# Maternal and Fetal Outcomes and Early Neuraxial Engagement in Obese Parturients

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## Abstract

Obesity has created challenges for healthcare consumers, providers, and healthcare institutions. The combination of obesity and pregnancy is correlated with increased morbidity, mortality, and healthcare costs. The clinical inquiry is, Does early neuraxial placement in obese parturients affect maternal and fetal outcomes? Review of 23 studies indicates a higher incidence of hypertension, preeclampsia, shoulder dystocia, hemorrhage, caesarean delivery, and failed intubations in the obese parturient. A retrospective analysis of 212 obese parturients with neuraxial analgesia, based on cervical dilation, evaluated the impact of early neuraxial placement. Comparison of early, late, and no neuraxial analgesia was conducted on the outcome variables of type of delivery (vaginal or caesarean), anesthetic (combined spinal-epidural, epidural, or general), pain scores, Apgar scores, and newborn umbilical artery pH. Additional adverse outcome variables were analyzed and included difficult CSE placement, shoulder dystocia, hemorrhage, fetal intolerance to labor, and NICU admissions. The results indicated decreased failure rate for epidurals (0.876%), lower numerical pain scores, and reduction in general anesthesia (0.9%), higher incidence of fetal intolerance (6.7%, p=0.012), and caesarean delivery in the early neuraxial group. Higher incidence of hemorrhage, (15%), shoulder dystocia (12%), and NICU admissions (8%, p= 0.014) were correlated with the no anesthetic group. Development of neuraxial guidelines and algorithms related to obese parturients could improve maternal and fetal outcomes, patient satisfaction, and reduce healthcare expenditures in the United States.


Keywords: obesity, parturient, pregnancy, epidural, neuraxial, anesthesia

The prevalence of obesity approaches 35% in adults and 17% in youths with an annual increase of 0.6% since 2005 (Johnson, Hayes, Brown, Hoo, Ethier, Centers for Disease Control & Prevention [CDC], 2014). The combination of pregnancy and obesity creates significant hemodynamic instability that predispose the expectant mother to adverse complications, and obesity is a contributing factor in 50% of obstetric deaths in the United States (Tan & Sia, 2011). The risk of dysfunctional labor resulting in instrumentation or caesarean delivery, postpartum hemorrhage, and morbidity and mortality is greater in the obese parturient (Tan & Sia, 2011. Evidence-based practice initiatives to enhance patient safety, satisfaction, and improve outcomes is essential in the current healthcare environment.

**Significance with Economics, Policy, and Health Systems**

The prevalence of obesity is 40% to 50% for women of childbearing age in the United States (McKinney, 2014). The number of 2013 live births in the United States was 3,957577 and the infant mortality rate for Missouri is 6.63% deaths per 1000 live births (Hamilton, Martin, Osterman, & Curtin, 2014). The healthcare cost for an obese parturient is five times greater than the parturient with a body mass index of 30kg/$m^2$ or less (Shah & Lattoo, 2008). Healthcare costs have created financial issues for healthcare consumers and providers. The comorbidities associated with obese parturients include hypertension, diabetes, pre-eclampsia, pulmonary issues, caesarean delivery, difficult neuraxial anesthesia placement, inadequate epidural analgesia, and airway issues (McKinney, 2014). The prevalence rates for caesarean delivery in obese parturients ranges from 19% to 40% (McKinney, 2014).

The World Health Organization classifies obesity as a body mass index (BMI) of 30.0-34.99 kg/ $m^2$ Class I, BMI= 35.0- 39.9 kg/ $m^2$ Class II, and BMI greater than 40 kg/$m^2$ Class III (McKinney, 2014). Studies have indicated a correlation between escalating BMI, morbidity, and

mortality (McKinney, 2014). Epidural analgesia is the preferred method of analgesia for the obese parturient (McKinney, 2014). Currently, no practice guidelines exist regarding obese parturients. Developing anesthesia practice guidelines and algorithms for obese parturients could decrease the risks associated with caesarean delivery, general anesthesia, loss of airway, and potential death.

**Local Issue**

The intervention site is an urban Missouri healthcare facility that provides healthcare for high risk obstetric parturients. The facility is located in a city with a population of 162,642 residents, 47% between 18-44 years of age, and a 26% obesity rate (Rainey, 2013). The university affiliated healthcare setting provided an opportunity to analyze an evidence based intervention. The university mission statement correlates with the Institute of Medicine`s (2011) recommendations for healthcare facilities to provide beneficial, patient centered care that is supported by evidence-based practice research.

**Diversity Considerations**

Cultural and ethnic factors influence the parturient`s decision to utilize an epidural analgesia during the labor and delivery process (Harkins, Carralho, Evers, Mehta, & Riley, 2010). Based on geographical locations in the United States, the rate at which women receive epidurals for labor ranges from 64% to 80% (Harkins et al., 2010). The setting population is diverse based on Rainey`s (2013) health assessment: 82,5% white, 8,9% Black, 8,6% other races, 3 % Hispanic, 6.1% foreign born, and 2.1 % linguistically isolated. The healthcare provider`s understanding of cultural influences, language barriers, and family dynamics related to utilization of epidural analgesia can facilitate and create a seamless transitional pathway for the patient to select the appropriate anesthetic for the labor and delivery process (Harkins et al.,

2010). Disparities in healthcare quickly become evident in the clinical environment if patients are not provided options for quality care that include pain management (Bartlett & Steele, 2006).

## Problem & Purpose

Obesity in the laboring parturient has been correlated with comorbidities and mortality (Elinas, 2012). Higher caesarean rates, preeclampsia, diabetes, pulmonary complications in obese parturients have created challenges for healthcare systems. The current healthcare system is strained by limited resources, escalating costs, and practice guidelines that vary based on regional and national preferences of healthcare providers and institutions.

