



PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF MASTER DEGREE IN OBSTETRICS & GYNAECOLOGY

**Title of the Protocol: Effect of 2hrs versus 6hrs oral feeding on recovery
of normal bowel functions after Caesarean Section
performed under regional anesthesia.**

Postgraduate Student: Lamia Arafa Mohammed Ismail

Degree: M.B.B.Ch - Faculty of Medicine - Ain Shams University (2014)

Resident at Kaha Hospital

DIRECTOR : Prof. Sherif Mohamed Ahmed Abd El Hamid

Academic Position : Professor

**Department : Obstetrics & Gynecology – Faculty of Medicine
Ain Shams University**

Co-DIRECTOR : Dr. Marwa Saber Sayed Senosy

Academic Position : Lecturer

**Department : Obstetrics & Gynecology – Faculty of Medicine
Ain Shams University**

**Faculty of Medicine
Ain Shams University
2020**



What is already known on this subject? AND

What does this study add?

Following LSCS, activity in small intestine starts within 2–3 hours and function is completely recovered within 6–12 hours. Stomach function returns 12–24 hours after surgery with the large intestine recovering fully between 48–72 hours. This study will compare the return of bowel movements in regionally anesthetized women undergoing cesarean section (C-section) given early oral feeding to that of women given late oral feeding.

1.INTRODUCTION/ REVIEW

Caesarean section is the most common surgery in the world. Women who have a lower segment Caesarean section (LSCS) usually have a choice of two or three options: general anesthesia, where they are unconscious, and two types of regional anesthesia known as “epidural” and “spinal” anesthesia (*Gehling and Tryba, 2009*).

Regional anesthetics numb the body from the waist down. The woman is awake for the birth and can see her child immediately afterwards. In an epidural anesthesia, the anesthetic is injected into the “epidural space” surrounding the spinal cord in the thoracic or lumbar regions of the spine. This only numbs the nerves that lead to the region of the spinal cord where the anesthetic was injected. Epidurals start relieving pain after 10 to 20 minutes. In spinal anesthesia, also known as spinal block, the medication is injected closer to the spinal cord into the cerebrospinal fluid in the subarachnoid space. This causes the entire lower half of the body to feel numb. Spinal blocks work faster than epidurals and a smaller amount of anesthetic medication is needed (*Othman, 2019*).

Current LSCS procedures are less complicated and involve shorter hospital stays than in the past, although several postoperative complications such as ileus (9.3%), nausea (4.6%) and vomiting (2.4%), can occur (*Masood et al., 2014*).

Following LSCS, activity in small intestine starts within 2–3 hours and function is completely recovered within 6–12 hours. Stomach function returns 12–24 hours after surgery with the large intestine recovering fully between 48–72 hours (*Othman, 2019*).



Bowel sound (examined by a physician), passing flatus, and bowel movement are the indicators of the return of bowel function (**Chapman et al., 2018**).

Factors influencing bowel activity include the size of the incision, operative time, blood loss, type of anesthesia, opioids, general health of the patient, nutrition, and psychiatric condition (**Chinachoti et al., 2013**).

Reviews of the literature reveal that early oral feeding (EF) can minimize protein depletion or destruction in the body, aid healing of the surgical wound, improve mental-state, reduce sensation of thirst and hunger (**Jalilian and Ghadami, 2014**).

Other benefits of EF include improved recovery of bowel function, decreased abdominal bloating, decreased time to pass flatus or stool, reduced number of used intravenous bags, reduced time for removal of urine catheter, decreased length of hospital stay, and lastly, improved overall satisfaction with the surgery (**Kathpalia, 2017**).

While support for advising EF is well documented, specific recommendations regarding the ideal time to begin feeding have not been clearly established (**Guo et al., 2015**).

2.AIM / OBJECTIVES

Aim of the study is to compare the return of bowel movements in women given early oral feeding to that of women given late oral feeding in regionally anesthetized women undergoing cesarean section (C-section).

Research question: Does bowel movement return earlier with early oral feeding in regionally anesthetized women undergoing cesarean section (C-section)?

Research hypothesis: Bowel movements return earlier with early oral feeding in regionally anesthetized women undergoing cesarean section (C-section) than women given late oral feeding.



3.METHODOLOGY:

Type of Study: Randomized controlled clinical trial.

Study Setting: The study will be conducted at Ain Shams University Maternity Hospital.

Study Population: The study will include one hundred forty women underwent uncomplicated elective C-section in obstetrics ward at Ain Shams University Maternity Hospital.

Inclusion criteria:

1. Singleton pregnancy.
2. Elective C-section.
3. Under regional anesthesia.
4. Desire to join the study after being giving research information.
5. Did not have another surgery during C-section except tubal ligation.
6. No history of gastrointestinal surgery or underlying diseases that affect digestion.

Exclusion criteria:

1. Women that will need to delay postoperative oral feeding more than 6–12 hrs (due to severe preeclampsia or late postpartum hemorrhage).
2. Women who had intraoperative and postoperative complications such as gastrointestinal injury, genitourinary tract injury, and postpartum hemorrhage (PPH), extensive adhesions.

Sampling Method:

This study will be conducted in Maternity hospital-Ain Shams University. A number of 140 women who went through uncomplicated caesarean section will be included in the study, 70 women will be a control group and 70 women will be the study group.

