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A multi-center randomized trial of two different intravenous fluids during labor

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Abstract

Objective—To determine if the intrapartum use of a 5% glucose-containing intravenous solution decreases the chance of a cesarean delivery for women presenting in active labor.

Methods—This was a multi-center, prospective, single (patient) blind, randomized study design implemented at 4 obstetric residency programs in Pennsylvania. Singleton, term, consenting women presenting in active spontaneous labor with a cervical dilation of <6cm were randomized to lactated Ringer's with or without 5% glucose (LR versus D5LR) as their maintenance intravenous fluid. The primary outcome was the cesarean birth rate. Secondary outcomes included labor characteristics, as well as maternal or neonatal complications.

Results—There were 309 women analyzed. Demographic variables and admitting cervical dilation were similar among study groups. There was no significant difference in the cesarean delivery rate for the D5LR group (23/153 or 15.0%) versus the LR arm (18/156 or 11.5%), [RR (95% CI) of 1.32 (0.75, 2.35), P=0.34]. There were no differences in augmentation rates or intrapartum complications.

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The authors report no conflict of interest.

Conclusions—The use of intravenous fluid containing 5% dextrose does not lower the chance of cesarean delivery for women admitted in active labor.

Keywords

Labor management; IV fluids; dextrose; cesarean delivery

Introduction

Factors that influence the ability of women to have a successful vaginal delivery have been studied extensively. However, most studies have focused primarily on maternal and fetal characteristics that predict successful labor.¹ Other than uterotonic agonists (mainly oxytocin), few studies have examined specific interventions that would enhance the likelihood of a vaginal delivery in laboring women. There are data generated through studies using intrauterine pressure catheter monitoring of labor that demonstrate the importance of effective myometrial contractility for the adequate progress of labor.² Exercise physiologists have shown that increased fluid intake and carbohydrate replacement improve skeletal muscle performance in prolonged exercise.^{3,4}

Although the uterus is a muscle that is undergoing work during labor, little attention has been paid to the impact that intrapartum fluid management and caloric supplementation might have on labor.¹ Adequate supplies of glucose are needed to maintain exercise tolerance and muscle efficiency, which are important factors in the progress of labor. Physiological requirements for glucose during labor in a 60kg woman are estimated to be around 10 grams per hour.⁵ We propose that even in the presence of adequate hydration, inadequate carbohydrate replacement in labor may contribute to prolongation of labor and an increased need for operative delivery. There are 2 studies suggesting a shorter duration of labor in nulliparous women when glucose was added to the intrapartum IV fluids, although neither study demonstrated a reduction in the cesarean delivery rate.^{6,7}

Because the cesarean delivery rate may be a more important clinical outcome than duration of labor, we designed this study to determine if adding 5% dextrose to a lactated Ringer's (D5LR) solution as the maintenance intravenous (IV) fluid in active labor was associated with a lower cesarean delivery rate compared to lactated Ringer's (LR) as the maintenance IV fluid.

Materials and methods

This was a multi-center, prospective, single (patient) blind randomized trial comparing LR versus D5LR as the maintenance IV fluid during the intrapartum period. CONSORT guidelines were followed. This study was conducted by a consortium of 4 residency programs: Lehigh Valley Health Network (Allentown, PA), Pennsylvania State University, College of Medicine (Hershey, PA), Reading Hospital (Reading, PA) and St. Luke's University Hospital (Bethlehem, PA) and was registered prospectively in a clinical trial registry (clinicaltrials.gov: NCT01110005). Pennsylvania State University, College of Medicine (Hershey, PA) served as the data coordinating center for this study. The protocol

for this effort was submitted and approved at each hospital's individual institutional review board (IRB).

