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Identifying the effective components of a standardized labor induction protocol: secondary analysis of a randomized, controlled trial

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Abstract

Objective: Standardized labor induction protocols utilizing evidence-based active management practices are associated with improved obstetric outcomes. However, these protocols are complex and include multiple components. We aimed to identify which of the individual components of an evidence-based labor induction protocol are most associated with reduced rates of cesarean delivery, maternal morbidity, and neonatal morbidity.

Study Design: This is a secondary analysis of a randomized trial comparing time to delivery among four labor induction methods. All patients enrolled in the trial had their labor managed with a multidisciplinary-developed, evidence-based standardized labor induction protocol. For each patient's induction, we assessed adherence to seven components of the protocol. Primary outcomes included cesarean delivery, maternal morbidity, and neonatal morbidity. Bivariate

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Authors' contributions

RH, LL, and SS conceived and designed this work. RH analyzed the data under the guidance of LL, SS, and RB. RH drafted the work, and it was substantially revised by LL, SS, and RB. All authors approved of the final version of this work and ensure its accuracy and integrity.

Ethics approval and informed consent

This study was approved by the institutional review board at the University of Pennsylvania and all women provided written consent before participation in this study.

Disclosure statement

The authors declare that they have no conflicts of interest.

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

analyses assessed the association of each protocol component with each outcome. Multivariable logistic regression determined independent predictors of each outcome.

Results: The 491 patients enrolled in the randomized trial were included in this analysis. For cesarean delivery, while adherence to four of the seven protocol components was associated with the outcome in bivariate analyses, only adherence to "cervical exams should be performed every 1–2 h in active labor" was associated with reduced cesarean rates when controlling for age, body mass index, and parity. For maternal morbidity, while adherence to "if misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use" was associated in bivariate analysis, it was no longer associated with the outcome in multivariable analysis. Finally, "cervical exams should be performed every 1–2 h in active labor" and "cervical exams should be performed every 2–4 h in latent labor" were associated with reduced neonatal morbidity both in bivariate analyses as well as when controlling for age, body mass index, and parity.

Conclusions: Within a standardized labor induction protocol, adherence to cervical exams every 1–2 h in active labor was associated with reduced cesarean rate, and adherence to cervical exams every 2–4 h in latent labor, as well as every 1–2 h in active labor is associated with reduced neonatal morbidity. Regular cervical examination during labor induction likely allows for intervention when cervical change is not made. This data warrants further investigation into the optimal frequency of cervical exams during labor induction. Furthermore, an understanding of which components of a complex, evidence-based labor induction protocol are most effective may be helpful for streamlining and education around this protocol as implementation occurs across diverse sites.

Keywords

Protocol components; labor induction; cesarean rate; maternal morbidity

Introduction

Labor induction makes up 20% of all deliveries in the United States (US), accounting for approximately 900,000 US women annually [1]. Decision-making during labor induction, such as frequency of cervical exams, when and if to perform artificial membrane rupture, use of oxytocin and intrauterine pressure catheters, as well as thresholds for cesarean section, are highly variable across and within centers [2,3].

The utilization of protocols to standardize care has been shown to decrease adverse outcomes in various medical fields, including obstetrics [4–9]. The American College of Obstetricians and Gynecologists (ACOG) has led a national effort to establish protocols and standardize labor and delivery management [7].

Our group retrospectively evaluated the hypothesis that standardization of labor induction can improve overall obstetric outcomes [10,11]. Cesarean delivery rate and maternal/neonatal morbidity were compared between women in a randomized trial of cervical ripening agents who were undergoing labor induction with a standardized protocol versus an observational cohort of women being induced at the same time, with labor management at the discretion of the provider. The standardized labor induction protocol included

recommendations for frequent cervical exams and interventions such as oxytocin and amniotomy at particular time points. We found that utilization of a standardized labor induction protocol was associated with a 70% reduction in neonatal morbidity overall (RR: 0.31, 95% CI: 0.13–0.70), as well as a 35% reduction in primary cesarean delivery rate specifically for Black women (RR 0.64 95% CI: 0.45–0.92), and was therefore associated with a reduced racial disparity in cesarean rate [10,11]. Importantly, utilization of the standardized labor induction protocol did not impact rates of chorioamnionitis (12.4% vs. 11.3%, $p = .67$), and reduced rates of endometritis (0.2% vs. 1.9%, $p = .01$) when compared to usual care [11].

