



A Randomized, Double-Blinded, Controlled Trial Comparing Parenteral Dextrose 5%, Ringer's Solution and Oral Intake on the Delivery Outcomes in Nulliparas

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Abstract

Objectives: According to the World Health Organization (WHO) statistics, the prevalence of C-section and unnecessary labor induction associated with adverse complications for the mother and baby is rising. This rate is higher in Iran, where many C-sections can be prevented by the proper management of labor and its duration. The present study was conducted to compare the effects of Ringer's solution, dextrose solution 5% and oral intake on the delivery outcomes.

Materials and Methods: The present randomized clinical trial was conducted on 201 nulliparous women in labor assigned to 3 groups using a randomized block design, each receiving either Ringer's solution plus oral fluids, dextrose solution 5% solution plus oral fluids or oral fluids alone. The solutions were intravenously administered at a rate of 125 mL/h in the groups receiving the solutions and the subjects in the oral fluids group could consume liquids of their choice (water, orange juice and apple juice). Delivery outcomes, including maternal outcomes (type of delivery, use of oxytocin and prolonged labor) and neonatal outcome (Apgar score) were recorded by the researcher. Data were analyzed using the one-way analysis of variance (ANOVA), the chi-square test and Fisher exact test.

Results: A significant difference was observed between the 3 groups in terms of administration of oxytocin ($P < 0.001$), cesarean section ($P = 0.003$), prolonged labor ($P = 0.001$) and the first minute Apgar ($P = 0.003$). However, no significant difference was observed in terms of the fifth minute Apgar score ($P = 0.770$).

Conclusion: The results suggest that the consumption of dextrose solution by nulliparous women reduces the C-section rate, the need for oxytocin administration, the frequency of prolonged labor and improve neonatal outcome compared to when Ringer's solution and oral fluids are used.

Keywords: Type of delivery, nulliparous, dextrose, hydration, maternal outcome, Ringer's solution

Introduction

Labor is a period beginning with uterine contractions and ending in the expulsion of the placenta. The process through which the baby is naturally born is called labor (1). During labor, uterine contractions lead to cervical dilation and effacement and finally the expulsion of the products of conception. Ineffective uterine contractions along with pelvic restraint are among the most common reasons for the poor progress and prolonged stages of labor and dystocia. Dystocia or difficult labor is characterized by a slowly-progressing or abnormal labor and is the most common cause of cesarean section that has adverse psychological effects on the mother and baby (1,2).

According to the World Health Organization (WHO) statistics, the prevalence of C-section and unnecessary labor induction associated with adverse complications for the mother and baby is rising (3-5). This rate is higher in Iran, where many C-sections can be prevented by the proper management of labor and its duration (6).

Extensive research has been conducted into the many

factors that affect the stages of labor (7); one of the subjects that has received less attention in research is the effect of liquids on labor (8).

Most of the energy consumed during labor is obtained through the oxidative pathway and maternal glucose is the main energy source for the fetus. Glucose is the primary energy substrate for the pregnant uterus and the physiological need for glucose is 10 g/h during labor and adequate supplies of energy are required during labor to help the mother maintain her strength (9,10). Ketosis occurs when fat metabolism occurs in the body due to the lack of adequate carbohydrate metabolism. Starvation during labor is associated with increased levels of beta-hydroxybutyrate and acetoacetate acid and unsaturated fats in the blood. Although not scientifically proven, these blood metabolite changes have been reported to likely affect the uterine activity and childbirth outcomes (11). One of the reasons for the intravenous administration of fluids during labor is the need to create a suitable metabolic environment that can support the body's needs

Received 3 September 2016, Accepted 14 February 2017, Available online 8 March 2017

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during labor (10).

A trial study conducted by Shrivastava et al compared the effects of normal saline solution with and without dextrose solution on labor process and found that solutions containing dextrose reduce the duration of labor and the need for oxytocin and prolonged labor (active phase more than 12 hours) (8).

Another randomized, controlled, clinical trial conducted by Eslamian et al showed the effect of increased amounts of fluids in reducing the duration of labor and the need for oxytocin administration (12).

In one study, Sharma et al concluded that solutions of dextrose reduce the need for oxytocin administration and fetal acidemia, but there was no difference in the type of delivery between study groups (13).

