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EFFECT OF IMMEDIATE VERSUS EARLY ORAL HYDRATION ON CAESAREAN SECTION POST OPERATIVE OUTCOMES (A RANDOMIZED CONTROLLED TRIAL)

Thesis

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قَالَ

سُبْحَانَكَ لَا عِلْمَ لَنَا
إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ
الْعَلِيمُ الْعَظِيمُ

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LIST OF ABBREVIATIONS

Abbrev.	Full term
BMI	: Body mass index
DM	: Diabetes mellitus
g	: Grams
HTN	: Hypertension
ICU	: Intensive care unit
IOL	: induction of labor
IQWiG	: Institute for Quality and Efficiency in Health Care
IV	: Intra-venous
kcal	: Kilocalorie
kg	: Kilogram
ml	: Milliliter
NICE	: National Institute for Health and Care Excellence
Ob/Gyn	: Obstetrics/gynecology
RCOG	: Royal College of Obstetricians and Gynecologists
SD	: Standard deviation
SPSS	: Statistical package for social science
UK	: United Kingdom
VBAC	: Vaginal birth after Caesarean section
WHO	: World Health Organization

Abstract

Objective: to evaluate the effect of immediate oral hydration initiated within 2 hours after uncomplicated Caesarean Section on the following post-operative outcomes: post-operative vomiting and abdominal distention, post-operative nausea and abdominal pain, the return of intestinal movements, duration of intravenous fluid administration, duration of hospital stay and participant satisfaction. **Methods:** This randomized controlled study was conducted at Ain Shams University Maternity Hospital; it was carried during the period from July 2016 to July 2017. 140 women, all of them underwent uncomplicated Cesarean Section under regional anesthesia were randomly assigned into two groups. In the immediate group: oral hydration was received in the first 2 hours postoperatively, and in the early group: oral hydration was received after 8 hours postoperatively. **Results:** All the results of the postoperative outcomes of both groups had non-significant differences except for the psychological satisfaction which was significantly higher in the immediate group with a ($p<0.001$). **Conclusion:** Immediate oral hydration group showed non-significant differences comparing with early oral hydration group regarding most of the postoperative outcomes, but the results were relatively better towards the immediate group. Also, immediate hydration is significantly better than early hydration regarding psychological satisfaction of women, allowing them to be more able to breastfeed their kids and to spend a less stressful time in the hospital.

Key words: immediate/early oral hydration, cesarean section, postoperative outcomes, vomiting, nausea

Protocol

INTRODUCTION

Caesarean sections performed every year are increasing in number dramatically all over the world. So, it became very important to give more attention for their postoperative care (**Malhotra, 2005**).

Return of intestinal movement and passage of flatus are considered important factors affecting the duration of postoperative hospital stay in addition to other factors like the used anesthesia, wound healing, and breastfeeding (**Mulayim et al., 2008**).

The traditional approach of giving the patient nothing orally postoperatively till bowel function returns (in the form of bowel movement or passage of flatus) followed by slow feeding is now challenged and became controversial (**Al-Ghareeb et al., 2013**).

The importance of early feeding postoperatively depends on that food intake is able to stimulate a reflex causing a coordinated propulsive activity and increasing the secretion of gastrointestinal hormones. These effects cause an overall positive effect on intestinal movement decreasing the duration of postoperative ileus (**Correia et al., 2004**). Early feeding also may be associated with reduced depletion of protein stores and improvement in wound healing with a faster recovery (**Orji et al., 2009**).

There was a belief that postoperative oral intake without return of intestinal movements may cause nausea, vomiting, and abdominal distention leading to wound breakdown. However, this belief has been changed because the duration of surgery became shorter, the regional anesthesia became more available, and intestinal

manipulation during surgery became minimal. All these factors provided the chance for early oral intake before bowel movements return (**Mulaiym et al., 2008**).

Several studies were done to compare between different regimens of postoperative hydration and feeding (**Mulaiym et al., 2008**). Many of which were done on the effect of early hydration after Caesarean section, but less studies were done on the effect of immediate hydration.

Hemorrhage is considered one of the most important complications occurring immediately and within 2 hours postoperatively. So, it should be checked well before starting immediate oral hydration after Caesarean section (**Mulaiym et al., 2008**).

Therefore, early oral hydration especially immediate supply of oral fluids after Caesarean sections needs further studying. Also, its impact on postoperative recovery and duration of stay in hospital needs to be studied widely as well.

