

Summer Student Research Program

Project Description

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PROJECT TITLE (200 Characters max):

A Prospective, Single Center Study of the Sedative Effects of Morphine and/or Phenergan on Parturients in the Recall of Labor Epidural Risks

HYPOTHESIS: Does the administration of pain relieving drugs effect the recall of epidural risks in actively laboring women?

PROJECT DESCRIPTION (Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)

Numerous studies have examined the effect of pain and anxiety on the informed consent process for epidurals in actively laboring women. Discussion for epidurals often occur after labor has already begun when the patients are experiencing intense contractions, sleep deprivation, emotional upheaval from pregnancy, and sometimes after the administration of pain medications that may cause sedation. Because of the extreme circumstances in which parturients are explained the risks and benefits of the epidural procedure, it has been speculated that these women are not in a position to be able to validly give informed consent.

Women, who are counseled on epidurals prior to labor, such as in antenatal epidural education classes, often have better recall and understanding of the complications. Not surprisingly, investigations, though limited, have shown a wide range of results measuring patient recall from poor to a high degree.^{1, 3, 6} Nonetheless, it seems that parturients are no less mentally capable of providing informed consent, regardless of their state of angst. Patients consistently indicate a moderate level of "understanding" of the epidural risks following discussion.³⁻⁴ Jackson, et al. demonstrated no correlation between the expected variables of labor pain, anxiety, duration of labor, previous epidural experience, opioid premedication, age, level of education, or desire for an epidural on patients' perception of understanding.² However, this study and others were limited in that they did not assess the patient's impairment after opioid premedication.¹⁻² The purpose of this study is to specifically determine the potentially sedative effects of premedication with morphine and/or phenergan on the recall of epidural risks in actively laboring women.

Trial Objectives

The objectives of the trial are to determine whether sedation from morphine and/or phenergan affect the informed consent process in laboring women. The risks for a labor epidural as outlined in the informed consent process will be used to measure the patient's level of recall of the discussion.

Trial Design

Actively laboring women who are admitted to the Labor and Delivery Suite at University Hospital and who request an epidural will be consented from a pre-written, standardized script which will include the risks and benefits of the procedure. These women may or may not have received premedication with morphine and phenergan. The administration of these medications

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is at the discretion of the obstetricians who are independent of the study team. In addition, the number of hours in labor, the patient's pain score using Visual Analogue Score (VAS) scale, and the time and amount of medication dose will be obtained at this time. A separate party, i.e. the assigned obstetric nurse, will assess the patient's level of sedation using the Ramsay Sedation Scale (RSS). Within 24 hours following labor, a third party who is blinded to the patient's status of premedication will conduct an interview and administer a questionnaire to obtain demographic information and the recall of the epidural risks. The survey will first ask the patient to spontaneously verbalize their recall of risks and then identify from a list of true and false risks. Subjects who deliver via caesarean section will not be interviewed post partum as those subjects maybe receiving analgesic medication that may in fact alter their ability to recall the events of the previous day. Data will be collected from 200 women.

Risks/Benefits

Since patients are not actively recruited to obtain an epidural, there is no additional risk imposed on subjects. Patients who are approached for the study will have already requested an epidural of their own accord. The discussion of informed consent is currently a routine part of the existing practice at University Hospital but patients will additionally be presented with a comprehensive explanation of the epidural procedure as well the risks and benefits. There are no immediate benefits to participation.

Alternatives

The alternative to study participation is that the patient will obtain the epidural and will not be surveyed within 24 hours of delivery.

Selection and Withdrawal of Subjects

Inclusion Criteria:

1. Actively laboring women admitted to L&D at University Hospital
2. English-speaking

Exclusion Criteria:

1. Non-english speaking due to the diversity of the patient population and limitations of the caregivers providing the consent discussion
2. Minors
3. Those individuals who deliver via caesarean section.

Subject withdrawal

Patients may withdraw participation from the study at any time. This will in no way delay the administration of the epidural. Patients who withdraw after labor will not have their interview or questionnaire data included in the results.

Quality Control and Quality Assurance

Each patient will be assigned a number at the time of the epidural request. The physician giving the consent will also obtain preliminary information including the patient's name, pain score, number of hours in labor, and the time and amount of premedication if applicable. This information will be entered into a ledger "A". In a separate ledger "B", only the patient's name and assigned number will be inputted. The third party interviewer will then use this ledger "B" as the list of subjects to be surveyed and remain blinded to the patient's data. The patients will also be instructed not to tell the third party whether or not they received premedication. At the

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conclusion of the study, the data will then be combined from both ledgers and the patients' identifiers can be omitted while only using the corresponding subject numbers.

References

1. Affleck. PJ, et al: Recall of Risks following Labor Epidural Analgesia. J Clin Anesth. 1998 Mar;10(2):141-4.
2. Jackson, A., et al. Informed consent for labour epidurals: what labouring women want to know. Can J Anesth 2000 Nov; 47 (11):1068-73.
3. Gerancher, J.C., et al. An evaluation of informed consent prior to epidural analgesia for labor and delivery. International Journal of Obstetric Anesthesia. 2000; 9: 169-173.
4. Patee, C., et al. Epidural analgesia for labor and delivery: Informed consent issues. Can J Anesth 1997 Sep; 44 (9):918-23.
5. Smedstad, K.G. and William Beilby. Informed consent for epidural analgesia in labour. Can J Anesth. 2000; 47, 11: 1055-1059.
6. Swan HID, Borshoff DC: Informed consent – recall of risk information following epidural analgesia in labor. Anesth Intens Care 1994; 22: 139 – 141.

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:
None

IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS?

Yes or No

(IF YES, PLEASE SUPPLY THE GRANTING AGENCY'S NAME)

THIS PROJECT IS: Clinical Laboratory Behavioral Other

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS

PENDING APPROVED IRB PROTOCOL # M0120080349

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS ENTERING FRESHMAN
SOPHOMORES ALL STUDENTS

THIS PROJECT IS WORK-STUDY: Yes or No

THIS PROJECT WILL BE POSTED DURING ACADEMIC YEAR FOR INTERESTED VOLUNTEERS?: Yes or No

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

The student will benefit from their participation in a structured research study. They will be exposed to Good Clinical Practice (GCP) which ensures the rights and safety of clinical trial subjects and the integrity of clinical data obtained during the conduct of a clinical trial. The student will have the opportunity to have a comprehensive review of the protocol, participate in a subject-investigator interactions, ongoing and risk appropriate safety monitoring throughout the conduct of the study and assist in data collection, analysis and reporting.