Subjects were candidates for participation if they were pregnant 36 weeks gestation in spontaneous active labor, <6 cm dilated, and were eligible for a vaginal delivery. No minimum cervical dilation was required and a pragmatic determination of active labor was made by the clinical judgment of the managing providers without pre-specified criteria. The initial cervical dilation inclusion criteria was specified to be <5 cm, but this was increased by 1 cm due to the difficulty with recruiting women in active labor unless they were more dilated. Exclusion criteria included: contraindication to vaginal delivery, multiple gestation, prior cesarean delivery, induction of labor, diabetes mellitus or another glucose dysregulation condition, concurrent use of steroids, active labor with cervical dilation of 6 cm, or participation in another research study.

Subjects in spontaneous labor were screened for eligibility upon admission to labor and delivery. Screen eligible subjects were provided information about study participation after the care providers made the decision for admission for delivery. After written informed consent was obtained, subjects were randomized to one of the two maintenance IV fluids, LR or D5LR. Randomization was stratified by clinical site and a random number generator was used to create permuted blocks of size (n=6) within each stratum, so that the treatment allocation ratio was 1:1 within each clinical site. Numbered opaque envelopes containing the randomization assignment were provided by the data coordinating center to each site and were chosen in sequence to determine the treatment assignment. Subjects were not informed of their specific treatment group assignment in an attempt to keep them blind to their assigned IV fluid. Management of labor was not directed by study protocol.

By protocol, the assigned IV fluid was used throughout labor as the maintenance fluid. LR was used for IV fluid boluses for all clinical indications such as pre-epidural volume expansion. No minimum or maximum infusion rate was specified in the protocol, although the maintenance infusion rate was expected to be 125 mL/hr per usual practice at all participating sites. Sites were encouraged to perform an initial urine dipstick analysis for urinary ketones on admission, as well as an umbilical artery blood gas immediately after delivery when feasible. Medical records were reviewed for information about labor course and complications for mother, fetus, and infant. Primary data sources included the prenatal record, intrapartum and delivery record, and the neonatal inpatient record.

The primary outcome of this study was cesarean delivery. Secondary outcomes included: the duration of labor (onset of labor to delivery), use of oxytocin augmentation, operative vaginal delivery, chorioamnionitis, umbilical artery blood gases, neonatal hypoglycemia (serum glucose <40mg/dL), need for neonatal special care nursery, and difficulties with initiating breast feeding. Onset of labor was determined by a clinical judgment of when strong contractions at least every 5 minutes began or if there was observed change in cervical dilation with an uncertain contraction pattern. Infant glucose levels were checked for symptomatic infants or with high risk conditions such as small or large for gestational age. Breastfeeding success was measured using the LATCH score, which is a 5 component assessment using scores of 0, 1 or 2. (LATCH score components include: Latch, Audible

swallowing, Type of nipple, Comfort, and Hold or positioning.)⁸ Other maternal or neonatal complications noted in the records were collected. The presence of ketonuria was assessed in order to determine its impact on outcomes.

Data were recorded at each site on Clinical Report Forms developed specifically for this project. Data were then entered into a Web-based Universal Questionnaire Data Entry System (WebUQ) developed by the Department of Public Health Sciences at Penn State University.

To determine the sample size for this trial, we estimated a baseline cesarean delivery rate for women in labor of approximately 24% based on a consensus among the participating institutions after scheduled repeat cesarean deliveries were excluded. We decided a priori that a 25% reduction in the cesarean delivery rate to 18% due to the use of D5LR would be a clinically meaningful effect on the primary outcome. In order to have a two-sided test with a significance level of 5% and a power of 80% we estimated that 723 subjects in each arm would be. We added an additional 5% to each arm as a buffer against potential loss of subjects to achieve a final sample size estimate of 762 per study arm.

