
Visual Aids for Induction of Labor
A Randomized Controlled Trial
(The VAIL Study)

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A Introduction

A1 Study Abstract

The ARRIVE trial identified induction of labor (IOL) at 39 weeks as a method of cesarean section risk reduction and has increased the incidence of IOL in primiparous patients.¹ Recent data indicate that nearly 20% of pregnant patients in the United States undergo IOL annually, and an even larger percentage of patients (45%) undergo IOL at Barnes Jewish Hospital.^{2,3} Multiple methods of induction exist for each patient, ranging from pharmacologic cervical ripening agents such as misoprostol to mechanical methods such as balloon catheters, among others.⁴ Patients are often counseled on these multiple methods of induction at the time of their admission for delivery, and although combined methods (pharmacologic + mechanical) have been shown to decrease time to delivery, no specific induction agent or combination has been shown to reduce the chance of cesarean delivery. Thus, there remains equipoise, and patient input on the choice of agent used (i.e. shared decision making) is valuable. Black women are also more likely to be dissatisfied with their birth experience than their non-Black counterparts, which was attributed to a gap in patient education regarding the IOL process.⁵ IOL disparities coincide with the baseline mistrust that minority populations have experienced regarding reproductive health. A recent pilot survey performed on our Labor & Delivery unit revealed stark racial disparities in patient knowledge about induction methods with a nearly 30% difference in knowledge scores between historically marginalized and non-marginalized populations. Systemic racism remains a concerning contributor to this difference in knowledge, however this also highlights shortcomings on behalf of the healthcare system and calls for improved, innovative attempts to provide and empower patients with the knowledge they need to make healthcare decisions.

A2 Primary Hypothesis

We hypothesize that a patient-informed visual aid utilized during IOL counseling can improve patient knowledge about the induction process and narrow racial gaps in patient satisfaction and knowledge.

B Background

B1 Prior Literature and Studies

A recent randomized controlled trial (RCT) by Rahman et al demonstrated that an educational video outlining IOL methods improved patient knowledge and satisfaction compared to standard counseling.⁶ While this study is promising, there remains a paucity of data regarding the use of other more affordable and generalizable educational visual aids in IOL counseling and the impact of such aids on historically marginalized populations. Furthermore, no studies to date have developed visual aids informed by the needs and experiences of historically marginalized patients.

B2 Rationale for this Study

Improving patient knowledge about the induction process is important, as it contributes to birth satisfaction. Patient education has been shown to improve birth satisfaction by increasing maternal empowerment and preparedness and is associated with decreased

cesarean rates and increased breastfeeding initiation.⁷⁻¹⁰ Visual aids, specifically videos and paper images, have been shown to improve patient confidence, satisfaction, and informed consent when used in medical decision making, particularly in underrepresented minority cancer survivors.^{2,11-14} Although obstetricians generally counsel patients on various induction methods prior to IOL initiation, there are few studies investigating the incorporation of visual aids into IOL counseling, which provides a unique opportunity for this study protocol.

C Study Objectives

C1 Primary Aim:

Develop a visual aid tool for induction education informed by the experiences and needs of historically marginalized pregnant women.

C2 Secondary Aim:

Determine the impact of a patient-informed visual aid on patient knowledge, satisfaction, and trust in physicians regarding induction methods.

D Study Design

D1 Overview or Design Summary

This is a multi-phased study of patients undergoing IOL. Only the second phase of the study will be detailed in this protocol, as this will be the RCT portion of the study's design. We will test the efficacy of the visual aid by conducting a randomized trial of routine counseling versus counseling with the use of a visual aid (informed by patient interviews in the first phase) at the time of admission for IOL and studying the effect of the visual aid on patient knowledge, trust in providers, and satisfaction.

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

Patients scheduled for or admitted for induction of labor and who are able to speak, read, and write in the English language.

2.a Exclusion Criteria

Patients undergoing induction termination or with a history of prior cesarean section, major fetal anomaly, known chromosomal anomaly, or fetal growth restriction with doppler abnormalities. Patients whose induction has already commenced will also be excluded.

2.b Subject Recruitment Plans and Consent Process

This will be a single center trial conducted on the following Labor & Delivery unit:

- 1) Barnes Jewish Hospital (BJH)/Washington University in St Louis(WUMC) (PI Staples)

Patients scheduled for an IOL will receive a telephone call from research staff prior to their induction date for approach/consent. All other patients admitted for IOL will be

screened for eligibility criteria on the day of their admission and approached by trained research staff for informed consent. Patients are approached for enrollment and randomized at time of admission, prior to the administration of their first induction agent.

