Effect of Normal Saline Infusion Versus Dextrose 5% Infusion on the Duration of Labor in Nulliparous Women
Randomized Controlled Trial

Thesis

Submitted for the Partial fulfillment

Of Master Degree in Obstetrics and Gynecology

Presented By

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Marwa Othman Abughanima

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List of Abbreviations

ACOG	:	American College of Obstetricians and Gynecologists
ACTH	:	Adrenocorticotropic hormone
AOGD	:	Association of Obstetricians & Gynaecologists of Delhi
ATP	:	Adenosine-5'-triphosphate
BMI	:	Body max index
cAMP	:	Cyclic Adenosine MonoPhosphate
CAPs	:	Contraction-associated proteins
CI	:	Confidence interval
COX	:	Cyclooxygenase
CRH	:	Corticotropin releasing hormone
CRH-BP	:	CRH-binding protein
CS	:	Cesarean section
CTG	:	Cardiotocography
DHEAS	:	Dehydroepiandrosterone sulfate
FHR	:	Fetal heart rate
GA	:	Gestational age
GBS	:	Group B streptococcus
GTP	:	Guanine triphosphate
HELLP	:	Hemolysis, Elevated Liver enzymes, Low Platelet count
HIV	:	Human Immunodeficiency Virus
IL	:	Interlukin
NAAT	:	Nucleic acid amplification tests
NICU	:	Neonatal intensive care unit
NO	:	Nitric oxide

List of Abbreviations (Cont.)

NS	:	Normal saline
RCOG	:	Royal College for Obstetricians and Gynaecologists.
Rh	:	Rhesus
SMNH	:	Safe Motherhood and Newborn Health
TNF	:	Tumor Necrosis Factor

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Protocol of Thesis
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INTRODUCTION

During labor, it is common for women to have no or little nutrient intake, inspite of the fact that the demand of energy increases as a result of skeletal and smooth muscle contraction **(Mendelson et al., 2002).**

Myometrial contractility is one of the multiple factors affecting the progress of labor **.** As adequate hydration improves the muscle performance in prolonged exercise and labor can be considered as a prolonged exercise, adequate fluid administration may improve the labor progress **(Movahed et al., 2015).**

Glucose is the main substrate for pregnant uterus. Adequate resource of glucose is needed to maintain exercise tolerance and muscle efficiency, because these are important factors in the progress of human labor and parturition. Therefore, it can be postulated that dysfunctional or prolonged labor procedure, a leading indication for primary cesarean delivery, could at least in part be raised from inadequate uterine forces or inappropriate coordinated contractions because of inadequate avilability of the substrate **(Steingrimsdottir et al., 1995).**

Garite et al. demonstrated that by increasing the rate of maternal hydration, a reduction in frequency of prolonged labor could be achieved, and possibly there will be a lesser need for oxytocin and cesarean delivery **(Garite et al., 2000).**

Eslamian and colleques confirmed the effect of increased parentral hydration on decreasing the duration of labor **(Eslamian et al., 2006)**. This work was followed by **Shrivastava et al.**, who demonstrated that parentral administration of dextrose solution was associated with shortened labor course in term vaginally delivered nulliparous women in spontaneous labor **(Shrivastava et al., 2008**).

Dappuzzo-Argiriou et al. demonstrated that the use of intravenous fluid containing 5% dextrose did not lower the chance of cesarean delivery for women admitted in active labor **(Dappuzzo-Argiriou et al., 2015).**

Fong et al. demonstrated that neither rate of delivery nor dextrose administration in intravenous fluid altered the labor length or delivery outcomes in nulliparous women who were presented in active labor **(Fong et al., 2015).**

Administration of a dextrose solution, regardless of concentration, was associated with a shortened labor course in term vaginally delivered nulliparas subjects in active labor **(Vineet et al., 2009).**

AIM OF THE WORK

This study aims to evaluate the effect of intravenus dextrose 5% infusion compared with intravenous normal saline infusion in acceleration of active phase of labour in nulliparous women.

Research question

Dose normal saline infusion differ from dextrose saline infusion on the duration of active phase of labor in nulliparous women ?.

Research hypothesis

Dextrose saline infusion may differ from normal saline infusion in acceleration of the active phase of labor in nulliparous women.