Statistical analyses were performed using an intent-to-treat paradigm. Risk ratios (RR) and 95% confidence interval for comparing the treatment arms with respect to the primary outcome of cesarean delivery proportions were estimated from a log-binomial regression model.⁹ The primary outcome of cesarean delivery proportions was also compared between the two treatment arms after adjusting for the presence of maternal ketonuria and the clinical site. Log-binomial regression models were used to compare the treatment arms in secondary analyses for binary outcomes. Continuous outcomes were analyzed using parametric (i.e., analysis of covariance models) or non-parametric (i.e., Cochran-Mantel Haenszel mean score tests based on rank scores) methods as appropriate based on normalcy distributions. A Cox proportional hazards model was used to compare the time from admission to delivery between the treatment arms where a cesarean delivery was considered a censored observation. All tests were two-sided and analyses were adjusted for clinical site, except where noted, and were performed using SAS software, version 9.3 (SAS Institute, Inc., Cary, NC) or S-Plus software, version 8.1 (TIBCO, Palo Alto, CA).

A Data Safety Monitoring Committee (DSMC) was created that consisted of representatives of each medical center (not involved in the study) and one independent member for a total of 5 members. Although an interim analysis was not planned, the DSMC periodically reviewed enrollment progress, outcomes, and safety data by treatment arm.

Results

A total of 318 subjects were randomized for the study between May 2010 and April 2013, 161 (50.6%) for LR and 157 (49.4%) for D5LR. Nine subjects were excluded from analysis: 3 were deemed ineligible, 5 did not have adequate documentation of informed consent, and 1 subject withdrew consent. Of the 309 subjects, 163 (52.8%) were recruited with the initial cervical dilation requirement of <5 cm and 144 (47.2%) after the change to <6 cm, with approximately equal numbers randomized to both arms for both study periods. There were

no known crossovers. Importantly, the trial was stopped short of the targeted sample size based on the recommendations of the DSMC after carefully considering the slower-than-expected recruitment rate and the lower-than-predicted rate of cesarean delivery as the primary outcome. Outcome data was available for 309 subjects, 156 from the LR arm and 153 from the D5LR arm. (CONSORT flow diagram available in Supplemental Digital Content, Figure 1)

Subject characteristics are reported in Table 1. There were no statistically significant or clinically important demographic or pregnancy differences noted between the 2 study groups. Characteristics that could influence labor progress and route of delivery were also similar including: cervical dilation on admission, rates of hypertensive disorders, and medical conditions. (Table 2)

For the primary outcome, there was no difference in the cesarean delivery rate after adjusting for recruiting site for the D5LR arm (23/153 or 15.0%) versus the LR arm (18/156 or 11.5%), [RR (95%CI) of 1.3 (0.7, 2.3), $P=0.34$]. Adjusting for the presence of admission ketonuria as a surrogate measure of glycemic and hydration status, did not change these results significantly with a cesarean rate for the D5LR arm versus the LR arm, RR (95%CI) of 1.4 (0.8, 2.4), $P=0.27$. Among those having a cesarean, the proportion performed for labor arrest disorders were lower with D5LR, but this did not reach significance, 16 of 18 (88.9%) for LR and 15 of 23 (65.2%) for D5LR, $P=0.14$. Using a Cox proportional hazards model adjusted for clinical site, there was no evidence of a statistical difference in the time from the onset of labor to delivery (i.e., whether vaginal or cesarean section) between the D5LR and LR arms (hazard ratio: 1.0; 95% CI: (0.8, 1.3); $p\text{-value}=0.99$). When indications for cesarean were examined, the proportions performed for arrest disorders were similar in the D5LR group, 16/18 (88.9%), compared to the LR group, 12/23 (65.2%), $P=0.14$.

There were no differences in oxytocin augmentation rates, overall operative delivery rates (cesarean, vacuum and forceps) and selected intrapartum or postpartum complications other than a borderline higher rate of identified postpartum hemorrhage in the LR arm (6.0%) versus the D5LR arm (1.3%), $P=0.05$. Umbilical artery blood gas results were similar between study arms. There was only 1 case of a gas pH of <7.00 , that was in the D5LR arm. There were 4 cases of Apgar scores <7 with all found in the D5LR group, but this difference was not significant. Overall Apgar scores were similar. There was a borderline lower rate of neonatal hypoglycemia (glucose <40 mg/dL) in the LR arm versus the D5-LR arm (7/50 (14%) versus 18/55 (32.7%), $p = 0.05$). LATCH scores were also similar between study arms. There were 6 cases of serious adverse events (1 in D5LR arm and 5 in LR arm), which were considered as not related to the study treatment (right foot polydactyly, tracheomalacia, trisomy 21, congenital heart defect, placental sulfatase deficiency and fetal right ovarian torsion).