Kubli et al also studied the effect of the amount and type of oral fluids during labor and found no differences in the type of delivery, use of oxytocin, prolonged labor and Apgar score between the studied groups (11).

Given these results, in the present study setting (Imam Khomeini hospital, Mahabad, West Azerbaijan, Iran), an IV access was established at a keep vein open rate for the majority of parturient women immediately upon the admission to the maternity ward and at the very beginning of the active stage of labor. This study seeks to find a suitable and low-cost method compatible with the physiological conditions of the mother's body that can supply her body's fluid and calorie needs for labor. Three groups were examined in the study; one group receiving Ringer's solution plus oral fluids during labor, another group receiving dextrose 5% plus oral fluids and another group receiving only oral fluids. The effect of each intervention was examined on the Birth outcomes in nulliparous women with term pregnancies.

Materials and Methods

Study Design and Participants

This double-blind (i.e. blinded researcher and participants), randomized, controlled trial was conducted on 201 nulliparous women in labor with low-risk pregnancies presenting to the maternity ward of Imam Khomeini hospital of Mahabad, Iran, from March to October 2016.

Inclusion criteria were: being nulliparous, ages between 18 to 35, gestational age between 38 to 41 weeks, singleton pregnancy with cephalic presentation, onset of first stage of labor and 4 cm dilation spontaneous onset of labor, maternal first trimester body mass index (BMI) of 18.5 to 24.9 kg/m², normal maternal pelvis (according to the experts and the researchers examinations), clinical and ultrasound prediction of no fetal macrosomia (weight more than 4 kg). Exclusion criteria were: women with labor induction (indications of labor induction such as prolonged rupture of membranes (over 18 hours), gestational hypertension, nonreassuring fetal status, diabetes or preeclampsia),

high risk pregnancies (gestational diabetes, preeclampsia, heart or kidney diseases, intrauterine growth restriction [IUGR], detachment or placenta praevia, etc) evidence of chorioamnionitis (maternal fever over 38°C) and fetal distress (abnormal non-stress test), intrauterine fetal death, use of epidural and professional athletes.

The sample size was calculated based on the general objectives of the study using the comparison of 2 means formula in G*Power. According to Sharma et al (13) and assuming a 25% reduction in the mean duration of labor with $M1 = 473.8$, $M2 = 355.35$, $Sd1 = Sd2 = 220.5$, $\alpha = 0.05$ and statistical power = 90%, the sample size was calculated as 61; to take account of a potential attrition of 10%, the final sample size was determined as 67 per group.

Sampling and Randomization

The subjects were selected through convenience sampling from the eligible pregnant women admitted to the hospital for delivery. The subjects were briefed on the study objectives and methods before submitting their informed written consent to participate in the study. The participants were assigned to three intervention groups (a group receiving dextrose 5% solution plus oral fluids, a group receiving Ringer's solution plus oral fluids and a group receiving oral fluids without any solutions) in randomized blocks of three and six at an allocation ratio of 1: 1: 1.

Intervention and Outcome Assessment

After the admission of the parturient women and establishing intravenous heparinization, the subjects in the oral fluids group were transferred to the labor room to consume their own choice of liquids (water, apple juice or orange juice) as per a dietitian's guidance. The researcher constantly visited the women from the time of admission until 2 hours post-delivery. In the groups receiving the solutions, the intended solution was infused using an infusion device at a rate of 125 mL/h from the time of admission until two hours post-delivery. The women in these groups did not maintain an NPO (no per oral) status and freely consumed liquids of their choice (water, orange juice and apple juice). During all the stages of labor, the parturients in each group were either standing, squatting, walking or lying on their left side as per their own wishes.

The labor process was carefully monitored and the rate of cervical dilatation and fetal head descent was recorded with each examination. The examination intervals were 2 hours in the active stage and 30 minutes in the second stage. It should be noted that the examination intervals could be smaller according to the parturient's state (such as in the case of reduced fetal heart rate, before any intervention, etc). The duration of the active stage was reported in minutes from the beginning of the 4 cm cervical dilatation to the full cervical dilatation. The second stage was also calculated and recorded in minutes.

