

Title: Do Peanut-Shaped Birthing Balls Reduce the Length of Labor in Patients with Epidural Analgesia?

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Background:

In the United States approximately 2/3 of laboring women receive epidural or combined spinal-epidural (CSE) analgesia.¹ A 1998 meta-analysis found that although epidural analgesia increases the length of labor by 56 min, it does not increase the incidence of cesarean delivery or forceps delivery for dystocia.² Additionally, maternal satisfaction is significantly increased in patients with epidural analgesia. For a number of reasons unrelated to epidural analgesia, the incidence of cesarean delivery has increased during the past 20 years, and in 2013, 32.7% of women in the United States had a cesarean delivery.³ Because more than 90% of women that have a cesarean delivery have a repeat cesarean for subsequent deliveries and cesarean delivery is associated with more serious complications than vaginal delivery, there are national initiatives to reduce cesarean delivery rates.⁴ In a recently published study conducted by nurses and doulas in an Arizona hospital, the use of peanut-shaped birthing balls (see Appendix, figure 1) in patients with epidural labor analgesia significantly reduced the length of labor and the incidence of cesarean delivery.⁶ Following epidural insertion and informed consent, patients were randomized to labor using a peanut ball or labor without using a peanut ball until complete cervical dilatation. The length of labor was reduced by 113 min (Stage 1 labor by 90min and Stage 2 labor by 23min) and the incidence of cesarean delivery was reduced by 57% (from 23.7 to 10.3%). No patient in either group experience complications. It is theorized that the birthing balls enhance labor by increasing the pelvic diameter, thus allowing for more rapid descent of the fetal head.

These results are incredibly significant for a single simple intervention and, if replicated, may have large scale public health implications. The purpose of the current study is to determine if a low-cost, safe, and easy to use physical prop actually improves labor outcomes. Thus, the hypothesis of this randomized prospective study is that use of peanut-shaped birthing balls following epidural administration will significantly reduce the length of labor and the incidence of operative delivery.

Method: After informed consent, up to 240 nulliparous parturients planning to request epidural analgesia for their labor pain will be enrolled in the study. Following CSE analgesia (patients will be standardized to the CSE technique because it has been suggested that CSE analgesia speeds the rate of cervical dilatation when compared to epidural analgesia⁷), patients will be randomized to either have a 45cm peanut-shaped birthing ball placed between the knees for the duration of stage 1 labor (until complete cervical dilation) or to labor as is customary without an object placed between the knees. To determine the impact of the birthing balls on the labor curve, patients will have a cervical exam within 15min of epidural placement and every four hours (or when clinically indicated) until complete cervical dilation. In addition, all patients will have a Bishop's score (used to assess the odds of successful vaginal birth) estimated by the obstetric team.⁸ Patients will be positioned

during labor in the lateral or semi-Fowler positions (see Appendix, figure 2) and asked to turn sides every hour. The length of labor from epidural insertion to delivery (the primary outcome) and the mode of delivery (secondary outcome) as well as usual variables such as the frequency and incidence of needing epidural top-ups, pain intensity, vital signs, fetal heart rate tracing, and patient satisfaction will be obtained throughout the course of labor and delivery. Following delivery, neonatal weight and Apgar scores will be recorded and all patients will be evaluated the day after delivery for satisfaction and any complications such as back or hip discomfort. Exclusion criteria: age<18, non-English speaking, multiparous women, patients with preeclampsia with documented abnormal liver enzyme function changes, contraindications to receiving neuraxial analgesia or any drugs used in this study.

Statistics and Analysis:

The primary outcome is the length of labor from epidural catheter insertion until delivery. Secondary outcomes include mode of delivery, maternal satisfaction and post-delivery complications. A power analysis was determined using historical data from epidural analgesia studies at FMC, recent FMC length of labor statistics, and estimations on length of labor reductions from the Banner Health report. To detect a 13% change in length of labor between groups with an estimated standard deviation of 46% from average length of labor (historical FMC mean \pm SD from epidural insertion to delivery is 325 \pm 150min), a minimum sample size of 101 per group is needed to provide a power of 0.8 and alpha of 0.05. We will enroll up to a total of 240 subjects (120 per group for 2 groups) in anticipation of potential exclusions. The study will conclude when 202 evaluable patients have completed the study.

Implications:

If peanut-shaped birthing balls improve labor outcomes without complications, practice protocols will be revised to include the routine use of them during labor in the Women's Center and possibly throughout all Novant birthing facilities. Further, publication of the results from this study will potentially affect public health policies.

Risks:

Epidural and CSE analgesia are commonly used (85%) in laboring patients at FMC (approximately 50-50 ratio). All of the usual risks for CSE labor analgesia apply including: inadequate anesthesia/analgesia, post dural puncture headache, backache, pruritus, nausea/vomiting, hypotension, as well as other very rare risks of respiratory depression, nerve injury, hematoma, infection and seizures. Although the Banner Health reports suggests that no patient experienced complications, we theorize that there is a small risk that use of the peanut-shaped birthing balls may increase the incidence of hip, pelvis or back discomfort following delivery. Patients will receive informed consent and will be treated as usual for any complications throughout labor and following delivery. All patients will be administered routine CSE medications throughout labor.

Benefits:

The results of this study may provide us a better understanding of the role of pelvic widening on labor outcomes.

Human Subjects Protection:

Written informed consent will be obtained from each subject. Study team members or the research nurse will obtain informed consent from patients in labor and delivery suite after determining their fulfillment for eligibility criteria in participation. The study and informed consent will be reviewed with the patients while they are in the labor and delivery suite. Once signed, a copy of the informed consent form will be placed in the patient's medical record and a copy will be given to the patient for their records.

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. The master study enrollment log containing the names, group allocation, and date of study will be kept secure in the department of OB Anesthesia, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed at the earliest opportunity, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any identifiable individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring:

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff. A data safety monitoring committee made up of 1 obstetrician and 1 obstetric anesthesiologist will be utilized and un-blinded to group allocation. They will review the interim results including review of vital signs, analgesic effects and the occurrence of any adverse events/side effects.

Reporting of Unanticipated Problems or Serious Adverse Events:

Any unanticipated problems, serious and unexpected adverse events protocol changes will be promptly reported by the principal investigator or designated member of the research team to the Institutional Review Board (IRB).

References:

1. Bucklin BA, et al. Obstetric anesthesia workforce survey: twenty-year update. *Anesthesiology* 2005; 103: 645-53.
2. Halpern SH, et al. Effects of epidural vs. parenteral opioid analgesia on the progress of labor: a meta-analysis. *JAMA* 1998; 280: 2105-10.
3. Martin JA, et al. Births: Final Report 2013. National Vital Statistics Report, 2015; Vol 64: Number 1. Also accessed at: <http://www.cdc.gov/nchs/fastats/delivery.htm>.
4. Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No 1. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014; 123: 693-711.
5. Isokinetics, Inc. www.isokineticsinc.com.
6. Tussey CM, et al. Reducing length of labor and cesarean surgery rate using a peanut ball for women laboring with an epidural. *Jr Perinatal Education* 2015, 24: 16-24.
7. Tsen LC, et al. Is combined spinal-epidural analgesia associated with more rapid cervical dilation in nulliparous patients when compared with conventional epidural analgesia? *Anesthesiology* 1999; 91: 920-5.
8. Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol* 1964; 24: 266-8.

Appendix:

Figure 1. Peanut-shaped birthing ball.



Figure 2. Lateral and Semi-Fowler Positioning During Labor.