### Intended Improvements with Purpose

Development of effective strategies that optimize maternal and fetal outcomes is essential to provide beneficial, safe, and cost-effective healthcare for the obese parturient. The purpose of this scholarly project is to determine if early neuraxial placement (cervical dilation between 0 to 3 centimeters) in obese parturients affects maternal and fetal outcomes. A retrospective analysis of obese parturients admitted to the obstetric unit at the healthcare institution was conducted. The type of delivery (vaginal, instrumentation, and caesarean), anesthetic (neuraxial versus general anesthesia), and length of hospitalization for the parturients were evaluated with early, late, and no anesthetic intervention to determine maternal and fetal outcomes. Fetal APGAR scores and umbilical artery pH were measured.

### Facilitators & Barriers

The Chairman of Anesthesia Department, preceptor, and chief anesthetist were facilitators for the retrospective cohort study. Project goal development, limited cost, anesthesia provider participation, realistic expectations, short timeline, ease of data collection and analysis, and anesthesia department and the university support reduced barriers for the study. Other

potential barriers included time factors, outlier participants, and small sample size. The stakeholders included obstetricians, labor and delivery nurses, nurse anesthetists, anesthesiologists, obese parturients, the university, and other high risk obstetric healthcare institutions in the United States. Developing guidelines that correlate with the retrospective analysis could reduce the number of adverse maternal and fetal outcomes, decrease length of hospitalization, and improve patient satisfaction. The economic impact of the obese parturient is substantial based on higher healthcare costs for maternal care, five times higher than normal weight parturients and the infants have a greater incidence of admission to the neonatal intensive care unit (Galtier-Dereuve, Boegner, & Bringer, 2000).

## Review of the Evidence

The inquiry, PICOT, for the study was, Does early neuraxial placement in the obese parturient affect maternal and fetal outcomes? The target population selected was the obese parturient with a body mass index (BMI) equal to or greater than 30kg/m$^2$ based on the World Health Organization`s classification of obesity (Tan & Sia, 2011). Inclusion criteria was formulated based on height, weight, BMI, and cervical dilation of the parturient at time of epidural placement (Brown, 2014). The retrospective analysis of interest was neuraxial placement, in the parturient, by the advanced practice nurse administering anesthesia or anesthesiologists. The effectiveness of early neuraxial placement was compared to late neuraxial placement after 3.5 centimeters cervical dilation. A third group of obese parturients with no anesthetic intervention was included in the analysis with the early and late intervention groups to yield relevant evidence (see appendix A for outcome measures). The time to analyze the anesthetic intervention and outcome was defined by neuraxial placement, delivery of the infant,

and hospital discharge. Timing was a critical component in the formulation of the clinical inquiry, PICOT. The setting was a high risk obstetric unit.

**Search Strategies**

The databases searched were the Cochrane Databases, Medline, Pubmed, CINAHL, Science Direct, National Library of Medicine (NLM), Dynamed, and Embase to conduct an literature review of relevant research including meta-analysis of qualitative and quantitative studies related to the keywords. The keywords included anesthesia, mo obesity, parturient, epidural, and obstetrics. Development of essential keywords narrowed the search to a greater number of primary sources. Data was extracted from domestic and international studies, reviews, and surveys between 2006-2014.

Synthesis of the literature provided 22 qualitative and quantitative studies that correlated parturient obesity with adverse maternal and fetal outcomes, discussed beneficial outcomes with epidural analgesia, and provided clinical recommendations for management of the obese parturient. The selected study designs included 3 meta-analysis reviews, 9 systematic reviews, 2 controlled trials without randomization, 3 cohort studies, 2 cross sectional studies, 2 case studies, and 1 up down sequential method study.

The Journal of American Medical Association, (JAMA), American Association of Nurse Anesthetists (AANA), and the American Society of Anesthesiologists (ASA) journals were reviewed. Science direct was useful regarding the number of published articles obtained with the keywords. Clinical practice guidelines for the obese parturient were not located in the advanced literature search. There is not a consensus in the juried journals related to the optimal time for epidural placement in the morbidly obese parturient. Synthesis of the literature supported the

premise that obesity and pregnancy is associated with adverse outcomes and early anesthetic intervention is essential to optimize patient outcomes.

**Evidence by Sub-Topics**

Four subtopics were identified to support the problem, intervention, and outcome measures: (a) BMI classification, correlation, and significance in the parturient; (b) early epidural placement in the obese parturient; (c) anesthesia techniques to facilitate epidural placement; and (d) adverse events associated with the obese parturient.

Obesity creates health challenges for the pregnant patient in addition to the physiological changes related to pregnancy (Ellinas, 2012). Maternal deaths related to childbirth have increased over the last decade in the United States and 50% of maternal deaths have been correlated with obesity, and 293,000 women worldwide died of pregnancy related complications (Morello, 2014). Obesity has been designated as a major health issue in the last decade based on literature that indicated higher morbidity and morbidity ratios (Creanga, Bateman, Kuklina, & Callaghan, 2014). The International Classification of Diseases tenth revision (ICD-9) categorizes obesity as a disease process with additional healthcare costs for healthcare consumers (Centers for Medicare & Medicaid Services [CMS], 2016). Innovative clinical approaches to reduce adverse events including loss of the obese parturient`s airway, hypoxia, and death were noted by Rao & Rao (2010). Researchers` recommendations were not supported by substantial methods content. Comorbidities associated with the obese parturient, management, and recommendations for development of evidence-based practice guidelines was supported by ninety-four qualitative and quantitative studies and expert committee opinions (Shah & Latoo, 2008).

Early epidural placement in the obese parturient is supported by Singhs et al. (2014) with no recommendations for the optimal timing of the epidural placement. Meta-analysis of nine

randomized controlled trials with a total sample size of 15,752 nulliparous women, percentage of obese women not documented, indicated greater satisfaction with labor outcomes and analgesia with epidural use as compared to other management intervention (Sng et al., 2014). Tan and Sia (2011) summarized the risks associated with the obese parturient which include greater prevalence of failed epidural analgesia, difficult epidural placement, caesarean delivery, airway issues, hypertension, low birth weight babies, and low apgar scores. Elinas (2012) concluded that further studies are indicated to support early epidural placement in the obese parturient.