Uterine contractions were assessed every 15 to 30 minutes at the beginning of the active stage and then every 10 to 15 minutes at the end of the stage and by placing the palm of the hand on the fundus of the uterus to assess the severity, duration and intervals between the contractions. In the lack of labor progress and with the diagnosis of delays exceeding two hours, oxytocin was administered as per the gynecologist's recommendations in order to expedite delivery. Ten units of oxytocin in 1 L of solution (Ringer or dextrose 5%) was infused according to the ward's routine procedures and the maximum dose of oxytocin could not exceed 40 milliunits per minute; if it exceeded this unit, the subject was excluded from the study. Fetal heart rate was monitored every 30 minutes in the active stage and then every 15 minutes in the second stage using a Sonicaid. In the case of abnormal fetal heart rate pattern, meconium passage or changes in the mother's vital signs, oxygen therapy was administered and the on-call physician was notified. Moreover, if the amniotic sac did not break on its own, an amnihook was used to perform amniotomy if needed (e.g. for the augmentation of labor), and after the full dilatation of the cervix, vaginal delivery was performed by the researcher. In addition, type of delivery, the need for oxytocin, the dose required, the frequency of prolonged labor (i.e. an active stage exceeding 12 hours) and Apgar score were recorded in detail after delivery.

The primary outcome in this study was the maternal outcomes (type of delivery, use of oxytocin and prolonged labor) in nulliparous women with vaginal delivery.

Data Collection

Data were collected using a demographic information form (age, gestational age, education, occupation, husband's education, husband's occupation, household income, weight, height and BMI), an examination checklist (examination results, vital signs, type of delivery, neonatal weight and Apgar score) and a partograph (fetal heart rate, amniotic fluid and the condition of membranes, cervical dilatation, position of the fetal head in the pelvis, the number of contractions and oxytocin use). The content validity method was used to validate the research tools, and after studying relevant books and articles, the necessary information was collected about the subject under study and the forms were prepared. The necessary modifications were made by eight faculty members of the Faculty of Nursing and Midwifery at Tabriz University of Medical Sciences.

Data Analysis

Data were analyzed using SPSS version 21.0. The homogeneity between the groups in terms of personal and demographic characteristics was evaluated using the one-way analysis of variance (ANOVA), the chi-square test, and Fisher exact test. The type of delivery and prolonged labor were compared between the groups using the Fisher

exact test, the frequency of oxytocin administration was compared between the groups using the chi-square test and the first and fifth minute Apgar scores were compared between the groups using the one-way ANOVA test. The level of statistical significance was set at 0.05 for all the tests.

Results

The present study was conducted from March to October 2016. A total of 300 pregnant women presenting to Imam Khomeini hospital of Mahabad selected through convenience sampling were examined and 50 of them were excluded due to not meeting the eligibility criteria and 49 others due to unwillingness to participate in the study. A total of 201 nulliparous pregnant women entered the study. The participants were randomly assigned to 3 groups of 67 and received either Ringer's solution plus oral fluids, dextrose 5% solution plus oral fluids or only oral fluids (Figure 1).

The mean age (SD) was 23.0 (3.4) years in the Ringer group, 22.8 (3.2) in the dextrose 5% group and 24.0 (4.4) in the oral fluids group. There were no significant differences between the three groups in terms of demographic and obstetric characteristics, including the mothers' age, gestational age, occupation, education, the husbands' education and household income (Table 1).

Vaginal delivery has the highest frequency in the three groups with the highest prevalence of dextrose solution 5%, as 94% of the participants in the Ringer group, 97% in the dextrose 5% group and 89.6% in the oral intake had done vaginal delivery.

In terms of the rate of cesarean delivery with the highest frequency of oral intake and lowest frequency of dextrose solution 5%, as the 4 participants in the Ringer group, 2 in the dextrose 5% group and seven in the oral fluids group had cesarean delivery, which suggests a statistically significant difference between the groups in this regard according to Fisher exact test ($P = 0.002$).

There was also a significant difference between the groups in terms of the frequency of oxytocin administration, as 58% of the participants in the Ringer group, 10.6% in the dextrose 5% group and 91.2% in the oral fluids group received oxytocin to augment labor ($P < 0.001$). Additionally, 5 participants in the Ringer group, 2 in the dextrose 5% group and 15 in the oral fluids group had prolonged labor (i.e. the active stage of labor lasting over 12 hours), which suggests a statistically significant difference between the groups in this regard ($P = 0.001$; Table 2).

