Evaluation of the use of leg elevation on a peanut ball to prevent hypotension following epidural anesthesia in laboring women

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RESEARCH PROTOCOL

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Title	Evaluation of the use of leg elevation on a peanut ball to prevent hypotension following epidural anesthesia in laboring women
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Purpose of Study

Women who receive epidural analgesic during labor often experience hypotension, typically within the first 30 minutes after epidural placement. This maternal low blood pressure can impact blood flow to the infant which is seen through decreases in the infant's heart rate. The current study aims to evaluate whether elevating patients' legs on a peanut ball for the first 40 minutes after epidural placement will decrease the incidence of maternal hypotension and fetal heart rate decelerations.

Hypothesis or Research Question

- Hypothesis 1: Laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of requiring intervention for low blood pressure compared to laboring women who receive epidural analgesia and do not elevate their legs.
- Hypothesis 2: Laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of hypotension compared to laboring women who receive epidural analgesia and do not elevate their legs.

  *hypotension is defined as SBP < 90 mmHg or an SBP decreases more than 20% from baseline

- Hypothesis 3: Infants of laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of late or prolonged decelerations compared to laboring women who receive epidural analgesia and do not elevate their legs.

Background

Aortocaval compression (ACC) by the gravid uterus is a known physiological phenomenon that is claimed to cause supine hypotension in full term pregnant patients. ACC has been noted as a possible cause of post-spinal hypotension (PSH). Hypotension is defined as a systolic blood pressure of less than 90mmHg or a diastolic blood pressure of less than 60mmHg. The left tilt is the usual solution to remedy the hypotension for laboring women. Maternal physiologic changes such as increased blood volume has an impact on the circulation system: low maternal blood pressure can result in decreased perfusion of the placenta. This negatively impacts maternal blood flow to the fetus which is noted on the fetal monitor as a Category II or III fetal heart tracing. While hypotension may not cause problems in some women, the fetus in utero is accustomed to and dependent on a certain blood pressure threshold.

A peanut labor ball (PB) is a non-latex, plastic, air-filled yoga ball that is shaped like a peanut. It is used during labor for maternal pain relief and maternal position changes. The goal of using the PB is to shorten the duration of labor by keeping open the laboring woman's pelvic floor and to decrease the incidence of cesarean sections or medical -assisted vaginal deliveries, by the sue of forceps and vacuums, among women who receive epidural anesthesia.

The purpose of this study is to examine the effectiveness of elevating a woman's legs on a PB in preventing hypotension among a sample of laboring women who receive an epidural analgesia.

Research Plan

- **Study Design**
  This study will use a randomized, non-blinded, controlled design with two arms:
    - Arm 1 (Intervention): Immediately after epidural placement, patient will be placed in a left tilt position with her hip on a wedge and both of her legs elevated on an orange peanut ball. She will remain in this position for approximately 40 minutes.
    - Arm 2 (Control/Standard Care): Immediately after epidural placement, patient will be placed in a left tilt position with her hip on a wedge. She will remain in this position for approximately 40 minutes.
- **Setting for the study**
  The study will take place on Good Samaritan Hospital's Labor and Delivery Unit. This unit consists of 20 labor rooms and provides care to approximately 11 laboring women each day.
- **Participants**
  The study will enroll 300 women who meet the following inclusion/exclusion criteria:

Inclusion Criteria:

- Laboring at Good Samaritan Hospital Labor & Delivery Unit
- 37+ weeks gestation
- Planned vaginal delivery
- Planned epidural analgesia

Exclusion Criteria:

- Under 18 years old
- Does not speak English
- Unable to consent to involvement in the research study
- Attended less than 3 prenatal care office visits
- Diagnosed with fetal demise
- Diagnosed with fetal anomalies
- Contraindications to both legs being elevated (ex: fractured bones, lower limb amputation, etc.)
- Contraindications to receiving 1L of IV fluids
- Requiring IV hypertensive medications
- Requiring IV magnesium

Sample Size Determination: A power analysis was conducted using a dichotomous outcome variable, requiring intervention for low blood pressure, with an expected difference [(33% incidence rate (Auroy et al., 1997), clinical significance would be a decrease to 15%)] (0.2), power of 0.8, and level of significance 0.05. It was determined that 120 patients would be needed in each group, for a total sample size of 240 patients. To allow us to also examine the impact on occurrence of infant decelerations and to allow for the possibility of removing participants from the final analysis due to missing data, we plan to enroll 300 patients (150 in each group).