Harkins et al.`s (2014) survey analysis discussed the factors that determine the parturient`s decision to utilize epidural analgesia during the labor and delivery process. The epidural usage rate for parturient, 75% -80%, was calculated by multiple regression. Factors that influence the parturient decision to utilize an epidural included past experiences, partner preference, and ethnic factors (Harkins et al., 2014). The parturients' concerns regarding prolongation of the second stage of labor may influence their decision to utilize epidural intervention for labor analgesia. The epidural failure rate for obese parturient can reach 42% with increased risk of dural puncture headache (Sahota, Carvalho, Balki, Fanning, & Arzola, 2013).

Development of anesthesia techniques to facilitate a functioning epidural for either a nonsurgical delivery, assisted instrumentation, or caesarean is essential to optimize maternal and fetal outcomes (Ellinas, 2012). A systematic review indicated techniques to optimize successful epidural intervention including ultrasound, epidural depth equation (EDE), and early anesthetic interventions (Ellinas, 2012). A survey of 194 parturients, 64 obese parturients, and 554 anesthesia providers indicated the importance of effective communication during placement of an epidural (Marroquin, Fecho, Salo-Coombs, & Spielman, 2011). Parturients were helpful in

assisting the anesthesia provider by identifying the midline in 76.6% obese parturients and 59.8% parturients with BMI<30kg/m2 (Marroquin et al., 2011).

Educating the healthcare consumer and developing strategies to reduce adverse maternal outcomes associated with obesity is a major concern and focus based on the number of studies associated with the obese parturient. Obesity is a health issue that effects 33% of adults in the United States . A case study by McKinney (2009) provided insight related to the challenges of providing safe effective care to an obese parturient. Communication, education, and a collaborative team approach reduced the risks associated with providing anesthesia to the obese parturient and potentially improved maternal and fetal outcomes. Developing guidelines that enhance the obese parturient healthcare outcomes correlates with the Institute of Medicine`s recommendations to formulate innovative evidence-based strategies to enhance patient care, satisfaction, and optimize beneficial utilization of healthcare resources.

## Theory

Kolcaba`s Theory of Comfort serves as the theoretical foundation for this project based on the physical, psychospiritual, environmental, and social components of the obese parturient during the labor and delivery process (Alligood & Tomey, 2010; see Appendix D). Koleba`s Comfort Theory has been described as a model that is congruent with evidence-based practice research (Alligood & Tomey, 2010). The traditional comfort needs of the parturient are obtained by nursing interventions that create optimal outcomes. Early neuraxial placement in obese parturients could provide analgesia, increase patient satisfaction, reduce adverse events, and improve maternal and fetal outcomes (Ellinas, 2012). The comfort measures are continually assessed in conjunction with intervening variables that include patient`s emotional state, support

system, cultural influences, and prognosis to determine the effectiveness of the intervention (Alligood & Tomey, 2010).

## Methods

### IRB Approval, Site Approval, Ethical Issues, Funding

The University of Missouri`s Health Sciences Institutional Review Board (IRB), Office of Research, approved this study. The site was a hospital specializing in women and children, and the healthcare facility was affiliated with a university. The chairman of the anesthesiology department supported the implementation of the study. Safeguarding the rights of the participants was mandated by specific research compliance guidelines which provide for researcher accountability and protection of the participants, institution, and investigators. Communication, education, and utilization of expert`s guidance enhanced the probability of a valid and successful retrospective analysis. Funding was sought but not received.

### Setting & Participants

The project setting was a Midwest hospital, level I trauma center, which provides healthcare for high risk obstetric patients. The obstetricians deliver approximately 180 babies per month. Anesthesia coverage for obstetric patients is maintained 24hrs/7 days a week by a designated anesthesia team specializing in obstetric anesthesia. The target population included 212 obese parturients with a body mass index (BMI) 30kgm$^2$ or greater, and cervical dilation of 1 to 3 centimeters or 3.5 to 10 centimeters during the stages of the labor and neuraxial placement or no placement. The retrospective data was extracted from the electronic medical records of obese parturient admitted to the obstetric unit. Exclusion criteria included parturients scheduled for caesarean delivery, low platelet count syndrome (HELLP), advanced maternal age (46-years and older), and maternal infection.

**EBP Intervention**

A retrospective analysis of the current evidence-based practice intervention of early neuraxial anesthesia determined the impact of early compared to late or no anesthetic intervention on maternal and fetal outcomes. The evidence supporting the practice intervention included twenty-two research studies related to obesity with pregnancy and implications to healthcare consumers and anesthesia providers. Recommendations for early epidural placement in the obese parturient were consistently evident in research studies published between 2006-2014. The literature correlated health risks and adverse events with obesity (Ellinas, 2012; see Appendix C).

The initial step on the project was a consult with the Chairman of Anesthesia Department, the Anesthesia Director, and Chief Anesthetist to discuss project goals, cost, anesthesia provider participation, expectations, timeline, data collection, analysis, and impact of intervention for the anesthesia department. Contacted stakeholders included obstetricians, nurse manager, and juried researchers to facilitate the research process (see appendix F).

Second, a five month timeline was implemented to complete data collection with an additional two months for data analysis and summary of findings and conclusions. The data collection process began on August 15. 2015 and ended on February1, 2016 (see appendix E Logic Model). The collection of retrospective data from April 1, 2015 to August 15, 2015 medical records included early epidural placement between 1 to 3 cm cervical dilation and late epidural placement between 3.5cm to 10 cm cervical dilation for the obese parturient who had been discharged. The primary investigator reviewed the electronic medical records and selected the sample population. The retrospective sample population included the parturient with a BMI equal to or greater than 30kg/m$^2$ admitted to the obstetric unit for labor and delivery.

Third, convenience sampling provided the outcome data from 212 obese parturients. A ledger, maintained by the nurse anesthetists, provided variables and outcome data that was placed in a separate location to preserve the anonymity and privacy of the sample population. The anesthesia regional record provided documentation for type of anesthetic, pain scores, and adverse events of all laboring parturients administered regional anesthesia. BMI scores were obtained from the obstetrician`s notes. Data collection was continuous until 212 subjects were obtained from the electronic medical records. Review of the retrospective data was evaluated weekly to address issues with the integrity of the analysis.