Women will be sequentially distributed to either one of the groups according



to the order by which they are enrolled in the study till both groups are completed.

Sample Size:

The study will be conducted on (140) women; they will be subdivided into 2 groups.

- **Group A:** 70 women (early oral feeding).
- **Group B:** 70 women (late oral feeding).

Sample size Justification:

Using PASS 11 program for sample size collection and according to previous literature (*Mawson et al., 2019*), comparing the return of bowel movement in women given early oral feeding to that of women given late oral feeding, a sample size of 70 in each group will be enough such effect after setting alpha error at 0.05 and 0.80 power of the test.

Ethical Consideration:

This study will be done after approval of the ethical committee of the department of Obstetrics and Gynecology, faculty of medicine, Ain Shams University. Informed consent will be taken from all participants before recruitment in the study, and after explaining the purpose and procedures of the study. The investigator will obtain the written, signed informed consent of each subject prior to performing any study specific procedures on the subject. The investigator will retain the original signed informed consent form. All laboratory specimens, evaluation forms, reports, video recordings and other records that leave the site will not include unique personal information to maintain subject confidentiality.

Study procedures and interventions:

- C-sections will be performed by residents or instructors and the regional anesthesia will be administered by anesthesiologists using the standard protocol.
- All participants will be advised and signed informed consent forms.
- The participants will be non-randomly allocated to receive early oral feeding in group I and late oral feeding in group II.



- In the post-partum ward following surgery, assessment forms will be given to the participants who will record gastrointestinal complications (these include nausea, vomiting, and abdominal bloating), time to passing flatus, time to passing stool, time to removing IV fluids, time to removing urine catheter, time to ambulation, and length of hospital stay.
- The early oral feeding group will be assigned to start sipping water at 2 hrs after surgery then progress to a soft diet and regular diet in the next meals, as tolerated.
- Oral intake will be stopped if the patient complains from abdominal pain or vomiting.
- The late oral feeding group will follow the same pattern but will begin sipping water at the 6 hrs post-operation.
- The study results will be collected by the assessor. This same individual also will hand out the forms and examine bowel sound.
- Group I will get 200 ml of water after 2 hrs after cesarean section followed by oral hydration as per woman desire then starting semisolid food at bowel movement, and group II will get oral hydration after 6 hrs of cesarean section.
- Auscultation of intestinal sounds will be done after 2hrs postoperative for the first 12 hours after cesarean section.
- Incidence of GIT upset symptoms, abdominal distention (by percussion), time of first bowel movement and 1st flatus will be recorded.
- Women satisfaction with a visual analogue scale will be considered before women discharge.

Outcomes:

- **1ry outcome:** The assessment of the return of bowel function after C-section, as gauged by time to 1st flatus.
- **2ry outcome:** The evaluation of GI complications, defined as mild ileus symptoms and severe ileus symptoms. The presence of anorexia, abdominal cramping, or mild distension on physical examination is defined as mild ileus symptoms. Marked abdominal distension with more than 3 episodes of vomiting in 24 hrs after surgery, or the inability to tolerate a liquid diet with delayed step diet is defined as severe ileus symptoms.



Statistical analysis:

Data will be analyzed by IBM SPSS statistics 17.0 and all outcomes will be tested for normality. For normally distributed data, two independent engines will perform Student's t-tests on the continuous data and generate the mean and standard deviation (SD). The category data will be analyzed using a Chi-square test. Results not following a normal distribution will be analyzed using a Mann-Whitney U test. P-values below 0.05 will be defined as statistically significant.

4.REFERENCES:

Chapman S, Thorpe G, Vallance A, Harji D, Lee M, Fearnhead N. Systematic review of definitions and outcome measures for return of bowel function after gastrointestinal surgery (2018). *BJS Open*; 3 (1):1-10.

Chinachoti T, Nilrat P, Samarnpiboonphol P. Nausea, vomiting and pruritus induced by intrathecal morphine (2013): *J Med Assoc Thai.*; 96:589-94.

Gehling M, Tryba M. Risks and side-effects of intrathecal morphine combined with spinal anaesthesia: a meta-analysis (2009). *Anaesthesia*; 64 (6):643-651.

Guo J, S. Long S, Li H, Luo J, Han D, He T. Early versus delayed oral feeding for patients after Caesarean (2015). *Int J Gynecol Obst.*; 128:100-5.

Jalilian N, Ghadami M. Randomized clinical trial comparing postoperative outcomes of early versus late oral feeding after Caesarean section (2014). *J Obst Gynaecol Res.*; 40:1649-52.

Kathpalia S. Early maternal feeding versus traditional delayed feeding after Caesarean section: a pilot study (2017). *J Obst Gynecol Ind.*; 67:178-82.

Masood SN, Masood Y, Naim U, Masood M. A randomized comparative trial of



early initiation of oral maternal feeding versus conventional oral feeding after Caesarean delivery (2014). Int J Gynecol Obst.; 126:115-9.

Mawson AL, Bumrungphuet S, Manonai J. A randomized controlled trial comparing early versus late oral feeding after cesarean section under regional anesthesia (2019). International Journal of Women's Health; 11 519–525.

Othman M. Early versus Late Oral Feeding on the Recovery of Normal Bowel Functions After Caesarean Section: A Randomized Controlled Study (2019). Adv Med Med Res.; 2 (1):21-25.