In the present study, we observed a significant difference and meaningful results in terms of the neonatal outcome in the first minute Apgar score after birth between the study groups using one-way ANOVA ($P = 0.003$); and according to a Sidak post hoc test, the difference in the first minute Apgar between Ringer and dextrose 5% was

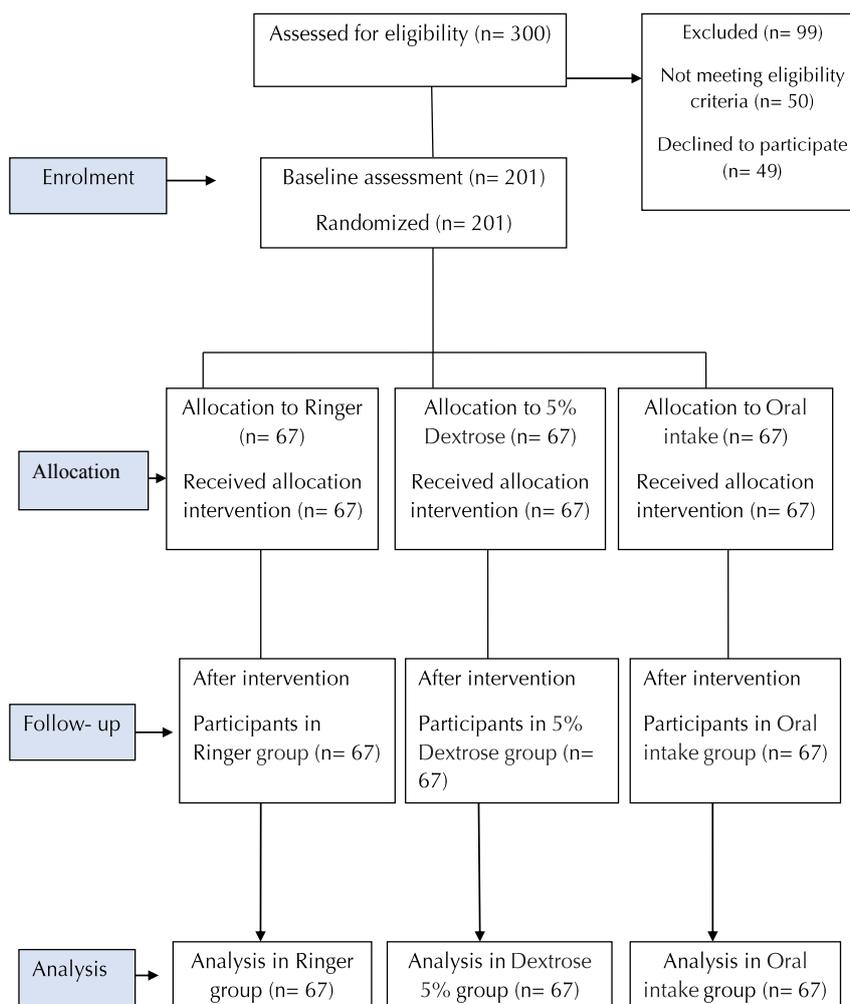


Figure 1. The Flow of Subjects Throughout the Study.

statistically significant ($P=0.004$). The Apgar score at five minutes after birth showed no significant difference between groups according to one-way ANOVA ($P=0.607$; Table 3).

Discussion

According to the results, statistically significant difference was observed in groups of delivery and in terms of the rate of cesarean delivery with the highest frequency of oral intake and lowest frequency of dextrose solution 5%.

A significant difference was observed between the 3 groups in terms of administration of oxytocin and prolonged labor, the highest frequency of oral intake and lowest frequency of dextrose solution 5% were reported.

A significant difference was observed between the three groups in terms of the first minute Apgar score. However, no significant difference was observed in terms of the fifth minute Apgar score.