However, protocols regarding labor, such as the standardized labor induction protocol used in our preliminary work, are complex and multi-pronged. It is therefore difficult to identify whether there are key components of the labor protocol that are driving the findings. Thus, we aimed to determine which specific components of our labor induction protocol were associated with improvements in three important obstetric outcomes: cesarean delivery rate, maternal morbidity, and neonatal morbidity. An understanding of which components independently affect outcomes will be critical as we move toward improving maternal and neonatal outcomes with induction standardization on a large-scale.

Materials and methods

We performed a secondary analysis of a randomized clinical trial comparing time to delivery among four different induction methods (misoprostol alone, cervical Foley alone, misoprostol/cervical Foley concurrently, cervical Foley/oxytocin concurrently) [12]. This study was performed at the University of Pennsylvania from May 2013 to June 2015. This study was approved by the institutional review board at the University of Pennsylvania and all women provided written consent before participation in this study.

Women were included in this study if they had labor induced for any indication and met the following inclusion criteria: full term (≥37 weeks), ≥18 years of age in cephalic presentation, with amniotic membranes not ruptured, and a cervical exam that required a ripening agent to begin labor. Women were excluded from the study if they had a prior cesarean delivery, had a multiple gestation, a contraindication to vaginal delivery, major fetal anomaly, did not speak English, or had a maternal condition requiring special management in labor such as HIV or eclampsia [12].

Women enrolled in this study were recommended to have their induction and labor managed with a standardized protocol specific to the cervical ripening method. The protocol was derived by two of the investigators (LDL, SKS) and approved by an institutional Obstetrical committee prior to initiation of the randomized trial. It was modeled after prior studies that utilized an active management protocol [13–17]. The protocol was used for induction management, as well as latent (defined as the stage of labor prior to 6 cm dilation) and active labor (defined as the stage of labor at ≥6 cm). The cervical ripening method was the only thing that could differ among women.

For the purpose of the current study, the protocol was divided into seven specific recommended components detailed in Table 1. Four of these components were recommendations for management within latent labor and three were within active labor. Examples of such components include “if misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use” and “if patient is ≥4 cm dilated and has intact membranes, perform amniotomy.” Adherence to each component for a given patient’s labor induction was determined based on review of the Electronic Health Record (EHR), using definitions of adherence described in Table 1. Of note, for protocol components where an intervention was recommended within a specific time frame, a 30-min grace period was allowed beyond the recommended time frame for there to be considered adherence to that component. For example, one protocol component is “cervical exams should be performed every 2–4 h in latent labor.” Adherence was defined as “were all cervical exams in latent labor performed less than or equal to 4.5 h apart?”

Delivery, maternal, and neonatal outcomes were recorded. Primary outcomes were (1) cesarean delivery for any indication, (2) composite maternal morbidity (defined as any of the following that occurred during labor, delivery, or in the 4 weeks postpartum: blood transfusion, endometritis, wound separation/infection, venous thromboembolism, hysterectomy, intensive care unit admission, or death) and (3) composite neonatal morbidity (defined as any of the following that occurred prior to neonatal discharge: neonatal resuscitation requiring supplemental oxygen outside of the delivery room or culture proven/presumed neonatal sepsis).

