The Effect of Early Versus Traditional Oral Hydration on Cesarean Section Postoperative Outcome: Randomized Controlled Trial

Thesis

Submitted for Partial Fulfillment of Master Degree in Obstetric and Gynecology

By

Basma Samy Badr

M.B.,B.Ch. Faculty of Medicine, Alexandria University 2012

Under supervision of

Prof. Dr. Ayman AbdelRazek Abulnour

Professor of Obstetrics and Gynecology
Faculty of Medicine - Ain Shams University

Dr. Heba Abdelbaset Allam

Lecturer of Obstetrics and Gynecology
Faculty of Medicine - Ain Shams University

Faculty of Medicine
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Basma Samy Badr

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List of Abbreviations

Abb.	Full term
BMI	Body mass index
CDMR	Caesarean Delivery on Maternal Request
CS	Cesarean section
EOH	Early oral hydration
ER	Enhanced Recovery
IQR	Interquartile range
NICE	National Institute for Health and Care Excellence
PONV	Postoperative nausea and vomiting
SD	Standard deviation
WHO	World Health Organization

Protocol

PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF
MASTER DEGREE IN OBSTETRIC AND GYNECOLOGY

Title: The effect of early versus traditional oral hydration on cesarean section postoperative outcome Randomized controlled trial

Postgraduate Student:**Basma Samy Badr**
Degree: M.B.,B.Ch. faculty of medicine, Alexandria University 2012

DIRECTOR: ***Prof.Ayman AbdelRazek Abulnour***

Professor of obstetrics and gynecology
Obstetrics and gynecologyDepartment-Ain Shams

Co-DIRECTOR: *Dr.Heba Abdelbaset Allam*

Lecturer of obstetrics and gynecology
Obstetrics and gynecology Department-Ain Shams University

Faculty of medicine
Ain Shams University
2018

What is already known on this subject? AND
What does this study add?

Traditionally, patients are not given fluids after cesarean sections until bowel function returns as evidenced by bowel sounds, passage of stool or flatus. since,uncomplicated cesarean sections have no effect on intestinal functions and with putting in minds the need of the mother for early hydration, movement, breast feeding and early discharge; In this study, the effectiveness and safety of early oral hydration after cesarean sections will be investigated.

1.INTRODUCTION/ REVIEW

Caesarean sections rates are increasing in number all over the world. So, it became very important to give more attention for their postoperative care.

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.**(Malhotra, Khanna,2005)**

The traditional approach of giving women 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.**(Mulayim, Celic,2008)**

The importance of early oral hydration postoperatively has an overall positive effect on intestinal movement decreasing the occurrence of postoperative ileus.

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 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. **(Al-Ghareeb,2013)**

Several studies were done to compare between different regimens of postoperative hydration.

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. It also may decrease the cost of hospital stay as it decreases the duration of intravenous fluid administration.**(Kathpalia,2017)**

There is also a proof of its association with breast feeding success and less suffering of the patient from thirst.

Early hydrated women showed too higher levels of satisfaction, and early hydration wasn't associated with increased risk of paralytic ileus or gastrointestinal symptoms, it also didn't lead to increased incidence of postoperative complications like postoperative fever, wound dehiscence or wound sepsis. **(Ogbadua,2018)**

Postoperative recovery speed is affected by some factors like the occurrence of pain, paralytic ileus, fatigue, sleep disturbances and postoperative nausea and vomiting. So, minimizing these factors is considered essential to enhance recovery. **(Henrik,2008)**

In this study, we will investigate the effectiveness and safety of early oral hydration after cesarean sections.

2.AIM/ OBJECTIVES

Hypothesis:

In women undergoing CS, early oral hydration may accelerates the return of intestinal movements, passage of flatus and stool.

Question:

In women undergoing CS, does early oral hydration may accelerate the return of intestinal movements, passage of flatus and stool ?

Aim of the study:

This study aims to asses the efficacy of early oral hydration in women undergoing CS, on accelerationof the return of intestinal movements, passage of flatus and stool.

3.METHODOLOGY:

- **Type of Study:**randomized controlled trial
- **Sample type:** randomized sample
- **Study Setting:** Maternity Hospital, Ain Shams University
- **Study Population:** Women delivered by uncomplicated cesarean section.

Patients and methods:

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 randomizelly chosen after operation by closed envelop in recovery room.

written consent will be obtained from each participant.