- **Data Collection**
  Before the study begins, information about the study will be provided to the nurses on the L&D unit including education about the study purpose, inclusion/exclusion criteria, and procedures.

  When a patient who meets the inclusion/exclusion criteria is admitted, a nurse will describe the study, answer any questions the patient has, and if the patient wants to enroll in the study, the study team nurse will review the information consent form. After the patient provides written informed consent, the nurse will remove the next envelope out of a box of prefilled and sealed opaque envelopes. The envelope will provide the Subject ID number to be used on all study-related documentation and the study Arm that the patient has been randomized to, either:

1. Leg Elevation Group
2. Standard Care Group

These envelopes will be filled using a computerized simple random number generator (1:1 randomization) prior to the start of the study.

In addition to the group assignment, the envelope will include a data collection form. Data will be recorded directly on this form during the patient's visit. The form will collect the following information:

- Whether patient was assigned to the leg elevation group or the standard care group
- Patient age
- Pregnancy history
- Height
- Weight
- Whether pregnancy is a singleton or multiple pregnancy
- Blood pressure documented at last prenatal office visit
- Threshold systolic blood pressure (20% decrease from office visit blood pressure) – The study team nurse will calculate threshold systolic blood pressure by calculating the systolic blood pressure from most recent office visit multiplied by 0.8
- Time of epidural placement
- Time legs elevated on peanut ball (Intervention group only)
- Time legs removed from peanut ball (Intervention group only)
- Did the infant have any late or prolonged decelerations within the 1 hour after epidural placement? Yes/No
- Did the RN have to perform any interventions to address prolonged or late decelerations during the 1 hour after epidural placement? Yes/No
- Did the anesthesia provider treat the maternal blood pressure during the 1 hour after epidural placement? Yes/No

RN will complete the data collection form and place the signed informed consent form and data collection form in a locked room designated for study materials.

On the data collection forms, RNs are instructed to call a member of the study team immediately if there are any safety concerns related to the leg elevation. If the study team receives a call about a safety concern, recruitment and enrollment of new participants will stop until the study team meets and reviews the incident and determines it is safe to continue. Any adverse events and serious adverse events will be reported to the IRB in compliance with IRB safety policies.

- **Intervention or experimental aspect of the study**
  After epidural placement, nurse will verify that patient received 1L of IV fluid and had Category I fetal heart tracing in the one hour prior to epidural placement. If

either of these aren't met, patient will be removed from study and no further procedures will take place.

If patient received 1L of IV fluid and had Category I fetal heart tracing in previous 1 hour, patients randomized to Arm 1 will be placed in a left tilt position with a hip wedge. Next both legs will be elevated on an orange peanut ball. the epidural placement. Their legs will be lowered approximately 40 minutes after after epidural placement. Peanut ball use during labor is a standard practice on this unit. The intervention will involve using the peanut ball for leg elevation

Patients randomized to Arm 2 will receive standard care. After epidural placement, they will be placed in a left tilt position with a hip wedge. Patient will remain in this position for 40 minutes after epidural placement.

After the 40 minutes of positioning or leg elevation, the next blood pressure obtained will be documented on the data collection form and then the study procedures are completed.

- **Statistical Analysis**
  Data recorded on paper data collection forms will be entered into a password protected database. Only study team members will have access to the database. No personal information will be entered into the electronic database. Data will undergo range checks when entered into the database, and quality control procedures will be performed to ensure accuracy of the data in the electronic database.

  Statistical analyses will be performed using Intellectus Statistics statistical software. The following analyses will be performed to address each hypothesis:

  Hypothesis 1: Laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of requiring intervention for low blood pressure compared to laboring women who receive epidural analgesia and do not elevate their legs.

  To compare the effects of leg elevation, a Chi Square test will be used to compare occurrence of receiving intervention for low blood pressure for patients who elevated their legs to patients who did not elevate their legs. A level of significance of $\alpha=0.05$ will be used.

  Hypothesis 2: Laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of hypotension compared to laboring women who receive epidural analgesia and do not elevate their legs.

  To compare the effects of leg elevation, a Chi Square test will be used to compare occurrence of maternal hypotension for patients who elevated their legs to

patients who did not elevate their legs. A level of significance of α=0.05 will be used.