Bivariate comparisons of adherence to each of the seven protocol components with each of the three primary outcomes were performed with Fisher exact tests and chi-square tests, where appropriate. Multivariable logistic regression was used to assess for independent predictors of each outcome. Demographic and clinical characteristics associated on bivariate tests ($p < .20$) with the outcome of interest were evaluated as potential covariates if they had biologic plausibility to be confounders. Thus, age, body mass index (BMI), and parity were placed into each model with the individual protocol components found to be associated with that outcome. Backwards stepwise elimination of covariates (with p-value >.20 for removal) was performed for each regression model to determine which covariates and protocol components to retain in the final models. The final multivariable models include all variables with a $p < .05$. Statistical analyses were performed with Stata 15 (StataCorp, College Station, TX). This study was performed with a fixed sample size determined by those who enrolled in the original study.

Results

Based on the sample size of the parent, randomized trial, 491 women were included in this analysis. Demographic and clinical characteristics are detailed in Table 2. Included women were of median age 27, 77.6% identified as Black, and 93.7% were overweight or obese at delivery by BMI. Of our sample, 27.7% ($n = 136$) underwent cesarean delivery, 7.3% ($n = 36$) met criteria for maternal morbidity, and 3.1% ($n = 15$) met criteria for neonatal morbidity.

Table 3 shows bivariate comparisons between adherence to each of the seven protocol components and each of the three outcomes. Adherence to four of the seven protocol components was found to be significantly associated with decreased cesarean delivery rates (Table 3; Column A): (1) “Cervical exams should be performed every 2–4 h in latent labor” (Cesarean rate among those adherent to this component vs. non-adherent: 21.0% vs. 34.3%, $p = .001$), (2) “If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use” (Cesarean rate among those adherent to this component vs. non-adherent: 20.3% vs. 48.8%, $p < .001$), (3) “Cervical exams should be performed every 1–2 h in active labor” (Cesarean rate among those adherent to this component vs. non-adherent:14.8% vs. 34.0%, $p < .001$), and (4) “If patient has same exam 2 h apart in active labor, and is already on oxytocin and has ruptured membranes, place intrauterine pressure catheter” (Cesarean rate among those adherent to this component vs. non-adherent:19.2% vs. 40.5%, $p = .002$). On multivariable testing, when controlling for age, BMI, and parity, only adherence to “Cervical exams should be performed every 1–2 h in active labor” was found to be an independent predictor of cesarean delivery (Table 4).

Adherence to only one of the protocol components was significantly associated with a decreased rate of maternal morbidity (Table 3; column B): “If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use” (Maternal morbidity rate among those adherent to this component vs. non-adherent: 3.6% vs. 14.6%, $p = .005$). Adherence to this component of the protocol did not remain significant in multivariable modeling (Table 4).

Finally, adherence to two protocol components was significantly associated with decreased rates of neonatal morbidity (Table 3; column C) (1) “Cervical exams should be performed every 2–4 h in latent labor” (Neonatal morbidity rate among those adherent to this component vs. non-adherent: 1.2% vs. 4.8%, $p = .03$) and (2) “Cervical exams should be performed every 1–2 h in active labor” (Neonatal morbidity rate among those adherent to this component vs. non-adherent:1.6% vs. 5.6%, p = .03). Adherence to both of these protocol components remained independent predictors of neonatal morbidity when controlling for age, BMI, and parity (Table 4).

Conclusions

The results of this study demonstrate that, within a standardized labor induction protocol, adherence to specific components of the protocol is significantly associated with decreased rates of cesarean delivery, maternal morbidity, and neonatal morbidity. In particular, while controlling for confounders, adherence to “cervical exams should be performed every 1–2 h in active labor” was associated with both reduced cesarean rate and reduced neonatal morbidity and adherence to “cervical exams should be performed every 2–4 h in latent labor” was associated with reduced neonatal morbidity. We hypothesize that, with increased frequency of cervical examination during labor induction, we can make more timely diagnosis of labor dystocia, more quickly intervene, and thus prevent lengthy and failed inductions, which may lead to cesarean delivery and morbidity for mother and baby.