Women who will undergo caesarean delivery under regional anesthesia during November, 2018 to June, 2019 will be enrolled.

Women who will receive general anesthesia or intra-abdominal drain insertion or any associated medical or surgical disease that precludedearly oral hydration will be excluded.

The women will be assigned to one of two study groups: Group I will get 200 ml of water after 1 hour after cesarean section followed by oral fluids as per woman desire then starting semisolid food at bowel movement, and group II will get oral hydration after 6 hours of cesarean section.

Auscultation of intestinal sounds will be done hourly for the first 12 hours after cesarean section (primary outcome).

Incidence of GIT upset symptoms, abdominal distention (by percussion), time of first bowel movement and 1st flatus will be recorded. Time of 1st

breast feeding and and hospital stay will be recorded.
Women satisfaction with a visual analogue scale will be considered before women discharge.
(secondary outcome).

All recordings will have a time frame at first 24 hours after cesarean section.

Inclusion Criteria:

1. Term Singleton Pregnancy.
2. Uncomplicated Elective Cesarean Section.
3. No intra or postpartum hemorrhage.
4. All patients will be under spinal anesthesia.

Exclusion Criteria:

1. Postpartum Hemorrhage.
2. Surgical Complications Such as intestinal or bladder injury.
3. Medical disorders such as Diabetes, Hypertension and anemia
4. multiple pregnancy and polyhydraminos.
5. BMI > 30 kg/m2

- **Sampling Method***:* Using (PASS©) version 11.0.10 (**NCSS©, LLC. Kaysville, Utah, USA**). The primary outcome is the occurrence of postpartum abdominal distension post-surgery until the time of hospital discharge. A previous study, **Ogbadua 2018** reported that the rate of occurrence of abdominal distension in group A (Early oral hydration) was 4.28%; while it was 20.0% in group B (Late hydration). So, it was estimated that group sample sizes of 70 in group one (Early hdration) and 70 (Late hydration) in group two achieve 80% power to detect a difference between the group proportions of 0.1580. 15% lost to follow up were taken into consideration while calculating sample size.

Reference for program:
Hintze, J. (2011). PASS 11. NCSS, LLC. Kaysville, Utah, USA.

Randomization

The patients will be randomized to either Group I or Group II based on the below tables with random numbers assigned to each group.The random numbers are generated by online Random number Generator computer program (stattrek.com/statistics/random-number-generator).

Group I

Group I									
118	95	73	106	7	90	89	58	26	91
114	107	37	24	38	29	57	64	100	27
99	120	122	5	94	77	43	74	72	110
112	21	46	96	4	98	65	6	59	56
104	15	66	36	115	49	54	55	68	88
80	117	61	18	17	28	52	11	39	93
8	126	86	127	130	134	138	132	137	136

Group II

Group II									
20	50	84	40	81	48	119	85	70	51
30	53	76	10	47	92	16	62	23	32
2	41	78	60	22	103	108	33	101	105
123	79	121	87	97	35	124	63	44	67
14	45	116	9	82	113	111	25	34	1
12	13	69	83	102	19	31	3	42	109
125	71	128	75	129	131	133	136	140	135

Allocation and concelment:

140 envelopes will be numbered serially and in each envelope the corresponding letter which denotes the allocated group will be put according to randomization table. Then all envelopes will be closed and put in one box. When the first patient arrives the recovery room, the first envelope will be opened and the patient will be allocatedaccording to the letter inside.

- **Sample Size**: 140 cases
- **Ethical Considerations:**from the beginning of the study and in accordance with the local regulations followed, this study will be declared for ethical and research approval committee by the council of Ob /Gyn. Department, Ain Shams University.
- **Statistical Analysis:**

The collected data will be revised, coded, tabulated and introduced to a PC using Statistical package for Social Science **(SPSS 15.0.1 for windows; SPSS Inc, Chicago, IL, 2001).** Data will be presented as Mean and Standard deviation (± SD) for quantitative parametric data, and Median and Interquartile range for quantitative non-parametric data. Frequency and percentage will be used for presenting qualitative data. Suitable analysis will be done according to the type of data obtained. **Student T** Test or **Mann Whitney test** will be used to analyze quantitative data while **chi square test and fisher exact test** will be used to analyze qualitative data.

- P- value: level of significance
  -P>0.05: Non significant (NS).
  -P< 0.05: Significant (S).
  -P<0.01: Highly significant (HS).

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