

Department of Obstetrics & Gynecology

A Multi-Center, Two-Arm, Single-Blind Randomized Trial of Two Different Intravenous Fluids During Labor (Poster).

Lisa M. Dapuzzo-Argiriou MD

Lehigh Valley Health Network, lisa_m.dapuzzo@lvhn.org

John C. Smulian MD, MPH

Lehigh Valley Health Network, john.smulian@lvhn.org

Meredith Rochon MD

Lehigh Valley Health Network, Meredith_L.Rochon@lvhn.org

Luisa Galdi DO

Jessika Kissling MD

See next page for additional authors

Follow this and additional works at: https://scholarlyworks.lvhn.org/obstetrics-gynecology

Part of the Obstetrics and Gynecology Commons, and the Statistics and Probability Commons

Published In/Presented At

Dapuzzo, J., Smulian, J., Rochon, M., Galdi, L., Kissling, J., Schnatz, P., Neubert, G., Gonzalez-Rios, A., Airoldi, J., Carrillo, M., Maines, J., Kunselman, A., Repke, J., & Legro, R. (2014, February 3-8). *A multi-center, two-arm, single-blind randomized trial of IV fluids during labor.* Poster presented at: The Society of Maternal Fetal Medicine 34th Annual Meeting, New Orleans, LA

This Poster is brought to you for free and open access by LVHN Scholarly Works. It has been accepted for inclusion in LVHN Scholarly Works by an authorized administrator. For more information, please contact LibraryServices@lvhn.org.

Authors Lisa M. Dapuzzo-Argiriou MD; John C. Smulian MD, MPH; Meredith Rochon MD; Luisa Galdi DO; Jessika Kissling MD; Peter F. Schnatz DO; George Neubert MD; Angel Gonzalez-Rios MD; James Airoldi MD; Mary Anne Carrillo MD; Jaimie Maines MD; Allen R. Kunselman MS; John Repke MD; and Richard S. Legro MD

A Multi-Center, Two-Arm, Single-Blind Randomized Trial of Two Different Intravenous Fluids During Labor

Lisa Dapuzzo, MD¹, John C. Smulian, MD, MPH¹,², Meredith L. Rochon, MD¹ Luisa Galdi, DO³, Jessika Kissling, MD³, Peter F. Schnatz, DO³, George Neubert, MD³, Angel Gonzalez Rios, MD⁴, James Airoldi, MD⁴, Mary Anne Carrillo, MD⁵, Jaimie Maines, MD⁵, Allen R. Kunselman, MS⁵, John Repke, MD⁵, Richard S. Legro, MD⁵

¹Lehigh Valley Health Network, Allentown, PA; ²University of South Florida-Morsani College of Medicine, Tampa, FL; ³The Reading Hospital, Reading, PA; ⁴St. Luke's University Hospital, Bethlehem, PA; ⁵Pennsylvania State University College of Medicine, Hershey, PA

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. Logbinomial regression was used to assess risk ratios (RR) and 95% confidence intervals (CI) after adjusting for participating center.

Results: There were 309 women analyzed from 4 hospital sites. 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. The postpartum hemorrhage rate was 6.0% in the LR arm and 1.3% in the D5LR arm, P=0.05). There also was a marginally higher rate of neonatal hypoglycemia (glucose < 40 mg/dL) and 5 minute Apgar scores <7 in the D5LR group versus the LR group.

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

Background:

- Adequate caloric and fluid intake is important for muscle performance
- The uterus is a muscle undergoing work during labor
- Data suggest adding glucose to maintenance IV fluids in labor
 - May shorten labor duration in nulliparas
 - May reduce umbilical artery acidemia and hypercarbia

Hypotheses:

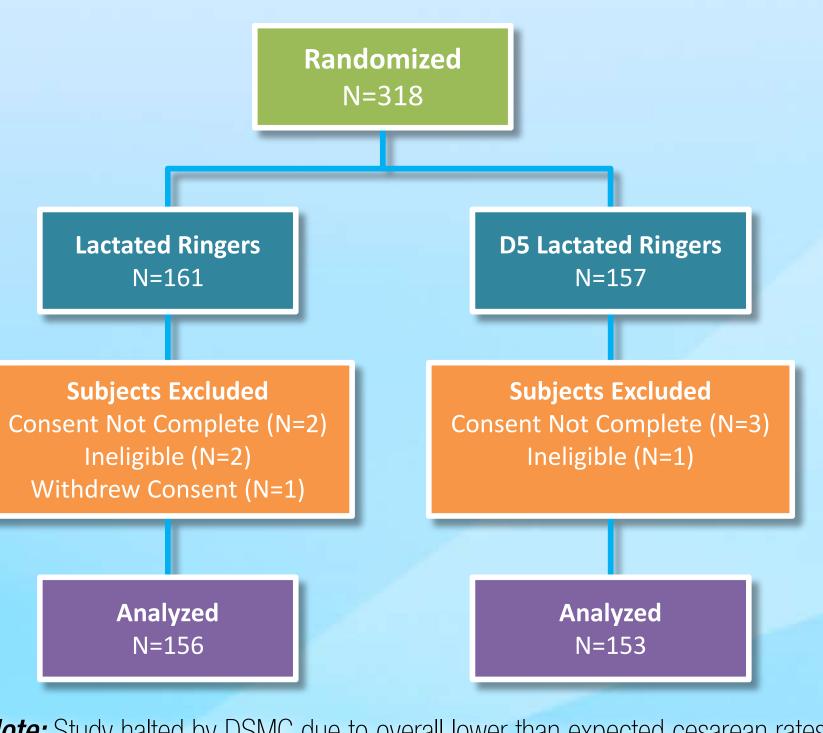
- IV hydration during labor with a glucose-containing fluid will lead to more efficient uterine contractility and will lead to a reduction of cesarean delivery and improved labor characteristics in women presenting in active labor.
- There is no increase in maternal or neonatal complications if glucose is used in IV fluids in labor