The utilization of protocols to standardize care has decreased adverse outcomes in various medical fields, including obstetrics [4–9]. This led us to study a novel means of reducing the primary cesarean rate: standardization of labor induction. Our prior work demonstrated that standardization of labor induction practices into a comprehensive protocol is associated with a reduction in the primary cesarean rate for Black women, as well as neonatal morbidity overall [10,11]. Yet, when complex, multi-pronged protocols such as this are implemented, it is important to critically evaluate individual components. An understanding of which protocol components are specifically associated with improved outcomes can (1) provide direct evidence to patients and their providers as to the benefits of individual components and (2) guide efforts to streamline protocols prior to large-scale implementation to avoid requiring providers to perform ineffective tasks.

The finding that important protocol components related to the frequency of cervical examination reflect the idea that, with frequent exams, we can monitor labor progress and more quickly diagnose issues with labor progress. There is a paucity of data outside of this work examining the value of frequent cervical exams in labor and induction. Abukhalil et al. performed a randomized trial of 109 nulliparous women presenting in spontaneous labor. These women were randomized to vaginal exams every 2 h versus every 4 h, with no difference in duration of labor, mode of delivery, maternal or neonatal morbidity [18]. Our work, on the other hand, evaluates the benefits of regular cervical exams during labor induction, an artificial stimulation of the labor process, which may require closer monitoring and more frequent intervention to produce a successful outcome. A 2013 Cochrane review found Abukhail et al. to be the only study of quality evaluating the frequency of cervical examination in reference to clinical outcomes [19].

Importantly, cervical examination also needs to be thought of in reference to the patient experience, as some studies report associated pain and discomfort, insufficient patient privacy, or feelings of disrespect [20,21]. Thus, further work should focus on the optimal cervical examination frequency during labor induction, as well as how to perform such examinations with a patient-centered focus.

This study has several strengths. It utilizes detailed labor induction data on a large sample size of women enrolled in a randomized trial. It is also unique in its overarching goal, to understand how adherence to specific protocol components within a complex intervention on labor and delivery individually impact outcomes.

This study also has several limitations. First, while we were able to establish seven discrete protocol components for which adherence could be assessed from the medical record, this study did not assess what may be legitimate reasons for non-adherence, such the interaction between protocol recommendations and fetal heart rate monitoring, or patient preferences regarding management. Second, several of the components were so well adhered to that it was difficult to see an association with our outcomes. If more inductions had been non-adherent with those components, an association with outcomes may have been able to be established. In addition, this analysis may be affected by confounding by indication. Some components may have been adhered to, not by active provider choice, but by the natural progression of labor. For example, a woman may have been examined more

frequently because she was feeling vaginal pressure due to the fetal head descending in labor. Therefore, that patient's reduced risk of cesarean may not have been secondary to the exam itself, but rather due to a faster labor course leading to symptoms resulting in more frequent cervical exams. Maternal and neonatal morbidity are also rare outcomes, at 7.3% and 3.1%, respectively, limiting their evaluation, particularly within regression modeling, in our small sample size. Finally, this is a secondary analysis of a randomized trial performed at one, urban, academic site, limiting generalizability.

An understanding of the impact of individual components of an effective standardized labor induction protocol may help as clinical practices work to implement such a protocol, as well as stimulate future research. The value of regular cervical examination to reducing the cesarean delivery rate and neonatal morbidity in this study may be subject to bias, but nonetheless warrants further investigation. In addition, our ongoing work includes a prospective, multi-site trial to evaluate the effectiveness of our standardized labor induction protocol in the real-world, while simultaneously assessing outcomes related to implementation, such as patient and provider acceptability.

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Table 1.

Standardized labor induction protocol as divided into 7 components.