PATIENTS AND METHODS

Study design

Prospective randomized controlled trial.

Study setting

This study will be done in Ain Shams University, Maternity hospital.

Study population

Patients will be recruited in this study those attending labor ward of Ain Shams University, Maternity hospital who are nulligravida, singleton gestation, 36 weeks or more.

Concent

A written concent will be taken from all patient to join this study.

Inclusion criteria

1. Primiparous.
2. Singleton gestation.
3. Cephalic presentation.
4. Spontanous active labour, Cervical dilatation 4 cm to 6 cm with or without ruptured membranes.
5. Gestation age 36 or more.

Exclusion criteria

1. Preeclapsia at admission.
2. Pregestational or gestational diabetes mellitus.
3. Non cephalic presentation.
4. Chorioamnionitis at admission.
5. Intrauterine growth restriction.
6. Patient admitted for induction of labour.

Sample size justification

Sample size was calculated using PASS 11.0 sample size calculation program and based on a study finding carried out by ***Farideh et al., 2015*** who found out that there was a significant difference in the duration of active phase between the groups (NS: 270.20 ± 13.37 minutes; D5NS: 206.67 ± 11.72 minutes) ($P < 0.001$). Sample size was estimated to be **120** nulliparous women with gestational age of ≥ 36 weeks in the active phase of spontaneous labor who will be divided into two groups, **60** women receiving either normal saline (NS) and **60** women receiving dextrose 5% in normal saline (D5NS) with a rate of 120 mL/hour. The calculated sample size would achieve 100% power to detect a difference of 63.5 between the null hypothesis that both group means are 270.2 and the alternative hypothesis that the mean of group 2 is 206.7 with known group standard deviations of 13.4 and 11.7 and with a significance level (alpha) of 0.05000 using a two-sided Mann-Whitney test assuming that the actual distribution is uniform. Sample size was inflated by 15.0% to account for lost to follow up.

The primary outcome will be the duration of active phase of labor in vaginally-delivered subjects.

Randomization Allocation :

120 patient will be randomly assigned to either:

Group A (60 patient): who will receive normal saline infusion.

Group B (60 patient): who will receive dextrose-saline infusion.Randomization will be done using computer random sequence generator.

Allocation concealment :

This will be done by sequence numbered, opaque sealed envelops, each envelop contain the method of intervention according to the random sequence. The envelop will be opened just before the intervention.

Methodology

All women will be subjected to:

History taking:

It includes name, age, occupation, marriage and special habits, last menstrual period, expected date of delivery, gestational age, any medical disorders and any previous surgeries.

Examination

General examination:

It includes blood pressure, arterial pulse and temperature.

Abdominal examination:

It includes fundal level, fundal grip, pelvic grip, uterine contractions, tenderness and scars of previous operations.

Local examination:

All women will be put in dorsal lithotomy position, using a proper light source and sterile gloves; sterile speculum free of gel will be placed into vagina.

Investigations

Complete blood picture, abdomino-pelvic ultrasound, CTG.

Management

All the women will be randomly assigned into two groups.
Group A: will be provided with normal saline (0.9%).

Group B: will be provided with dextrose saline.

Fluid will be administrated in all the cases by infusion pumps at a rate of 120ml/hour and the women will not consume anything by mouth.

Intervention

Each women will have vaginal examination every 2 hours; artificial rupture of membranes will be done at 4cm cervical dilatation; if any woman have existed leakage, immediate vaginal examination would be performed to rule out cord prolapse and her cervical finding will be noted.

The initial examination will be recorded as well as the serum initiation time. Next, examination will be conducted and the parturition procedure will be controlled.

For a dilatation progress lower than 1.2cm/hour, uterine contraction will be controlled and oxytocin will be administered in case of insufficiency.

Oxytocin in 5 IU/L of solution with an initial rate of five drops per minute will be administered to enhance uterine contractions. The patient would be prepared for cesarean section in case of no change in dilatation for two hours and no decend for one hour. In normal rate parturition and accomplishment of dilatation, it's time as well as fetus outcome time and Apgar score subsequent to labor will be recorded.

Outcomes:

The primary outcome is the duration of labor in active phase.