In a similar study, Shrivastava et al (8) examined and compared three groups, including a normal saline group and dextrose saline 5% and 10% groups; it was reported

that 18 (22%) participants in the normal saline group, 7 (9.3%) in the dextrose saline 5% group and 5 (6.8%) in the dextrose saline 10% group had prolonged labor (i.e. the active stage of labor lasting over 12 hours), which suggests a statistically significant difference between the groups in this regard ($P = 0.01$), which is consistent with the present study.

No significant difference was observed between the 3 groups in terms of administration of oxytocin ($P = 0.08$), cesarean section ($P = 0.21$) and Apgar the fifth minute ($P = 0.77$), which is not consistent with the present study, perhaps because no oxytocin was administered in the second stage of labor in the present study, while Shrivastava et al imposed no limitations on the administration of oxytocin in their groups and their dextrose 5% and 10% groups actually received more oxytocin.

Kubli et al examined the effect of a specific isotonic solution during labor and compared it with the effect of water consumption and found statistically significant differences in the administration of oxytocin, cesarean section and Apgar the first minute duration of labor

Table 1. Socio-Demographic Characteristics of Participants by Treatment Groups

Demographic Characteristics	Ringer, (n=67) No. (%)	Dextrose 5%, (n=67) No. (%)	Oral intake, (n=67) No. (%)	P
Age (y) ^a	23.0 (3.4)	22.8 (3.2)	24.0 (4.4)	0.141 ^b
Gestational age (wk) ^a	39.2 (0.7)	39.1 (1.0)	39.0 (1.0)	0.355 ^b
Mothers education level				0.341 ^c
Illiterate	10 (15.0)	1 (1.5)	1 (1.5)	
Primary	17 (25.4)	18 (27.0)	16 (24.0)	
Secondary	21 (31.3)	15 (22.4)	38 (57.0)	
High school	14 (21.0)	30 (45.0)	8 (12.0)	
University	5 (7.5)	3 (4.5)	4 (6.0)	
Job				0.353 ^d
Housewife	57 (85.1)	53 (79.0)	59 (88.1)	
Employed	10 (15.0)	14 (21.0)	8 (12.0)	
Husbands education level				0.625 ^c
Illiterate	10 (15.0)	5 (7.5)	16 (8.0)	
Primary	21 (31.3)	17 (25.4)	29 (43.3)	
Secondary	10 (15.0)	5 (7.5)	9 (13.4)	
High school	13 (19.4)	33 (49.3)	20 (30.0)	
University	13 (19.4)	7 (10.4)	8 (12.0)	
Income household				0.123 ^c
Income more than spending	1 (1.5)	2 (3.0)	3 (4.5)	
Income to spend	48 (71.6)	41 (61.2)	60 (89.6)	
Less income to spend	28 (27.0)	24 (36.0)	4 (6.0)	

^a Data are presented as mean (standard deviation) number of pregnancies; ^b One-way Analysis of Variance (ANOVA); ^c Chi-square test for trend; ^d Chi-square test.

Table 2. Comparison of Maternal Outcomes by Study Groups

Labor outcomes	Ringer, (n=67) No. (%)	Dextrose 5%, (n=67) No. (%)	Oral intake, (n=67) No. (%)	P
Vaginal delivery	63 (94.0)	65 (97.0)	60 (89.6)	0.002 ^a
Cesarean delivery	4 (6.0)	2 (3.0)	7 (10.4)	0.002 ^a
Oxytocin use	38 (58.0)	7 (10.6)	60 (91.2)	<0.001 [#]
Prolonged labor	5 (7.5)	2 (3.0)	15 (22.7)	0.001 ^a

^a Based on the Fisher exact test; [#] Based on the Chi-square test.

caused by the 2 substances (11); this finding is consistent with the present findings.

The increased hydration and carbohydrate consumption due to the adequate supply of nutrients to the uterus and the rapid removal of toxic products through an improved metabolism helped improve skeletal muscle function and reduces the need for oxytocin administration in the present study, which is consistent with the results obtained by Maughan et al (14), who examined the effects of hydration on exercise physiology and showed that increased intake of liquids and carbohydrate replacement improve skeletal muscle function in lengthy exercises.