The study staff will review the informed consent with the patient in a private setting free of coercion and undue influence. The study staff are not directly involved in the patient's care. The patient will be made aware that their decision to enroll or decline will not impact her clinical care. If the patient agrees to be in the study: the study staff will obtain the patient's signature and current date on the consent form. The study staff will sign their own name on the consent form, and write the current date on the consent form. A copy of the signed consent form will be given to the patient. If the patient does not agree to be in the study: The study staff will end the discussion, and thank the patient for her time, the patient will not be screened or enrolled in the study, the study staff will emphasize that the patient's access to medical care and/or other services provided will not be affected by her decision whether or not to screen for or take part in the study. Furthermore, she will be notified that she has the right to withdraw from the study at any point.

2.c Randomization Method and Blinding

The patient's primary team of obstetric providers will be instructed to counsel the patient on induction methods as they do normally, either with or without a standardized visual aid. Eligibility criteria will be reviewed again prior to the initiation of the patient's induction. If the patient continues to meet inclusion criteria, the research team will proceed with randomization. Using a web-based randomization sequence on REDCap, patients will be randomized in 1:1 ratio to standard counseling or counseling with a visual aid immediately prior to initiation of their IOL.

Although providers and patients will not be blinded to intervention, the primary outcome of patient knowledge is an objective measure that will be collected by study staff and reported directly by patients.

2.d Interventions

Patients undergoing IOL and meet the study inclusion criteria will be randomized to:

1. Standard counseling: Patients randomized to this group will be counseled on IOL methods by a physician without the use of a visual aid.
2. Visual aid counseling: Patients randomized to this group will be counseled on IOL methods by a physician with the use of a standardized visual aid created based on patient feedback/qualitative interviews prior to the initiation of the RCT protocol.

2.e Risks and Benefits

The proposed study involves few risks to the subjects, including loss of confidential health information, and differences in healthcare outcomes, including knowledge, satisfaction, and trust in medical providers. The study is not designed to provide direct benefits to research participants. Nonetheless, if our hypothesis that a patient informed visual aid for IOL education increasing patient knowledge is correct, then subjects randomized to counseling with a visual aid will have the benefits of increased knowledge of the different induction of labor methods. On the contrary, if our hypothesis is disproven, the risks to the patient include decreased satisfaction and trust in their medical providers. More importantly, results from this study have the potential to improve

outcomes for women undergoing IOL. Because the anticipated risk to participants is minimal, the risks-benefit ratio is very favorable.

2.f Protection Against Risk

Pre-screening for eligibility criteria via medical record review will be conducted, and potential participants will be approached both prior to arrival and upon arrival to Labor and Delivery. None of the data obtained in pre-screening will be saved. The study design, expectations, and risks/benefits will be explained, and potential subjects will be given a written informed consent form by a study team member. Consent will be documented by using a signed consent form. Trained study team members will have sufficient time to explain the study and the informed consent carefully in a private room, and eligible patients may decide to enroll any time prior to their IOL as long as they still meet eligibility criteria.

Informed consent will always be obtained before a subject participates in any component of the protocol. For all participants, the consent form will be explained to participants as well as having them read the consent themselves. This consent will contain a detailed description of all study procedures, as well as any possible risks and/or benefits. Patients will be asked to sign the consent form. It will be clearly communicated to the patients during the consent process that their decision to participate will not affect their obstetric care. A copy of the consent forms will be kept in a locked cabinet in the research office and participants will be given a copy of the consent forms for their own records.

Clinical data will be entered into REDCap, a secure, web-based application. Access to the data username/password keys is restricted in accordance with our University's HIPAA policy. Data will be anonymized with study identifier only.

Adverse events will be monitored by a data and safety monitoring board (see separate section).

2.g Withdrawal of Subjects

Patients or their primary obstetric providers may choose to withdraw their patients at any point in the study. The study staff will be notified and all study interventions will be withdrawn appropriately (or randomization will be held if this decision is made prior to randomization). Patients will be notified of this process at the time of consent.

For patients that withdraw after randomization, clinical outcomes will be followed and recorded securely. For patients that withdraw before randomization, no clinical data will be followed or recorded.

E Safety and Adverse Events

1.a Safety and Compliance Monitoring

If subjects have any issues or concerns, or feel as though they were harmed in any way they will be instructed to contact the PI or a member of the research team. Contact information will be provided in the informed consent document.

Data and research monitoring will be undertaken annually by the study's PI and respective IRB offices at each site.

All adverse events will be reviewed by the PI, although, none are anticipated. There will be a data and safety monitoring board (DSMB) composed of three individuals with expertise in perinatology and clinical trials. The DSMB will meet once (either via teleconference or discussion through email) after 75% recruitment to review severe and non-severe adverse neonatal or maternal outcomes.