Fourth, analysis of retrospective data included the following dependent variables for the obese parturient: adverse events, caesarean verses vaginal delivery, pain scores, neuraxial verses general anesthesia, fetal apgar scores, and umbilical artery ph. Inclusion and exclusion criteria provided guidelines for any cofounding variables that could affect the validity of the retrospective data for the early neuraxial sample population compared to late neuraxial and no anesthetic intervention groups. Statistical Package for the Social Sciences (SPSS) was utilized by the primary investigator and statistician for analysis of Chi Square, t-tests, and ANOVA results. A confidence intervals of 95% was set by the primary investigator.

**Change Process, EBP Model**

Lewin`s Change Theory was utilized to implement changes in clinical care based on the retrospective analysis findings (Rotter et al., 2010). The theory is composed of three phases of controlled change described as unfreezing, change, and refreezing to sustain the change process (Kritsonia, 2011). Adverse maternal and fetal outcomes for the obese parturient creates disequilibrium and supports the need for change in clinical practice to optimize maternal and fetal outcomes. The change phase includes development of the initiative to administer early

neuraxial analgesia (1 to 3 cm cervical dilation) in the obese parturient (Prasada Rao & Rao, 2010). Refreezing is the implementation phase supported by evidence-based practice research (Kritsonia, 2011). Developing guidelines and protocols may enhance the successful implementation of the initiative and improve sustainability of the evidence-based scholarly project.

**Study Design**

A retrospective cohort study with three groups was utilized to compare early epidural intervention, late epidural intervention, and no anesthetic intervention group on maternal and feta outcomes. Secondary outcomes addressed variables impacting quality care. The target population was selected by convenience sampling.

**Validity**

Increasing the sample size to 212 reduced some bias potential. Strong inclusion criteria was formulated to control cofounding variables to enhance the validity and homogeneity of the target population. Communication with research experts and the statistician regarding confounding variables, selection bias, and adequate sample size were used to improve internal and external validity. The generalizability of the findings could improve content in clinical pathways or care management for obese parturients.

**Outcomes**

The maternal outcomes measured were method of delivery (vaginal or caesarean), type of anesthesia (neuraxial or general anesthesia), and length of hospitalization. The fetal outcomes measured included apgar scores and umbilical artery pH. Adverse events that included hemorrhage, epidural failure, fetal intolerance, forceps or vacuum instrumentation, and shoulder dystocia were included in the analysis.

## Measurement Instruments

For pain measurement within the maternal outcomes, the numerical rating scale (NRS) was the measurement tool selected based on values ranging from 0 to 10 to describe patient pain levels (Younger, Mc Cue, & Mackey, 2009). The NRS is a reliable and valid unidimensional tool utilized prior to and during epidural interventions in the laboring parturient (Beilin et al. 2004). Ferreira-Valente, Pais-Robeiro, & Jensen (2011) compared the responsiveness of the NRS with other pain scale measurement tools in a sample population of 127 subjects and the NRS was the most responsive and reliable measurement tool. The tool was developed by J. Solodiuk PHD and permission to utilize the NRS in research and clinical practice was granted by the author.

The Donabedian Model is the second tool selected to assess the epidural placement and outcomes based on three components consisting of structure, process, and outcome criteria (Donabedian, 2005). The Donabedian Model is advocated by the Agency for Healthcare Research and Quality (AHRQ) and the Institute of Medicine as a highly reliable tool applicable to various clinical settings (Quigley & White, 2013). Permission to reuse the Donabedian Framework was requested from the publisher John Wiley and Sons. The other outcome measures of maternal type of delivery, incidence of hemorrhage, length of hospitalization, type of delivery, and newborn APGAR scores, NICU admissions, and umbilical artery pH values were obtained directly from the documentation in the electronic medical records.

## Quality of Data

Inclusion criteria, and exclusion criteria enhanced the quality of the data collected. The obese parturient with neuraxial analgesia for pain management was categorized as an independent variable and the maternal and fetal outcomes were dependent variables. Formulating a sample size of 212 enhanced the probability of valid outcome results in a

nonrandom convenience selection method. A priori power analysis was conducted with a power of 0.80, medium effect size, alpha= 0.05, and confidence interval of 95% and indicated a sample size of 212. Benchmarking early neuraxial placement as a quality performance measure is an innovative method not currently indicated as a standard of care for obese parturients.

### Analysis Plan

Multiple regression power analysis was the statistical test for the power analysis for determination of adequate sample size. A Chi-Square analysis determined if a significant relationship existed between early epidural intervention in obese parturients and measured outcomes. Utilization of SPSS software and analysis of covariances (ANOVA) determined the prevalence of caesarean delivery, inadequate epidural analgesia, effective pain management, general verses regional anesthesia, APGAR scores, and umbilical artery pH. A t-test validated if the sample means differed in the neuraxial and no anesthetic intervention groups.

## Results

### Setting & Participants

The retrospective analysis was conducted at an academic healthcare facility. Data was successfully collected after review of 715 electronic medical records of women admitted to the obstetric unit from April 1, 2015 to August 15, 2015. The desired sample size was 212. Demographic data included parity, age, and type of insurance.

The 212 parturients in the sample (see Appendix, Table I) had a mean age of 27.48 years old, mean BMI of 34.63and a median of two prior pregnancies with a range of 1-10. The type of insurance coverage for parturients was predominantly government (62.7%) compared to either private (34.0%), self (1.4%), or no insurance (1.9%). The median length of hospitalization was 2.8 days with a range of 1-32. In the sample, 75 (35%) had early neuraxial placement (0-3

centimeters cervical dilation), 111(52%) had late neuraxial placement (3.5 to 10 centimeters cervical dilation), and 25 (12%) had no anesthetic intervention. Two subjects received neuraxial intervention for preterm labor, failed to progress, and were transported to the antepartum unit.