Measure (stage of labor)	Protocol recommendation	Definition of adherence
#1 (Latent)	If a foley balloon is utilized, it is to be removed 12 h after placement or when falls out.	If a foley balloon was utilized, did it fall out/was it removed by 12.5 h after placement?
#2 (Latent)	If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use.	If misoprostol was used, was it used for less than 24 h and less than or equal to 6 doses?
#3 (Latent)	Cervical exams should be performed every 2–4 h in latent labor.	Were all exams in latent labor performed less than or equal to 4.5 h apart?
#4 (Active)	Cervical exams should be performed every 1–2hrs in active labor.	Were all exams in active labor performed less than or equal to 2.5 h apart?
#5 (Latent)	If patient is ≥ 4 cm dilated and has intact membranes, perform amniotomy.	If the patient reached 4 cm, was the patient already ruptured or amniotomy performed at that exam?
#6 (Active)	If patient has same exam 2 h apart in active labor, and already has ruptured membranes, oxytocin should be started.	If active labor was reached and the patient was already ruptured with 2 exams at the same dilation 2 h apart, was oxytocin started/running?
#7 (Active)	If patient has same exam 2 h apart in active labor, and is already on oxytocin and has ruptured membranes, place intrauterine pressure catheter.	If active labor was reached and the patient was already ruptured and on oxytocin with 2 exams at the same dilation 2 h apart, was an intrauterine pressure catheter placed?

This table describes how adherence to each component was defined for the purposes of this analysis.

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Table 2.

Demographic and clinical information.

Demographic	*N* (%)
Maternal age[a]	27 [22–32]
Race	
Black/African American	381 (77.6)
Caucasian	76 (15.5)
Asian	11 (2.2)
Other/Unknown	23 (4.7)
BMI at delivery	
<25.0 (Normal weight)	29 (6.3)
25.0–29.9 (Overweight)	123 (26.9)
30.0–34.9 (Obese Class 1)	110 (24.0)
35.0–39.9 (Obese Class 2)	105 (22.9)
≥40.0 (Obese Class 3)	91 (20.0)
Insurance	
Private	165 (33.6)
Public/Uninsured	326 (66.4)
Nulliparous	290 (59.1)
Gestational age at induction[a]	39 [38–40]
Diabetes	
Gestational diabetes	33 (6.7)
Pre-gestational	11 (2.2)
Chronic hypertension	40 (8.1)
Pregnancy related hypertension	
GHTN/Preeclampsia without severe features	114 (23.2)
Preeclampsia with severe features	50 (10.2)
Indication for induction	
Later term/post-term	64 (13.0)
Maternal[b]	148 (30.1)
Fetal[c]	225 (45.8)
Elective/Other[d]	54 (11.0)
Bishop score at induction[a]	3 [2–4]
Cervical dilation at induction[a]	1 [1–1.5]

[a]Median (inter-quartile range);

[b]Examples include: chronic hypertension, gestational hypertension (GHTN), preeclampsia, diabetes, renal disease, history of venous thromboembolism, cardiac disease or other chronic medical condition where induction was recommended;

[c]Examples include: Oligohydramnios, intrauterine growth restriction, abnormality on fetal testing;

[d]Examples of “other” include: history of an intrauterine fetal demise, vaginal bleeding at term, cholestasis.

Table 3.

Bivariate comparisons between adherence to each of the seven protocol components and each of the three outcomes (Column A: Cesarean delivery; Column B: Maternal morbidity, and Column C: Neonatal morbidity)