Of the total of 201 subjects examined in this study, 38 (58%) in the Ringer group, 7 (10.6%) in the dextrose 5% group and 60 (91.2%) in the oral fluids group needed oxytocin administration, suggesting a statistically significant inter-group difference in this variable. Nevertheless, in a study on the effects of carbohydrate intake during labor, Scheepers et al found no significant differences between their different study groups in terms

of oxytocin administration (15).

The results of the present study are not consistent with Shrivastava and colleagues' findings on this subject, which may be due to the lack of limitations on oxytocin administration in the latter, as 80 subjects (82%) in the normal saline group, 89 (92%) in the dextrose saline 5% group and 89 (90%) in the dextrose saline 10% group received oxytocin in that study. Moreover, Shrivastava et al. had also used epidural analgesia for labor. Kukulu et al argued that women who use epidural analgesia for labor have a longer labor and need more oxytocin (16).

Furthermore, in the present study, the need for oxytocin administration was lower in the dextrose 5% group than in the other groups, which is consistent with the results obtained by Sharma et al (13).

The limitations of this study include the mothers' different physical abilities and physiological responses to contraction, which affect the duration of the second stage of labor and the administration of oxytocin. This factor was relatively controlled by providing similar training to

Table 3. Comparison of Neonatal Outcome by Study Groups

Apgar score at 1 min	Ringer, n = 67	Dextrose 5%, n = 67	Oral Intake, n = 67	P
	Mean (SD)	Mean (SD)	Mean (SD)	
	9.0 (0.0)	8.8 (0.4)	8.9 (0.1)	0.003 ^a
Mean difference (95% CI)				
Ringer compared with dextrose 5%		0.16 (0.04 – 0.29)		0.004 ^b
Ringer compared with oral intake		0.03 (-0.09) – 0.15)		0.913 ^b
Dextrose 5% in comparison with oral intake		-0.13 (-0.26 – -0.01)		0.026 ^b
Apgar score at 5 min	Ringer, n = 67	Dextrose 5%, n = 67	Oral Intake, n = 67	P
	Mean (SD)	Mean (SD)	Mean (SD)	
	10.0 (0.0)	9.9 (0.1)	9.9 (0.1)	0.607 ^a
Mean difference (95% CI)				
Ringer compared with dextrose 5%		0.01 (-0.03 – 0.06)		0.770 ^b
Ringer compared with oral intake		0.01 (-0.03 – 0.06)		0.770 ^b
Dextrose 5% in comparison with oral intake		0.00 (-0.04 – 0.04)		1.0 ^b

^a Based on the one-way Analysis of Variance (ANOVA).

^b Based on the sidak Post hoc test.

all the research subjects on ‘pushing’ during the second stage. Moreover, the cervical response to spontaneous or oxytocin-induced contractions of the uterus differs in different people. The full assessment of individual differences such as pelvis shape and pelvic soft tissues and their resistance against the passage of the fetus is impossible; however, the researchers sought to overcome these limitations by randomly assigning their participants to the three study groups.

Conclusion

The administration of dextrose 5% solution during labor supplies the energy needs of the subjects by increasing ATP, prevents the production of harmful metabolites that are produced during anaerobic cycles in the lack of access to carbohydrates and which negatively affect the uterine contraction strength and ultimately shortens the duration of labor and Improves maternal and neonatal outcome by this mechanism. Dextrose 5% solution led to more favorable results during labor compared to the Ringer’s solution and oral fluids and can be safely used in labor.

Ethical Issues

First, permission to conduct the research was obtained from the Ethics Committee of Tabriz University of Medical Sciences with the ethics code TBZMED.REC.1394.972 and the trial was registered at the Iranian Registry of Clinical Trials (identifier: IRCT201602213027N35; <http://irct.ir>) and a letter of introduction was obtained from the Research Deputy of the Faculty of Nursing and Midwifery and was then presented to the Director of Mahabad Hospital.

Conflict of Interests

We hereby declare that there is no conflict of interests.

Financial Support

This study was approved and funded by Tabriz University

of Medical Sciences, Tabriz, Iran.

Acknowledgments

This paper is the result of a master’s thesis in midwifery. Hereby, the authors would like to express their gratitude to the authorities and professors of the Nursing and Midwifery Faculty of Tabriz University of Medical Sciences and the personnel of the maternity ward at Imam Khomeini Hospital of Mahabad.

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