**Intervention Course**

The project design and budget was developed by reflective evaluation of the current anesthesia practices for obese parturients (see appendix A, Cost Table I). The anesthesia intervention and birth ledgers for the obstetric unit were analyzed to obtain 212 subjects. Inclusion criteria was utilized to eliminate women who had scheduled caesarean deliveries. Date of birth data was reviewed to eliminate women less than 18 years old. The number of pregnancies for each parturient was noted in the anesthesia record. The BMI scores were reviewed and women with scores equal to or greater than 30kg/m$^2$ were selected. Cervical dilation was reviewed in the obstetrician`s notes to determine dilation at time of neuraxial intervention. The majority of numerical pain scores prior to and post neuraxial placement were obtained from the obstetrician notes. The APGAR scores were reviewed in the obstetrician notes. Complications regarding neuraxial placement, successful conversion to a surgical epidural anesthetic, or general anesthesia was noted in the anesthesia record The data was de-identified and placed into an excel spreadsheet template (see appendix I, Table I). The outcome data was imported into SPSS and the analysis verified by a statistician (see appendice E: Logic Model).

**Outcome Data by Subtopic**

**Maternal outcomes**. Vaginal delivery was more common than caesarean delivery (80% vaginal, 19% caesarean). In the sample, 87.8% (186) of the parturients received neuraxial intervention; in the parturients with neuraxial placement, 40.3% had early placement while the remaining 59.7% had late placement. Combined spinal epidural was successfully utilized in 138

parturients (65.1%), and 45 parturients (21.2%) utilized the epidural for eitherr or surgical intervention, and two parturients (.9%) were converted to general anesthesia for surgical intervention. The conversion of the epidural to general was low (0.5%) and included twins, one vaginally and the second by emergent intervention for caesarean delivery. Parturients in the early intervention group were more likely to have fetal intolerance to labor (6.7 %) in contrast to 0% in the late and no intervention groups (x2= 7.483; *p*= 0.011). A small number of parturients in the total sample of 212 experienced complications including hemorrhage (5.2%), shoulder dystocia (5.7%), forceps or vacuum assisted delivery (2.8%), difficult epidural placement (3.3%), and preeclampsia (2.8%), The no anesthetic group experienced a marginally higher incidence of hemorrhage (15.4%) compared to the two other groups ($x^2$=5.056, *p*= 0.065).

**Fetal Outcomes.** APGAR scores were obtained from 207 newborns at one minute (mean 7.19, sd = 1.99) and 202 newborns at five minute (mean of 8.37, sd=1.35). Three sets of twins received lower APGAR scores at one minute (mean of 6.00, sd=2.00) and five minutes, (mean of 7.67 sd=1.53). The following dependent variables related to complications associated with the obese parturient were analyzed with the Fisher`s exact test statistic: NICU admissions, fetal intolerance, and fetal mortality. NICU admissions were significantly higher in the no anesthetic intervention group (7.7%) compared to the early (0%) or late (0%) intervention groups ($x^2$=7.371; *p*=0.014). Fetal intolerance to labor (2.4%) was higher in the early neuraxial group. The no anesthetic intervention group was associated with a higher incidence of neonatal intensive care unit (NICU) admission and fetal mortality. Fetal mortality included diagnosis of fetal demise prior to labor induction or lethal anomalies that warranted labor induction. The relationship between neuraxial placement, fetal complications, and fetal and maternal health outcomes was evaluated (see appendix J, Table 2). NICU admissions were significantly higher in

the no anesthetic intervention group (7.7%) compared to the early (0%) or late (0%) intervention groups ( $x^2$=7.371; *p*=0.014).

The early neuraxial group (28%) had a higher incidence of complications compared to the late intervention group (16.2%). The low intervention group with no anesthesia (15.4 %) indicated a higher incidence of hemorrhage compared to the other two groups ($x^2$=5.056, *p* =0.065). Parturients who received no anesthetic interventions experienced greater incidence of multiple complications ($x^2$= 12.5 *p*=0.007). No significant differences were observed for vaginal birth after caesarean, trial of labor after caesarean, shoulder dystocia, forceps or vacuum delivery, difficult epidural placement, APGAR scores, newborn umbilical artery pH, length of hospitalization, and pain scores across intervention groups.

**Cervical dilation, maternal and fetal outcomes**. Bivariate assessment of the relationship between cervical dilation (early, late) and maternal and fetal outcomes was conducted (see Appendix J, Table 3). Those parturients dilated 0 to 3 centimeters were more likely to have fetal intolerance than expected by chance ($x^2$=9.946; p=0.007). Hemorrhage, shoulder dystocia, forceps or vacuum delivery, difficult epidural placement, NICU admission rates. APGAR scores, newborn umbilical artery PH, length of hospitalization, and pain scores were not significantly related to cervical dilation at time of intervention.

## Discussion

Current practice related to neuraxial analgesia and specific timing of the placement vary based on geographical regions and provider preferences (Ellinas, 2012). The project site has no specific guidelines for anesthetic management of obese parturients. The healthcare providers at the project site were supportive of the retrospective analysis and provided feedback related to

independent variables for the obese parturients and outcome data. Combined spinal anesthesia is the primary anesthetic utilized for the laboring parturient for pain management.

The major positive findings related to early neuraxial analgesia indicated reduced epidural failure rates, successful conversion of a labor epidural to a surgical epidural, reduced general anesthetics, and potential for decreased loss of airway and death. Significant reduction in numerical pain scores was associated with early and late neuraxial placement (see appendix L). The number of complications associated with early neuraxial anesthesia were lower than the no anesthetic intervention group.