Protocol components	*N* (%)	Column A: Cesarean delivery	*p* Value*	Column B: Maternal morbidity	*p* Value*	Column C: Neonatal morbidity	*p* Value*
Latent labor							
1. If a foley balloon is utilized, it is to be removed 12 h after placement or when falls out.							
n = 363 foley balloons placed			.13		.07		.64
Yes, adherent with protocol	351 (96.7%)	103 (29.3%)		27 (7.7%)		13 (3.7%)	
No, non-adherent with protocol	12 (3.3%)	6 (50.0%)		3 (25.0%)		0 (0)	
2. Cervical exams should be performed every 2–4 h in latent labor.							
n = 491 (all patients)			.001		.53		.03
Yes, adherent with protocol	243 (49.5%)	51 (21.0%)		16 (6.6%)		3 (1.2%)	
No, non-adherent with protocol	248 (50.5%)	85 (34.3%)		20 (8.1%)		12 (4.8%)	
3. If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use.							
n = 238 inductions with misoprostol used			<.001		.005		.28
Yes, adherent with protocol	197 (82.8%)	40 (20.3%)		7 (3.6%)		4 (2.0%)	
No, non-adherent with protocol	41 (17.2%)	20 (48.8%)		6 (14.6%)		2 (4.9%)	
4. If patient is ≥4 cm dilated and has intact membranes, perform amniotomy.							
n = 481 (all patients reached 4 cm, but 10 rupture dilations were unknown)			.35		.62		1.00
Yes, adherent with protocol	357 (74.2%)	91 (25.5%)		24 (6.7%)		11 (3.1%)	
No, non-adherent with protocol	124 (25.8%)	37 (29.8%)		10 (8.1%)		3 (2.4%)	
Active labor protocol components							
1. Cervical exams should be performed every 1–2 h in active labor.							
n = 449 patients reached active labor			<.001		.58		.03
Yes, adherent with protocol	305 (67.9%)	45 (14.8%)		19 (6.2%)		5 (1.6%)	
No, non-adherent with protocol	144 (32.1%)	49 (34.0%)		11 (7.6%)		8 (5.6%)	
2. If patient has same exam 2 h apart in active labor, and already has ruptured membranes, oxytocin should be started.							
n = 449 patients reached active labor			1.00		1.00		1.00
Yes, adherent with protocol	356 (98.1%)	88 (24.7%)		27 (7.6%)		13 (3.7%)	
No, non-adherent with protocol	7 (1.9%)	1 (14.3%)		0 (0)		0 (0)	
3. If patient has same exam 2 h apart in active labor, and is already on oxytocin and has ruptured membranes, place intrauterine pressure catheter.							

Protocol components	*N* (%)	Column A: Cesarean delivery	*p* Value*	Column B: Maternal morbidity	*p* Value*	Column C: Neonatal morbidity	*p* Value*
n = 449 patients reached active labor			.002		.30		.29
Yes, adherent with protocol	411 (91.7%)	79 (19.2%)		26 (6.3%)		11 (2.7%)	
No, non-adherent with protocol	37 (8.3%)	15 (40.5%)		4 (10.8%)		2 (5.4%)	

* *p* Values represent the bivariate comparison between adherence to each protocol component and the outcome in that column.

Table 4.

Multivariable regression models for cesarean delivery, maternal morbidity, and neonatal morbidity.

Variables	Initial model aOR (95%CI)	*p* Value	Final model aOR (95%CI)	*p* Value
Cesarean delivery				
Cervical exams should be performed every 2–4 h in latent labor.	0.89 [0.52–1.50]	.65	NA	
If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use.	1.00 [0.99–1.01]	.91	NA	
Cervical exams should be performed every 1–2 h in active labor.	1.10 [0.99–1.22]	.07	1.08 [1.01–1.15]	.02
If patient has same exam 2 h apart in active labor, and is already on oxytocin and has ruptured membranes, place intrauterine pressure catheter.	0.98 [0.91–1.06]	.65	NA	
Maternal morbidity				
If misoprostol is utilized, it should not be continued beyond 6 doses or 24 h of use.	1.00 [0.99–1.02]	.09	NA	
Neonatal morbidity				
Cervical exams should be performed every 2–4 h in latent labor.	0.35 [0.09–1.32]	.12	0.28 [0.08–1.01]	.05
Cervical exams should be performed every 1–2 h in active labor.	0.33 [0.10–1.09]	.07	0.32 [0.10–0.99]	.049