid	10 (10.2%)	2 (2%) *
Anti-emetic after 1st solid	7 (7.1%)	0 (0%) *
Those with nausea or vomiting, time to next diet (hours)	9.43 (5.87)	8.0 (8.49)
Time to 1st flatus (hours)	14.4 (9.4)	21.0 (10.4)*
Time to 1st stool (hours)	44.4 (18.7)	65.6 (25.4)*
Mild ileus symptoms (%)	3 (3.1%)	3 (3.1%)
Severe ileus (%)	0 (0%)	0 (0%)
Satisfaction VAS (0–100)	90 (80–100)	60 (40–80)†

Data expressed as number (percentage), mean (standard deviation), or median (interquartile range). *$p < 0.05$, †$p < 0.001$

blood loss would be excluded, and our low institutional rate (1.3%) of immediate post-partum haemorrhage necessitating a return to the operating theatre, we believed that this would be a safe interval. After their initial drink, they were further monitored for another 30 minutes prior to discharge to the ward, making a total recovery time of one hour.

We found that the early-fed patients had reduced time to first drink by 13.5 hours and reduced time to solid food intake by 15.8 hours, although the theoretical "head-start" was only two hours by the design of the study. Patients randomised to the early feeding group received a drink within the first hour of surgery, whereas the control group did not. Patients in both groups then returned to the wards, where the obstetrical resident would conduct a postoperative review in the second hour post-surgery, assess for bleeding, pain, vital signs, and order feeds/solids, in keeping with current ward practice.

The duration of IV hydration was shortened by 9.6 hours in Group E patients. Ray and Rainsbury[17] also found that early introduction of oral fluids after laparotomy permitted effective hydration and earlier discontinuation of IV fluids. The shorter duration of IV hydration could protect the mother from the discomfort of frequent IV cannula changes, risks of fluid extravasation, and phlebitis. IV cannulae removal was primarily determined by the requirement to give antibiotics in our institution, but the impact of early feeding on its duration cannot be discounted. Theoretically, since the first antibiotic dose was given intraoperatively, the IV cannulae could be removed 16 hours post-surgery after completion of the two subsequent doses eight hours apart. Yet, we found that IV cannulae were removed at a mean 20.5 hours in Group E patients compared to 24.7 hours in the control group. Early feeding significantly reduced this duration by 4.2 hours. We believe that the obstetricians felt more confident of ordering its removal after witnessing more rapid dietary expansion from early feeds to solids. It is probable that further reductions could be achieved if postoperative antibiotic prophylaxis were omitted.

Early ambulation was determined largely by the absence of a urinary catheter, and early feeding reduced this by only 4.3 hours. Perhaps only the more motivated women would ambulate freely despite having an IV infusion and pole, and urinary bag. We believe that urinary catheterisation for 24 hours is unnecessary and a review of this practice is needed. Early feeding led to earlier initiation of breastfeeding by 12.3 hours in our institution. We speculate that patients felt less encumbered by the IV infusion, and earlier diet resumption aided return to "normality", although this may not be extrapolatable to other institutions due to differences in practice regarding establishment and encouragement of breastfeeding.

Active bowel sounds were present in the immediate postoperative period in 90.8% in Group E versus 95.9% in Group C. However, absence of bowel sounds did not correlate with more nausea or vomiting, or ileus. Reintroducing early drinking postoperatively was not associated with increased nausea, unlike earlier solid intake (10.2% versus 2%). Based on the results, drinks/feeds should not be withheld. Since patients were allowed to refuse food and ate when they wanted to, they could regulate their own physiological needs, and resume a normal diet when they felt up to it. There did not appear to be any untoward consequences of increased nausea and it was easily treatable. Seven patients in Group E required only a single dose of 10 mg Metoclopramide (including the patient who vomited three times). Overall, a large proportion did not have nausea after solids (90%). Objectively, despite the 10.2% versus 2% incidence of nausea in the group given solids earlier, they still registered higher maternal satisfaction in favour of the early feeding regimen. It should thus be left to the patient's choice as to when to resume a normal diet with food made available to them.

We found a low incidence of 3% ileus in a homogeneous population of patients such as ours when they were fed early. Other studies reported rates of ileus ranging from 26% to 31% in a heterogeneous population. Thus, our sample size only reached a power of 51% to demonstrate a 16% difference. 194 patients per group would have been required to detect a difference between the 3% ileus rate and the initially presumed rate of 10% at 80% power. The exclusion of patients in labour is perhaps one contributory factor for our low rates of ileus, albeit speculative. It is not the sole cause. Labouring women receiving opioid analgesics are known to have delayed gastric emptying;[18] and other modes of analgesia, such as inhalation of Entonox (50% oxygen and 50% nitrous oxide), and obstetric interventions to augment labour, namely oxytocin infusions, are emetogenic. Additionally, all our patients received our institution's standard anti-emetic prophylaxis for Caesarean section and regional anaesthesia which results in sympathetic blockade that may contribute to the maintenance of bowel motility.[19]

Women in Group E had a more rapid return of bowel function with a shorter time to passage of first flatus and first bowel movement. Women fed earlier were ready for discharge at a mean of 17.7 hours earlier than the control group (44.3 hours versus 62.0 hours). This theoretically translates to a reduction in hospital stay, but the actual length of hospital stay was not different (68 hours versus 69.4 hours) in this cohort of patients. Medical care is subsidised in our country but patients are required to pay a fee for maternity services. Delivery fees are fixed but an additional fee is required for hospital stays beyond three days and this indirectly acted as an incentive to promote discharge at but not before the third day in an

overwhelming 92% of patients. We believe that early feeding would have resulted in reduced hospitalisation if not for the current payment scheme. The hospital system should be tailored to allow flexibility for motivated patients with good social support and easy access to transport, to be discharged earlier upon request. Then, implementation of an early-feeding regimen, same-day admission, and a more flexible "delivery package" should yield a tangible reduction in operational costs, with savings to both patients and the hospital.

The expanding role of anaesthesiologists as peri-operative physicians may allow for education and intervention to improve many aspects of patient care, including enteral nutrition. We found that the simple offer of oral fluids to patients in the immediate postoperative period was sufficient to alter obstetrician behaviour towards being more confident in feeding these patients early, resulting in higher maternal satisfaction, earlier discontinuation of IV hydration, earlier ambulation, and breastfeeding initiation in our local population.

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