We anticipate one interim analysis when 75% of the sample size is recruited, but the exact timing will be at the discretion of the DSMB. Analyses will be performed by the study statistician and presented to the DSMB, which will make recommendations regarding further conduct of the trial. The Haybittle-Peto stopping rule will be used as a guide under which the interim analyses of the primary outcome (patient knowledge) would have to demonstrate an extreme difference between groups ($p < 0.001$) to prematurely stop the trial.

For confidentiality, only members of the research team will have access to the study information. Subjects will be assigned a unique study ID that will be used. This data base is in REDCap, which is a HIPAA-compliant, encrypted and password protected database. Any hard copies will be maintained in a locked cabinet in a locked office by a member of the study team. Work will only be done on secure campus computers.

The central command and coordinating center will be Washington University in St Louis. All data analysis will be performed at Washington University in St Louis. Each site PI and study staff will meet every other week at each site to review compliance and protocol adherence. Nursing staff are encouraged to communicate openly with the study team with concerns regarding the protocol. The study PI and the PI's faculty mentor will meet through video conference once a month with the data manager (Cassandra Hardy, RN) and statistician (Dr. Fan Zhang).

1.b Definitions of Adverse Events

Detailed information concerning reportable adverse events will be collected and evaluated throughout the conduct of the protocol (**Table 1 a and b**).

Table 1a: Adverse events (Less likely/less common)

Adverse Event	Definition
Acidemia	Umbilical cord arterial pH <7.10
Chorioamnionitis in the second stage of labor	Chorioamnionitis as diagnosed by the treating physician after complete dilation (after trial entry)
Severe postpartum hemorrhage	Estimated blood loss >1000ml for vaginal delivery and >2000ml for cesarean
Neonatal intensive care unit admission (NICU)	NICU admission > 12 hours for any reason prior to hospital discharge

Table 1b: Serious adverse events (These are all rare)

Serious adverse event	Definition
Maternal	

Maternal death	Any maternal death
Life-threatening maternal event	Life threatening events in the mother are defined as those that in the view of the research staff and PI put the individual patient at imminent substantial risk of dying, or if continued participation in the study might have resulted in death
Maternal admission to the intensive care unit	Maternal admission to the intensive care unit for any indication
Unplanned hysterectomy	Unplanned hysterectomy performed during cesarean or following a vaginal delivery
Neonatal	
Neonatal death	Neonatal death prior to discharge
Life-threatening neonatal event	Any life-threatening neonatal event, defined as those that in the view of the research staff and PI put the individual patient at imminent substantial risk of dying, within the first 24 hrs of life
Serious neonatal birth injury	Major neonatal injury including skull fracture, brachial plexus injury, cephalohematoma

The DSMB will review all serious adverse event reports and other interim safety data and will report back to the study PI and faculty mentor. The study PIs will report findings to the IRB.

F Study Outcome Measurements

Primary Outcome: Patient knowledge of IOL

Secondary Outcomes: Patient satisfaction, patient trust in providers

G Data Management

G1 Data Collection

We will collect data from electronic medical records on the patient's medical history, antepartum history, intrapartum course, and postpartum course. Relevant data will initially be collected to assess eligibility. Once the subject is randomized, further comprehensive data will be collected and stored in central REDCap.

G2 Data Management

The study statistician (Dr. Fan Zhang) and the central data manager (Cassandra Hardy, RN) at WUSM will be responsible for coordinating the overall data management. The PI and PI's faculty mentor will be responsible for day-to-day supervision of data management and protocol adherence. Data will be collected and managed with a central REDCap. The PI and PI's faculty mentor will meet through video conference once a month with the data manager and statistician to review progress on enrollment and any adverse events.

H Data Analysis

H1 Sample Size Determination and Power

Using the current standard of care for IOL counseling within pilot data analysis, the mean knowledge scores were 2.18 ± 0.79 (or 73 out of 100%). We estimate **84 patients**

(42 standard counseling and 42 visual aid) will be required to detect an increase in knowledge scores to 2.70 while accounting for 10% loss due to no survey data with 80% power, a two-tailed test, and 0.05 alpha.

H2 Analysis Plan and Statistical Methods

Baseline characteristics will be compared between groups using appropriate descriptive statistics. Univariate analyses will be used to compare baseline demographics between the control and intervention groups. The outcomes of knowledge, trust, and satisfaction scores will be compared using the Mann-Whitney U test or Student's t-test. We will utilize the intention-to-treat principle. We plan to conduct a stratified analysis with interaction testing to assess the effect of race (historically marginalized vs non-marginalized) on the relationship between the visual aid and knowledge, trust, and satisfaction scores. Although we may not be powered to detect differences between these sub-groups, this analysis will provide key pilot data for future interventions targeting marginalized communities.