Hypothesis 3: Infants of laboring women who receive epidural analgesia and elevate their legs on a peanut ball will experience a lower incidence of late or prolonged decelerations compared to laboring women who receive epidural analgesia and do not elevate their legs.

To compare the effects of leg elevation, a Chi Square test will be used to compare occurrence of late or prolonged infant decelerations for patients who elevated their legs to patients who did not elevate their legs. A level of significance of α=0.05 will be used.

Interim data analysis will occur (1) once approximately 1/3 of the participants have been enrolled and (2) once approximately 2/3 of the participants have been enrolled. If interim calculations at time (1) or time (2) note a significant difference between groups in maternal hypotension or frequency of late or prolonged fetal decelerations, data collection will be completed at that time and final analysis will be completed.

Ethical Considerations

- **Informed consent**
  All study staff will complete CITI training. A study staff member will meet with potentially eligible patients and describe the study and answer any questions. If the patient is interested and meets all the inclusion/exclusion criteria, the study staff will review the *Informed Consent Form* and obtain written informed consent. Patients will receive a copy of their signed Informed Consent form.

  Informed Consent forms will be stored in a locked room that only staff will have access to. After the study closes, the signed Informed Consent forms will be boxed and sent to off-site storage and securely stored until the infant turns 21 years of age. At that time, the hard copy forms will be shredded.

- **Privacy information**
  Personal identifiers will not be entered into the electronic database. Hard copy data collection forms and Informed Consent forms will be stored in a locked room that only staff will have access to. Electronic data will be stored on a password-protected folder on the U drive. Only study staff will have access to the electronic study documents. After data analysis and dissemination is completed, hard copy forms will be boxed and sent to off-site storage and securely stored until the infant turns 21 years of age. At that time, the hard copy forms will be shredded.

Results

A randomized controlled trial was conducted with patients enrolled between October 29, 2022 and May 29, 2025. Patients were enrolled if they were at least 37 weeks gestation, laboring at Good Samaritan Hospital labor and delivery unit, planned to have epidural analgesia, and planned to have a vaginal delivery. They were excluded if they were under 18 years old, did not speak English, were unable to provide informed consent, attended less than 3 prenatal care office visits, were diagnosed with fetal demise, were diagnosed with fetal anomalies, had contraindications to both legs being elevated, had contraindications to receiving 1L of IV fluids, required IV hypertensive medications, or required IV magnesium.

A total of 104 patients were consented. Patients were randomized using a simple random number generator (1:1 randomization) into one of two study arms:

- Arm 1: Leg Elevation group (n=58)
- Arm 2: Standard Care group (n=44)
- 2 changed mind before randomization

Several patients in each arm were removed from the study before completion, resulting in **92 patients** who completed study:

- Arm 1: Leg Elevation group (n=58 consented - 4 removed = 54 completed study)
    - Delivered before epidural placed (1)
    - Had Category II tracings after consent signed and before epidural placed (2)
    - Breech and had c-section (1)
- Arm 2: Standard Care group (n=44 consented - 6 removed = 38 completed study)
    - Emergency c-section before epidural placement (1)
    - Had Category II tracings after consent signed and before epidural placed (3)
    - Didn't have 1L fluid bolus administered (2)

Demographics:

	Leg Elevation Group n=54	Standard Care Group n=38	Comparison of Groups N=92
Age, years Mean (SD)	30.4 (4.4)	29.9 (4.2)	30.2 (4.3) No difference, t=0.55, p=0.291
Height Mean (SD)	65.1 (2.3)	65.6 (3.0)	65.3 (2.6) No difference, t=0.82, p=0.206
Weight Mean (SD)	198.2 (37.4)	195.6 (35.1)	197.1 (36.3) No difference, t=0.34, p=0.368

There's no significant difference between the two groups on age, height, weight, singleton or multiples, or number of previous pregnancies, number of previous births, number of living children, or number of previous abortions.

Hypothesis 1:

There is a significantly lower frequency of requiring RN or MD intervention for hypotension or late decelerations among patients in the intervention group (11%) compared to patients in the control group (29%), $X2 = 4.71$, $p=0.03$.

Hypothesis 2:

There is no significant difference in frequency of low blood pressure among patients in the intervention group (13%) compared to patients in the control group (21%), $X2 = 1.07$, $p=0.30$.

Hypothesis 3:

There is no significant difference in frequency of late decelerations among patients in the intervention group (19%) compared to patients in the control group (32%), $X2 = 2.09$, $p=0.15$.