Moreover, early oral hydration after Caesarean section might be beneficial in many ways, it may facilitate early return of intestinal movements and reduces the risk of hospital infections, leading to early hospital discharge (**Mulaiym et al., 2008**), it also may decrease the cost of hospital stay as it decreases the duration of intravenous fluid administration with less use of cannulae with a prove of its association with breastfeeding success and less suffering of the patient from thirst and hunger (**Al-Ghareeb et al., 2013**).

AIM OF THE WORK

The aim of this study is to evaluate the effect of immediate oral hydration initiated within 2 hours after uncomplicated Caesarean section on the following post-operative outcomes:

1. Post-operative vomiting and abdominal distention.
2. Post-operative nausea and abdominal pain.
3. Return of intestinal movements.
4. Duration of intravenous fluid administration.
5. Duration of hospital stay.
6. Participant satisfaction.

Research hypothesis

In women undergoing uncomplicated Caesarean section under regional anesthesia, it may be similar to initiate oral hydration immediately within 2 hours post operatively than to delay it after 8 hours.

Research question

In women undergoing uncomplicated Caesarean section under regional anesthesia, is it similar to initiate oral hydration immediately within 2 hours post operatively than to delay it after 8 hours?

METHODS, PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Setting

This study will be conducted at Ain Shams Universal Maternity Hospital.

Study design

A Prospective Randomized controlled trial.

Eligibility criteria

- Inclusion criteria:
 - Uncomplicated pregnancy.
 - Uncomplicated elective or emergency Caesarean section under regional anesthesia.
- Exclusion criteria:
 - Having medical disorders in the form of: HTN, DM, and Hepatic disorders.
 - Having bleeding disorders.
 - Having intraoperative bowel or bladder injury.
 - Having intraoperative or immediate postoperative severe bleeding.
 - Having chronic gastrointestinal problems, like chronic constipation, peptic ulcer, esophagitis, hiatus hernia or irritable bowel syndrome.
 - Having abdominal adhesions.

Interventions

All participants which are 140 women will be randomly assigned to two groups (each group will be including 70 women). Immediately after reaching the postpartum ward, history taking and vital signs measurement will be applied for each

participant to make sure that they don't have any exclusion criteria, then an informed consent will be taken from each one of them.

- Group I (experimental group " Immediate hydration") "70 women":

They will be allowed to start oral fluids immediately (within the first 2 hours post operatively) beginning with water or clear fluids (but not milk or soda containing drinks), the amounts will be according to their needs, solid food will be given gradually after tolerating the drinks and intravenous fluids will be given beside all of that and till the return of intestinal movements.

- Group E (control group "Early hydration") "70 women":

They will receive the routine intravenous fluids and the oral fluids will be given after 8 hours post operatively and gradually, solid food will be allowed after that gradually too and the intravenous fluids will be stopped after return of intestinal movements.

After reaching the postpartum ward, the participants will be asked about occurrence of nausea, vomiting, abdominal distention, abdominal pain and passage of flatus (every 1 hour in the first 2 hours and then every 2 hours till the return of intestinal movements “depending on that 0 hour is the onset of surgery end”).

Auscultation for detecting the intestinal sound will be done 2 hours post operatively then every 3 hours, timing of removal of the intravenous cannula will be registered and finally the participant will be asked before discharge about her satisfaction with the timing of the oral hydration and if she will choose it again in the future. No antiemetic or laxatives will be given routinely to the participants.

Discharge from the hospital will be done when the following criteria are met; toleration of the regular diet without nausea or vomiting, return of intestinal

movements, breastfeeding success, normal vital signs and absent wound complications.

Outcomes

Primary outcomes

Postpartum vomiting and abdominal distention: From the surgery end till the time of hospital discharge.

Secondary outcomes:

Postpartum nausea and abdominal cramps: From the surgery end till the time of hospital discharge.

Return of intestinal movements: In the form of hearing the intestinal sounds or passage of flatus.

Duration of intravenous fluid administration: From the time of surgery end till removal of the intravenous cannula.

Duration of hospital stay: Time between the surgery onset and the hospital discharge.

Participant satisfaction: And if she tends to repeat the same oral hydration timing in the following deliveries.

Allocation

Randomization

Will be performed at first by computer generated random sequence.

Allocation concealment

By using sealed opaque consecutively numbered envelopes, each envelope will include the type of intervention and will be opened by the participant after reaching the postpartum ward (and after making sure that she doesn't have any exclusion criteria).