In order to examine whether nulliparas represented a different responder population we analyzed this group separately for the primary outcome. The cesarean delivery rates for the nulliparas only subset were LR 18/86 (20.9%) vs. D5LR 20/83 (24.1%); $p= 0.56$. Additional analyses were performed to examine the effect of cesarean delivery on the obstetric outcomes based on whether the cesarean was performed at a cervical dilation of <4 cm or

4cm using this variable as both a direct and interaction term. The results (not shown) remained unchanged after this adjustment was applied.

Discussion

This trial was designed to assess whether the addition of glucose to maintenance IV fluids for women in spontaneous active labor would lead to a lower cesarean delivery rate without significantly increasing complications. Although the trial was stopped prior to reaching the targeted sample size, there was no suggestion that this population benefited from the addition of glucose to the intravenous fluids. The cesarean delivery rates, oxytocin augmentation rates and duration of labor were similar. Even after adjusting for the presence of ketonuria at the time of admission, there was no identified benefit from using a glucose solution. There were no significant differences in any of the potential complications other than a marginally higher rate of neonatal hypoglycemia and 5 minute Apgar scores <7 among those receiving D5LR. The lack of a difference in neonatal admission to a special care nursery suggests that the glucose and Apgar differences did not significantly affect overall neonatal health. Based on these results, adding glucose to a LR IV fluid solution does not improve maternal outcomes and may lead to increased neonatal needs for enhanced care resources.

Previous literature evaluating intravenous fluid interventions for improving labor outcomes is limited. In a randomized controlled study of 2000 subjects comparing IV fluid rates, Garite et al¹⁰ showed a lower proportion of prolonged labor, and possibly a decreased need for oxytocin, with the higher IV fluid rates (up to 250 ml/hr), suggesting that inadequate hydration may contribute to dysfunctional labor and possibly an increased rate of cesarean section. Several smaller studies have not consistently confirmed these findings.^{10,11,12} IV infusion rates were not specifically controlled in our protocol, but the overall infusion amounts did not differ between groups. The lower amount of study fluids in the D5LR group is explained by the use of LR for all IV fluid boluses regardless of group. These were recorded as consistent with group assignment for the LR group, but not for the D5LR group. More LR was used overall, but this is explained by the use of LR for the bolus IV fluid in both groups. The subanalyses using ketonuria status does provide some insight that the presence of ketonuria as a surrogate measure of both hydration and caloric balance, does not affect labor success in our study population. Fisher and Huddleston¹⁴ demonstrated that adding 5% glucose to intrapartum IV fluid of lactated Ringer's solution reduces umbilical cord acidemia and hypercarbia without changing the cord levels of glucose or base excess. Sharma, et al⁶ also found slightly higher umbilical artery pH values with a 5% dextrose solution. As with our study, several smaller studies were unable to confirm these findings.¹⁵⁻¹⁷

There are only 2 published trials of glucose containing solutions to improve the success of labor. Both of these trials were confined to nulliparous women. Sharma, et al⁶ randomized 250 women to either normal saline (NS) or NS alternated with NS plus 5% dextrose at 175 ml per hour. They found no difference in the cesarean rate between groups, although labor was shorter with fewer prolonged labors in women delivering vaginally. Shrivastava, et al⁷ randomized 289 women to either NS without dextrose, NS with 5% dextrose or NS with

10% dextrose. They noted shorter durations of the second stage and total labor in both groups receiving dextrose. There were no differences in the cesarean rates among the 3 groups. Our trial was not confined to nulliparous women, which reflects a representative group presenting in active labor, although we had equal representation of nulliparous women in both groups. Our subanalysis of just the nulliparous women showed no difference in the cesarean rate or the duration of labor.