If there is an imbalance in baseline characteristics, we will perform adjusted analyses to account for relevant covariates using multivariable logistic or linear regression.

I Study Timeline

	0-3 months	3-6 months	6-9 months	9-12 months	12-15 months
Protocol Development					
Trial registration					
Staff recruitment and training					
Study forms and database					
Subject recruitment/trial	X				
Data collection & management	X				
Protocol & IRB finalized	X				
Recruitment start	X				
50% recruitment		X			
100% recruitment		X			
Data analysis complete			X		

J References

1. Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *New England Journal of Medicine*. 2018;379(6):513–523. doi:<https://doi.org/10.1056/NEJMoa1800566>
2. Berger B, Schwarz C, Heusser P. Watchful waiting or induction of labour – a matter of informed choice: identification, analysis and critical appraisal of decision aids and patient information regarding care options for women with uncomplicated singleton late and post term pregnancies: a review. *BMC Complementary and Alternative Medicine*. 2015/05/07 2015;15(1):143. doi:<https://doi.org/10.1186/s12906-015-0663-y>
3. Cahill AG, Tuuli MG, Stout MJ, López JD, Macones GA. A prospective cohort study of fetal heart rate monitoring: deceleration area is predictive of fetal acidemia. *American Journal of Obstetrics and Gynecology*. 2018/05/01/ 2018;218(5):523.e1–523.e12. doi:<https://doi.org/10.1016/j.ajog.2018.01.026>

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4. Irani RA, Foster S. Overview of the mechanisms of induction of labor. *Seminars in Perinatology*. 2015/10/01/ 2015;39(6):426–429. doi:<https://doi.org/10.1053/j.semperi.2015.07.001>
 5. Hamm RF, Srinivas SK, Levine LD. Risk factors and racial disparities related to low maternal birth satisfaction with labor induction: a prospective, cohort study. *BMC Pregnancy and Childbirth*. 2019/12/30 2019;19(1):530. doi:<https://doi.org/10.1186/s12884-019-2658-z>
 6. Rahman S, Kripalani S, Keegan E, et al. An educational video's impact on the induction of labor experience: a randomized controlled trial. *American Journal of Obstetrics & Gynecology MFM*. 2022/01/01/ 2022;4(1):100495. doi:<https://doi.org/10.1016/j.ajogmf.2021.100495>
 7. Bailey JM, Crane P, Nugent CE. Childbirth Education and Birth Plans. *Obstetrics and Gynecology Clinics of North America*. 2008/09/01/ 2008;35(3):497–509. doi:<https://doi.org/10.1016/j.ogc.2008.04.005>
 8. Sperlich M, Gabriel C, St. Vil NM. Preference, knowledge and utilization of midwives, childbirth education classes and doulas among U.S. black and white women: implications for pregnancy and childbirth outcomes. *Social Work in Health Care*. 2019/11/26 2019;58(10):988–1001. doi:10.1080/00981389.2019.1686679
 9. Afshar Y, Wang ET, Mei J, Esakoff TF, Pisarska MD, Gregory KD. Childbirth Education Class and Birth Plans Are Associated with a Vaginal Delivery. *Birth*. 2017/03/01 2017;44(1):29–34. doi:<https://doi.org/10.1111/birt.12263>
 10. Meedya S, Fahy K, Yoxall J, Parratt J. Increasing breastfeeding rates to six months among nulliparous women: A quasi-experimental study. *Midwifery*. 2014/03/01/ 2014;30(3):e137–e144. doi:<https://doi.org/10.1016/j.midw.2013.12.010>
 11. Farrell EH, Whistance RN, Phillips K, et al. Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. *Patient Education and Counseling*. 2014/01/01/ 2014;94(1):20–32. doi:<https://doi.org/10.1016/j.pec.2013.08.019>
 12. Mbanda N, Dada S, Bastable K, Ingalill G-B, Ralf W S. A scoping review of the use of visual aids in health education materials for persons with low-literacy levels. *Patient Education and Counseling*. 2021/05/01/ 2021;104(5):998–1017. doi:<https://doi.org/10.1016/j.pec.2020.11.034>
 13. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*. 2017;(4)doi:<https://doi.org/10.1002/14651858.CD001431.pub5>
 14. Hirschey R, Bryant AL, Walker JS, Nolan TS. Systematic Review of Video Education in Underrepresented Minority Cancer Survivors. *Cancer Nursing*. 2020;43(4)