Materials and Methods:

- Multi-center (4 regional OB/GYN residency programs)
- Prospective randomized single-blind
 Singleton in spontaneous labor with
- cervix <6cm dilationNo glycemic dysregulation condition,
- No glycemic dysregulation condition steroids, prior cesarean, induction
- Randomized to maintenance IV fluid of either
 - Lactated Ringers (LR)
 Lactated ringers with 5%
 glucose (D5LR)
- Any needed bolus of IVF was LR
- Randomization stratified by site
- Analyses
 - Risk Ratios (RR) and 95% CI
 - Log-binomial regression models
 - Parametric and non-parametric tests
- Data Safety Monitoring Committee

Results:

Figure 1. Randomization Flowchart



Note: Study halted by DSMC due to overall lower than expected cesarean rates and revised sample size calculation showing unattainable target of 3374 subjects.

Primary Outcomes:

- No difference in cesarean delivery rate
 - D5LR-15% and LR-11.5%RR (95% CI) of 1.32 (0.75,
 - RR (95% CI) OF 1.32 (0 2.35); P=0.34
- No difference in cesarean delivery rate after adjusting for ketonuria
- RR (95% CI) of 1.37 (0.78, 2.41); P=0.34
- No difference in labor onset to delivery time
 - Cox proportional hazards (95% CI) of 1.00 (0.80, 1.26); P=0.99

Table 1: Demographic and labor characteristics compared between treatment arms of LR and D5LR solution. LR D5LR (N=156) (N=153) p-value (N=153) (N=153)

	(11.00)	(1.1.00)
Maternal age (years)	26.8 ± 4.9 [156]	26.7 ± 4.9 [153]
Nulliparity	86/156 (55.1%)	83/151 (55.0%)
Hispanic	12/156 (7.7%)	21/152 (13.8%)
Race		
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%)
> 12th Grade Education	93/136 (68.4%)	89/133 (66.9%)
Tobacco use	17/153 (11.1%)	15/152 (9.9%)
Alcohol use	4/153 (2.6%)	9/145 (6.2%)
Initial BMI (kg/m²)	26.5 ± 5.8 [148]	26.1 ± 6.5 [147]

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

69.8 ± 15.1 [152]

Note: Data reported as mean \pm 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 LR and D5LR solution.

and D5LR solution.						
	LR (N=156)	D5LR (N=153)	Risk Ratio (95% CI)	p-value		
Cesarean delivery	18/156 (11.5%)	23/153 (15.0%)	1.3 (0.7, 2.3)	0.87		
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		
Umb artery gases						
рН	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 pCO2	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		

arms of lactated Ringer's (LR) solution and D5 lactated Ringer's (D5LR) solution.

(D5LK) SOIUTION.					
	LR (N=156)	D5LR (N=153)	p-valu		
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]	0.06		
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		

Note: Data reported as mean \pm 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.

© 2014 Lehigh Valley Health Network

Conclusions:

• The addition of glucose to maintenance intrapartum IV fluids for women in spontaneous active labor at <6m:</p>

Note: Data reported as mean \pm SD [n] for continuous variables and proportion (%) for categorical variables, time to

delivery (hours) is reported as median (25th, 75th percentile) [n]. P-values adjusted for recruitment site (except for chorioamnionitis, meconium, shoulder dystocia, postpartum hemorrhage, and base deficit).

- Does not reduce the cesarean delivery rate
- Does not shorten labor

69.5 ± 17.5 [148]

- Does not lower oxytocin augmentation rate
- Does not change complication rates except marginally more cases of neonatal hypoglycemia and 5 minute Apgar scores <7, and marginally fewer postpartum hemorrhages

Funding:

Clinical Trials Registry number NCT01110005. This project is funded, in part, under a grant with the Pennsylvania Department of Health using Tobacco CURE Funds. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions. This project described also was supported by the National Center for Research Resources, Grant UL1 RR033184 and is now at the National Center for Advancing Translational Sciences, Grant UL1 TR000127. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Initial weight (kg)

A PASSION FOR BETTER MEDICINE."

