RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Title of Project: **The effects of antenatal and perinatal education of labor analgesia options on maternal anxiety, labor analgesia and maternal satisfaction**

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Funding Source(s): **NJMS Anesthesiology Department**

1. Purpose/Specific Aims

The specific aim of the study is to determine if education in the antenatal period and repeated upon arrival to Labor and Delivery regarding labor analgesia options is useful in reducing maternal anxiety and improving patient satisfaction.

1.1 Objectives

The study objectives are as follows:

1. To educate patients as to the various options available to them for labor analgesia.
2. To determine if the education material provided is helpful to patients in choosing a preference for a particular analgesia modality.
3. To determine if the education provided is helpful in reducing maternal anxiety.

1.2 Hypotheses

The hypothesis is that providing written material regarding labor analgesia options will improve maternal satisfaction and lessen anxiety in regard to labor.

2. Background and Significance

Background

Many analgesic options exist for laboring parturients, but labor may not be the best time to start informing patients of their options. Many patients begin the labor process with a plan in place for their analgesia. Unfortunately, internet resources regarding labor analgesia that are available to the lay parturient are poor and often lead to misconceptions about the options and their risks. A significant number of patients refuse neuraxial analgesia based on misunderstandings, concerns about the procedure, or a lack of faith in the provider. Some women want a "natural childbirth" and/or control over their labor experience. Forty-seven percent of minority women feel inadequately educated about anesthesia, are less likely to trust physicians, and are less likely to receive epidurals. However, greater than 10% of obese women changed their preference toward epidural analgesia following antenatal consultation. Also, 50% of patients planning for analgesia-free labor request neuraxial analgesia after experiencing labor pain.3

Additionally, the question exists as to the quality of informed consent from a patient undergoing contraction pain and possible sedation from analgesic medications. The

consensus is that parturients can provide informed consent. However, the process of informed consent for labor analgesia is not standardized; the options and risks presented to patients are dependent upon the individual practitioner obtaining the consent. Regarding epidurals, patients want to be informed of all risks and complications associated with the procedure.5, The patient's recall of the risks and benefits of the epidural procedure improved by 50% with written material in addition to verbal discussion, and recall improved by more than a factor of five when consent during labor was preceded by antenatal education. Parturients want a "pre-operative" visit with an anesthesiologist and have a strong desire for pre-labor education of anesthesia/analgesia options. Early antenatal education allows for unpressured time to teach, relieves anxiety, develops rapport, and provides opportunities for additional testing, if needed.3 Finally, the timing of epidural placement has not been shown to change outcomes, but when initiated late in the labor process, often other analgesia modalities were used that confounded the analysis of outcomes. Therefore, earlier request, which may come with prior knowledge and avoidance of misconceptions, and earlier placement of epidurals may lead to fewer analgesic interventions in the parturient and possibly less morbidity for the patient and fetus.

3. Research Design and Methods

This is a prospective study where written educational material will be dispensed to women when they visit the antenatal clinic during the course of their gestational visits. The material will again be provided upon admission to Labor and Delivery and a conversation will take place with the anesthesia care provider regarding the options for analgesia.

3.1. Duration of Study

The study will commence upon receipt of the written educational material in the subject's preferred language. The material will provide a second time upon arrival to the Labor and Delivery Suite and at that time a discussion will be held with the anesthesia care provider regarding the options and their risks and benefits for analgesia and anesthesia for labor and delivery (15-20 minutes). The study will end following delivery when the subject completes the survey on the post-partum unit on F Green. The survey is expected to take 10-15 minutes.

3.2 Study Sites

Components of the study will be done in 3 different locations: The study will be conducted at the antenatal clinic area, Labor and Delivery Suite UH F Orange and the UH Post-partum Unit F Green.

3.3 Sample Size Justification

We aim for the completion of 100 surveys which will believe will provide us with information to establish as to whether or not this written literature is an effective method in reducing anxiety and improving patient satisfaction.

3.4 Subject Selection and Enrollment Considerations

All comers to the antenatal clinic and labor and delivery unit will receive the same educational information. Those women who are not English or Spanish speaking will not be provided with the written educational material and information letter.

3.5.1 Inclusion Criteria

1. Postpartum women ages 18 and older
2. Patients who speak and read English or Spanish
3. Patients who received our informational pamphlet while pregnant or in labor
4. Patients who are able to consent and make medical decisions
5. Patients undergoing labor or trial of labor after cesarean delivery
6. Patients who undergo cesarean delivery after trial of labor

3.5.2 Exclusion Criteria

1. Patients unable or unwilling to complete questionnaire
2. Patients unable to consent or make medical decisions
3. Patients less than 18 years of age
4. Patients unable to read and speak English or Spanish
5. Patients in whom any of the analgesic options were contraindicated
6. Patients with a history of an anxiety disorder
7. Patients with precipitous labor or late presentation that precluded an analgesic intervention
8. Patients with fetal distress that precluded an analgesic intervention
9. Patients planned for elective cesarean section.

3.5.3 Subject Recruitment

Education materials will be left in both languages in the waiting area of the obstetrical clinic. They will be placed in an area where they are clearly visible for the potential subjects. A member of the anesthesia faculty visits the clinic several times per month but it is not likely he will see each and every patient coming to the clinic.

3.5.4 Consent Procedures

The consent letter will be presented to each patient while in the post-partum unit. The nature of the study will be explained to the patient and they will be given sufficient time to read the letter and pose any questions they may have. The subject will be asked if they are agreeable to completing the survey. A written consent from the subject will not be obtained.

3.5.5 Subject Costs and Compensation

There are no costs or compensation associated with participation in the study.

3.6 *Chart Review Selection*

Not applicable

4. Study Variables

4.1 Independent Variables or Interventions

Not applicable

4.1.1 Drug or Device Interventions
Not applicable

4.2 Dependent Variables or Outcome Measures
Study instruments are as follows:
Labor Pain Control Pamphlet –English and Spanish
We will provide information of available labor analgesia options (epidural, combined spinal/epidural, spinal, remifentanil patient-controlled analgesia, and intravenous opioids) to expecting mothers. Using a pamphlet written in English or Spanish disseminated to pregnant women in clinic or in the labor and delivery unit, the procedures and their risks and benefits will be explained in simple terms.
Questionnaire- English and Spanish
After delivery, patients will be asked to complete a questionnaire addressing their thoughts about the pamphlets and their overall satisfaction with their labor analgesia. Our analysis will focus on the utility and effect of education materials on maternal informed consent for labor analgesia, on maternal choice of analgesia modality, and on maternal anxiety regarding their labor analgesia plan.

4.3 Risk of Harm
The investigators are not aware of any risk to subjects participating in this study.

4.4 Potential for Benefit
The potential benefit maybe that the subject is less anxious about the labor and delivery experience. The information gleaned from this data will be helpful to the investigators in regard to determining the needs of the patient population that is served.

5. Data Handling and Statistical Analysis
The paper survey will be inputted to an excel spread sheet in a password protected computer. This computer is located in the research office in the anesthesiology department. This data will only be accessible to members of the study team. The survey is anonymous. No link to the personal health identifiers and data will be kept. The data will be kept for 6 years. Data will be presented as mean, standard deviation and percentage. Demographic data will be analyzed using student t test and Chi-Sq as appropriate.

6. Data and Safety Monitoring
Not applicable

7. Reporting Results

7.1 Individual Results
Not applicable
7.2 Aggregate Results
Not applicable

7.3 Professional Reporting

Study results will be shared at National Anesthesiology meetings such as American Society of Anesthesiology or the Society of Obstetrical Anesthesia and Perinatology.

8. Bibliography

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