Strengths of this study include a randomized design that produced appropriately similar subjects between both study arms. The primary outcome of cesarean delivery was a fixed endpoint and not vulnerable to the subjectivity of determining the time of onset of labor. The implementation of the protocol in multiple obstetric units reflects a broad and representative obstetric experience making this more generalizable.

Weaknesses of the study include study closure before reaching the estimated sample size. This was done on the recommendation of the DSMC who based their decision on the slow recruitment rate and the much lower-than-estimated cesarean delivery rate (13.2% versus 25%). We found it unexpectedly difficult to find women admitted in active labor with cervical dilation of <6cm. The labor units were unlikely to admit women in early labor due to efforts to reduce cesarean delivery rates. Therefore, a significant portion of women admitted in active labor had more advanced cervical dilation, which is a group that is most likely to deliver vaginally. If we used the actual cesarean rate in the LR group of 11.5% with an expected 25% reduction in the cesarean rate due to D5LR to recalculate the sample size (two-sided test, significance level of 0.05 and a power of 80%), we would need 3374 total subjects to complete the objectives, which is not practical or feasible.

Because there was no funding for performing protocol-specific testing for urine ketones, umbilical cord gases and neonatal glucose, there were some missing laboratory data. However, the missing data were relatively evenly distributed between treatment arms, which lowers the likelihood of a selection bias. We cannot exclude the potential for bias in assessing neonatal hypoglycemia due to participation in the study, but the labor nurses and physicians were instructed to not provide information to the nursery staff on the specific fluids infused which would limit any bias effects. Previously undiagnosed maternal glucose intolerance could also have affected neonatal outcomes, but there is no reason to expect that situation to favor one group over the other. Finally, we did not include women having an induction of labor, which may be a group more vulnerable to prolonged restriction of caloric intake and, therefore, might benefit more from caloric supplementation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Demographic and labor characteristics compared between treatment arms of lactated Ringer's (LR) solution and D5 lactated Ringer's (D5LR) solution.

	LR [N=156]	D5LR [N=153]	P
Maternal age (years)	26.8 ± 4.9 [156]	26.7 ± 4.9 [153]	0.87
Nulliparity	86/156 (55.1%)	83/151 (55.0%)	0.99
Hispanic	12/156 (7.7%)	21/152 (13.8%)	0.09
Race			0.19
Caucasian	127/156 (81.4%)	129/151 (85.4%)	
African American	11/156 (7.1%)	4/151 (2.7%)	
Other	18/156 (11.5%)	18/151 (11.9%)	
Private Insurance	116/153 (75.8%)	111/152 (73.0%)	0.57
> 12th Grade Education	93/136 (68.4%)	89/133 (66.9%)	0.84
Tobacco use	17/153 (11.1%)	15/152 (9.9%)	0.72
Alcohol use	4/153 (2.6%)	9/145 (6.2%)	0.13
Initial BMI (kg/m ²)	26.5 ± 5.8 [148]	26.1 ± 6.5 [147]	0.63
Initial weight (kg)	69.8 ± 15.1 [152]	69.5 ± 17.5 [148]	0.87
Weight gain (kg)	12.0 ± 6.6 [150]	13.5 ± 9.9 [148]	0.14
Hypertensive disorders	2/156 (1.3%)	0/153 (0%)	0.17
Ketonuria on admission	15/106 (14.2%)	8/103 (7.8%)	0.23
Admission dilation (cm)	4.0 (3.0, 4.0) [156]	4.0 (3.0, 4.0) [152]	0.92

BMI-Body Mass Index

Data reported as mean ± SD [n] for continuous variables and proportion (%) for categorical variables, with the exception of admission dilation (cm) which is reported as median (25th, 75th percentile) [n] due to non-normally distributed data. P-values adjusted for recruitment site.