## Limitations

The early neuraxial group was associated with a higher incidence of caesarean deliveries. Higher caesarean rates in the early neuraxial group could be a cofounding variable associated with a third dependent variable of dysfunctional labor correlated with low cervical dilation and higher caesarean rates in the obese parturient (Wispelway & Sheiner, 2013). The findings correlated with a study by Machado (2012) that indicated a higher risk of caesarean deliveries in obese parturients (33.8%) compared to the normal weight parturient (20.7%). he low failure rate (1%) for conversion of labor epidurals for surgical intervention may be attributed to the routine clinical practice of either administering 3% 2-chloroprocaine or carbonated 2% lidocaine with epinephrine for emergent surgical intervention. One failed epidural for surgical intervention included twins, one delivered vaginally with successful epidural anesthesia and the second by general anesthesia due to the emergent caesarean delivery. One sample subject with BMI (65) was converted from a labor epidural to spinal anesthetic for surgical intervention. The findings correlate with Campbell and Tran (2009) discussion of successful utilization of chloroprocaine and lidocaine in 899 women during a three year period to reduce the need for general anesthesia

and the potential devastating consequences of emergent general anesthesia. In the current study, ineffective pain management was correlated with failure to convert a laboring epidural to an effective surgical anesthetic. The numerical pain scores indicated lower scores after neuraxial in the majority of the 177 parturients that utilized neuraxial anesthesia (See appendices J, Table I).

Incomplete documentation of BMI, cervical dilation, numerical pain scores, APGAR scores, and newborn umbilical pH values was found in the electronic medical records. Documentation of post-neuraxial pain scores was indicated in 87 of the 187 sample subjects with a median score of less than 1. Improvement in documentation for post neuraxial pain scores is a recommendation based on the potential need to convert a continuous labor epidural to surgical anesthesia and potentially avoid risks associated with general anesthesia. Modification of the anesthesia record to include BMI scores is a second recommendation.

Elevated BMI scores are correlated with adverse events that include postpartum hemorrhage (Ranasinghe & Birnbach, 2009). Bloomberg (2011) noted a greater incidence of postpartum hemorrhage for the obese parturient (5.2%) compared to the normal weight parturient (4.4%) and more pronounced with the utilization of instrumentation (13.6%). In the current study, the early neuraxial group was associated with a higher incidence of caesarean deliveries.
Higher caesarean rates in the early neuraxial group could be a cofounding variable associated with a third dependent variable of dysfunctional labor correlated with low cervical dilation and higher caesarean rates in the obese parturient (Wispelway & Sheiner, 2013). Utilizing multiple imputation for post neuraxial pain scores provided values for the missing data.

## Interpretations

Expected outcomes included a lower epidural failure rate (.9%) for caesarean delivery and lower numerical pain scores. Unexpected results included greater incidence of hemorrhage,

shoulder dystocia, and higher number of NICU admissions in the no anesthetic intervention group. A study by Driessen et al. (2011) noted the protective factor associated with epidural placement and severe postpartum blood loss based on the healthcare provider`s ability to aggressively perform bimanual uterine massage to control the hemorrhagic effects of uterine atony. Postpartum hemorrhage is associated with 19.1% of maternal deaths in healthcare facilities (Bateman. Et al., 2010). Education of healthcare providers related to the benefits of neuraxial intervention could reduce the severity of hemorrhage, decrease length of hospitalization and reduce healthcare costs.

## Conclusion

Because maternal deaths related to childbirth have increased over the last decade in the United States, developing innovative anesthetic management is essential to improve maternal and fetal outcomes for the obese parturient (Morello, 2014). Early neuraxial intervention reduced the risk of general anesthesia, potential loss of airway, and possible death in the retrospective analysis. Developing clinical pathways for management of obese parturients aligns with the Institute of Medicine`s recommendations to formulate innovative evidence-based strategies to enhance patient care, satisfaction, optimize beneficial utilization of healthcare resources, and reduce costs (Brown, 2014). Avoiding neuraxial analgesia could increase the risk of adverse outcomes in a population characterized by comorbidities and higher rates of mortality. The findings support the necessity of anesthesia consultation and neuraxial intervention for the obese parturient to reduce morbidity and mortality. Future studies are indicated to support the project findings on early neuraxial placement. A large scale randomized controlled trial to support this evidence based practice of neuraxial analgesia could generate new interest in developing guidelines and standards of care for obese parturients. Dissemination of the findings include

submission for publication in the AANA Journal with scheduled presentation at the MOANA conference in April 2016.

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Appendix A: Cost Table for Early Epidural Intervention in Obese Parturient

| **Time Period** | **Human Resources/ Materials** | **Percentage of Effort** | **Calculation (Salary x Time)** | **Estimated Costs** | **Actual Costs** |
|---|---|---|---|---|---|
| **April 2015-April 2016** | Nurse Anesthetist/ | 25% Full Time Equilvalent | $150k/Annually 25%= $37,500 | $37,500.00 | Payment in-kind =DNP recipient |
| **August 2015-November 2015** | Data Entry Specialists 5 | 20 hours/ week x 16weeks | Rate per hour $10 hour x 320 hrs | $3,200.00, | non-monetary compensation , acknowledged in research |
| **August 2015-February 2016** | Statistician | 5 hours/ week x 24 weeks | Rate / hour $135 | $1,600.00 | Statistician contracted $1,600.00 |
| **April 2015-April 2016** | Sustainability experts | 2 hrs/week x | Rate / hr= $30 | $1.440.00 | 2 Professors 1=PHD/.1=MD, non-monetary compensation |
| **April 2015-April 2016**<br><br>**Dissemination costs** | Miscellaneous office supplies, ink cartridges, printer, computer, gift cards, poster fees<br>Travel to Wisconsin | 20 hrs | | 1,0000.00<br><br>$1,600.00 | $1,0000.00<br><br>$1,600.00 |
| **Total program Expenditures** | | | | $43,300.00 | $4,200.00 |

Note: Adapted from “Guidelines for Budget Preparation” by Office of Research & Commercialization, 2014,p1.

# Appendix B: Definition of Terms

**AANA:** American Association of Nurse Anesthestists.

**ACOG:** American Congress of Obstetricians and Gynecologists

**APGAR Scores:** The numerical score given to newborn at one and five minute intervals ranging from 1 to 10 based on observation of heart rate, respiratory effort, muscle tone, reflex irritability, and color. Low apgar scores = 6 or less based on ACOG standards.