Table 2

Obstetric outcomes compared between treatment arms of lactated Ringer's (LR) solution and D5 lactated Ringer's (D5LR) solution.

	LR [N=156]	D5LR [N=153]	Risk Ratio (95% CI)	P
Cesarean delivery	18/156 (11.5%)	23/153 (15.0%)	1.3 (0.7, 2.3)	0.34
Cesarean delivery (adjusted for ketonuria)			1.4 (0.8, 2.4)	0.27
Time to delivery (hours)	12.1 (8.4, 18.0) [150]	12.8 (7.6, 18.3) [150]		0.69
Augmentation	88/156 (56.4%)	92/153 (60.1%)	1.1 (0.9, 1.3)	0.40
Any Operative Delivery (C/S, Forceps, Vacuum)	25/156 (16.0%)	31/153 (20.3%)	1.3 (0.8, 2.1)	0.31
Intrapartum fluids (ml)				
Randomized fluid	2058 ± 1176 [109]	1472 ± 998 [115]		<0.01
Total fluids	2086 ± 1263 [110]	2043 ± 1378 [115]		0.89
Meconium	5/152 (3.3%)	4/150 (2.7%)	0.8 (0.2, 3.0)	0.75
Chorioamnionitis	6/152 (3.9%)	5/150 (3.3%)	0.8 (0.3, 2.7)	0.78
Postpartum hemorrhage	9/151 (6.0%)	2/149 (1.3%)	0.2 (0.0, 1.0)	0.05
Shoulder dystocia	5/152 (3.3%)	5/150 (3.3%)	1.0 (0.3, 3.4)	0.98
Umbilical artery (UA) gases				
pH	7.24 ± 0.07 [48]	7.22 ± 0.08 [59]		0.67
pH 7.15	7/48 (14.6%)	12/59 (20.3%)	1.0 (0.5, 2.3)	0.96
UA pCO ₂	54.8 ± 11.1 [49]	55.0 ± 11.4 [59]		0.55
Base deficit >12	3/48 (6.3%)	6/58 (10.3%)	1.7 (0.4, 6.3)	0.46

Data reported as mean ± SD [n] for continuous variables and proportion (%) for categorical variables, with the exception of time to delivery (hours) which is reported as median (25th, 75th percentile) [n] due to non-normally distributed data. P-values adjusted for recruitment site except for chorioamnionitis, meconium, shoulder dystocia, postpartum hemorrhage, and base deficit. Analyses were not adjusted by clinical site of recruitment for these 5 outcomes due to sparse numbers which led to model convergence issues.

Table 3

Neonatal outcomes compared between treatment arms of lactated Ringer's (LR) solution and D5 lactated Ringer's (D5LR) solution.

	LR [N=156]	D5-LR [N=153]	P
Birth weight (g)	3428 ± 404 [156]	3408 ± 417 [153]	0.64
Male sex	83/156 (53.2%)	83/153 (54.3%)	0.88
Apgar at 5min	9.0 (9.0, 9.0) [155]	9.0 (9.0, 9.0) [153]	0.64
Apgar at 5min, <7	0/155 (0.0%)	4/153 (2.6%)	0.06
Respiratory difficulty	4/153 (2.6%)	6/150 (4.0%)	0.52
Suspected sepsis	3/151 (2.0%)	2/144 (1.4%)	0.69
Neonatal hypoglycemia	7/50 (14.0%)	18/55 (32.7%)	0.05
Hyperbilirubinemia with phototherapy	3/154 (1.9%)	1/146 (0.7%)	0.36
NICU/special nursery admission	19/156 (12.2%)	17/153 (11.1%)	0.79
LATCH Scores	8.0 (7.0, 9.0) [90]	8.0 (7.0, 9.0) [87]	0.15

Data reported as mean ± SD [n] for normally distributed continuous variables, median (25th, 75th percentile) [n] for non-normally distributed variables or ordinal variables, and proportion (%) for binary variables. P-values adjusted for recruitment site.