**BMI:** Body mass index calculated by height and weight.

**CSE**: Combined spinal epidural anesthesia. The epidural space is identified with loss of resistance, spinal needle utilized through the epidural needle to administer a spinal dose of local anesthetic and a catheter is threaded into the epidural space for continuous labor analgesia. The advantage of CSE, spinal provides rapid analgesia and the epidural infusion provides analgesia until delivery of infant.

**Epidural:** anesthetic technique utilized for pain management frequently referred to as neuraxial technique, injection of local anesthetic medication around the nerves of the central nervous system.

**Low birth weight:** 2,500 gms or less.

**Neuraxial:** Combined spinal and epidural anesthesia, type of regional anesthesia.

**Parturient:** A female or woman about to give birth. High risk parturients correlated with increased risk of maternal and fetal co-morbidities

**SPSS:** Statistical Package for the Social Sciences, software used for statistical analysis

| Appendix C: Synthesis Table | | | | | | |
|---|---|---|---|---|---|---|
| **First Author, Year, Title, Journal** | **Purpose** | **Research Design Evidence Level and Variables** | **Sample & Settings** | **Measures & Reliability (if reported)** | **Results and Analysis Used** | **Limits & Usability** |
| **Early Epidural Placement** | | | | | | |
| Laughon, Berghetti, Reddy, Sundaram, Lu, & Hoffman (2014) Neonatal and maternal outcomes with prolonged second stage of labor. Obstetrics & Gynecology. | Compared length of second stage labor with and without epidural analgesia to determine if epidural placement significantly prolongs labor, review risks of prolonged second stage labor | Retrospective cohort study from 19 hospital in U.S. Level III, variables cesarean delivery for nonreassuring FHR, asphyxia, shoulder dystocia, and NICU admission | n= 208,695 women with 228,438 deliveries from 2002-2008 Thomas Jefferson University | Electronic medical records accessed Consortium on Safe Labor determined the optimal course of labor to enhance maternal and fetal outcomes. Length of second stage of labor for parturient 97.9 with epidurals. | CI=95%, Adjusted odds ratio, p>.001 IRB approval | Research indicated increased maternal and fetal morbidity and mortality with prolonged second stage labor greater than 2 hrs. , RCT would support findings. Research noted potential for false positives |
| Sng, Leong, Zeng, Siddique, Assam, Lim, Chen, & Sia (2014). Early verses late initiation of epidural analgesia for labor. The Cochrane Collaboration | Summarize effectiveness of early verses late epidural intervention for parturient | Systematic Review (Melnyk & Fineout-Overholt, 2011). Level IRCT Trials. Variables; early and late epidural intervention. Dependent variables cervical dilation, hypotension, duration of labor, caesarean section, instrumental birth, apgar scores | n=15,752 nulliparous pregnant women, 9 RCT`s, Singapore, China, | Relative effect (CI 95%), Quality of evidence, Grade Working Group (high to very low, risk), Cochrane Handbook for Intervention Reviews. Dichotomous summary risk ratios analyzed. | RevMan analysis software (2014). Sufficient heterogeneity & low risk of allocation bias. No significant differences in caesarean sections, stages of labor, maternal fever, malposition, instrumentation delivery, or apgar scores related to timing of epidural placement. | Selection bias, no blinded analysis. Maternal pain relief and satisfaction greater with early epidural intervention. Questins related to neuraxial verses systemic opioids on uterine activity, further RCT recommended**.** |

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|---|---|---|---|---|---|---|
| Tan & Sia (2011). Anesthetic considerations in the obese gravida. Seminars in Perinatology | Summarizes the risks associated with the obese gravida, provides recommendations for early anesthetic interventions | Systematic Review of pre-anesthetic recommendations, labor analgesia, general anesthesia risks, postoperative and postpartum care discussed | Combination of RCT, meta-analysis, observational surveys, quantitative and qualitative studies totaling 84 | Method selection for studies was not indicated | Early epidural placement for obese parturient recommended and supported by extensive studies and literature | Clinical significance & strong applicable |
| Harkins, J., Carvalho, B., Evers, A., Mehta, S., Riley, E. (2010) Survey of the factors associated with a woman`s choice to have an epidural for labor analgesia | Discussed factors that determine parturient`s decision to utilize epidural analgesia during labor process, primary sources for decision related to epidural placement | Survey Level III, Parturient education, prior epidural, partner preference, language, age, type of insurance | n= 320 parturient women University of Florida Lucy Packard Children`s Hospital | Epidural usage rate was between 75-80% range, ethnic factors, past experience and partner preference influenced parturient`s decision. Reliability of findings high, no CI noted. | Multiple regression value p value adequate 0.01 Chi Square, univariant analysis. SPSS | Limitations information obtained after delivery process, , potential for bias questionable. Reliable predictive model needed to determine and support decision factors |
| **Anesthesia Techniques to facilitate epidural placement** | | | | | | |
| Sahota, J.S., Jose, C., Carvalho, M., Mrinalini Balki, M., Niall, F, & Cristian, A. (2013). Ultrsound estimated for midline epidural punctures in the obese parturient; Paramedian sagittal oblique is comparable to transverse median plane. Society for Obstetric Anesthesia and Perinatology | Summarizing the estimates for midline epidural punctures in the obese parturient, failure rates, and techniques to improve epidural placement in the obese parturient, imaging utilized. World Health Organization`s three classifications of obesity utilized | Level III Controlled trial without randomization imaging utilized. World Health Organization`s three classifications of obesity utilized | n= 60 women with BMI of 39.6 kg/m2 Mount Sinai Hospital, University of Toronto | Bland Altman analysis, 95% CI, mean and median calculations indicated 6.5 cm to 6.6cm distance to epidural space from skin in the obese parturient. descriptive statistics, Pearson`s correlation coefficient | The distance to the epidural space in obese parturients is comparable with either the paramedian sagittal oblique or transverse median plane techniques<br><br>Potential for bias | Clinically applicable further studies indicated to support evidence |

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|---|---|---|---|---|---|---|
| Singh, Wirth, Phelps, Badve, Shah, Sah, & Vallejo. (2013). Epidural catheter placement in morbidly obese parturients with the use of an epidural dpth equation prior to ultrasound visualization. The Scientific World Journal | Summarizes the utilization of the epidural depth equation (EDE) in conjunction with ultrasound to facilitate epidural placement in BMI > 40KG/m2 obese parturient. Does EDE improve imaging results/ estimation of depth from skin to epidural space? | Controlled trial without randomization. Level III. Variables demographic and obstetric data , number of pregnancies, cervical dilation, epidural placement attempts | N=160 parturients, timeline August 2010-June 2011. University of Pittsburgh | Pearson`s correlation coefficients >0.91, descriptive statistics | CI=95% Correlation between EDE and ultrasound enhanced estimation of depth of epidural space in obese parturients, depth mean 6.6cm . Power was not indicated | Clinical applicability to reduce incidence of dural puncture and failed epidural analgesia. No Limitation discussed, no p value indicated |
| Elinas, E. (2012). Labor analgesia for the obese parturient. Anesthesia - Analgesia | Focused review that discussed anesthetic challenges in obese parturient and techniques to optimize outcomes | Systematic review variables: obesity , epidural versus combined spinal epidural , landmarks for epidural placement timing of placement disadvantages and advantages including rapid dosing of epidural for Caesarean delivery Level III, V, VII | 52 references indicated that included meta-analysis, systematic review, RCT`s, surveys, no methods section noted or sample exclusion and inclusion criteria | No confidence interval or power noted, reliability of review needs further analysis to support recommendation s | Supports early anesthetic intervention with epidural placement, beneficial aspects of early epidural placement outweighs risks | Limited as sole support to change clinical practice, further evidence indicated |
| Marroquin, B., Fecho, Salo-Coombs, V., Spielman, F. (2011). Can parturients identify the midline during neuraxial block placement? Journal of Clinical Anesthesia | Survey based on questionnaires to summarize parturient`s ability to identify midline during epidural placement formulated by anesthesia providers | Survey Level VII Variables: type of neuraxial block epidural / combined spinal-epidural, BMI, patient position, number of needle redirections | n=194 parturients, n=64 obese parturients. 554 questionnaire s completed by anesthesia providers | Statistical analysis and methods were limited SPSS & Sigma Plot graphical software. Class II obesity utilized in sample population | Parturients assistance helpful in identifying midline in 76.6% obese and 59.8% less than 30kg/m2. Adequate power $p< 0.05$ | Limitations recall bias regarding number of needle redirections, factors that created barriers including edema and scoliosis were not noted. Further research indicated for clinical applicability |

| | | | | | | |
|---|---|---|---|---|---|---|
| Sanford, C., Rodriquez, R., Schmidt, J., Austin, P. (2011). Evidence for using air or fluid when identifying the epidural space. AANA Journal | Determine quality of epidural analgesia related to anesthesia provider techniques that utilized air verses fluid for loss of resistance with epidural placement. | Integrative review composed of Systematic Review & Meta-analysis, level 1, RCT level II, Retrospective effectiveness study, level VI, Observational study level IV, Evidence appraisal method guidelines (Melnyk & Fineout-Overholt)., Triangulation design. | 4 studies, 2-United Kingdom, 1-United States, 1-Israel, Critical appraisal. | n=638 parturients limited information related to sample characteristics population. . concise inclusion, and exclusion criteria for sample size needed. | Moderate to high quality . Combined risk difference- for partial block -0.08 with 95% confidence interval, suggests not significant difference in the type of medium utilized for epidural placement. Insufficient data. Yates continuity correction utilized. Inconclusive results and reliability questionable | Limitations, only 2 higher level of evidence sources, heterogeneity, , power inadequate, moderate quality, small sample size, amount of loss of resistance medium not standard, no measurement for quality of epidural analgesia , sample population bias Additional studies recommended |
| Panni. M. & Columb (2005). Obese parturients have lower epidural local anaesthetic requirements for analgesia in labor. British Journal of Anaesthesia | Estimate the minimal anesthetic local anesthetic requirements for labor epidurals in the obese parturients | Up down sequential allocation study variables obese parturients with BMI 30 kg/m2, parturients with BMI less than 30kg/m2, gestational age 36 to 41weeks , cephalic presentation, Testing intervals correlated with different local anesthetic concentrations Level IV | n= 32 parturient women requesting epidurals for labor analgesia | Adequate power p less than 0.001.CI=95% Research conducted at Duke University. Anova, Welch`s t-test means and median calculations | Obese parturients have significantly less local anesthetic requirements for epidural analgesia sample size inadequate. Reduce volume in epidural space correlated with reduce local anesthetic by 1.64% | Lower doses of local anesthetic concentrations recommended to reduce risks of high block levels and hemodynamic instability |

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|---|---|---|---|---|---|---|
| Nicholson & Ridolfo (1989). Advoiding the pitfalls of eidural anesthesia in obstetrics. Journal of the American Association of Nurse Anesthetists. | Summarize the beneficial use and risks associated with epidural placement in the parturient. | Systematic review. Level V. complications associated with epidural placement, total spinal, acute systemic toxicity, subdural injection, Horner's syndrome, infection | Number of studies reviewed not indicated 14 references listed. University of Cincinnati School of Nurse Anesthesia | Validity of references not indicated | Epidural analgesia can be a safe , effective method to provide optimal pain relief. Close observation of the diligent anesthesia provider reduces complications. | Adherence to practice guidelines is essential to reduce incidence of adverse epidural complications. Bias high |
| **Adverse events resulting in Caesarean delivery, Postdural Puncture Headaches for obese parturient** | | | | | | |
| Dodd, Crowther, Grivell, & Deussen (2014). Elective repeat caesarean section versus induction of labor for women with a previous caesarean birth. The Cochrane Collaboration | Summarize the risks and benefits of labor induction for parturients with prior caesarean birth. Compared outcomes of parturients that selected caesarean and elective inductions. | Meta-analysis & Intervention review randomized controlled trials and cluster trials Level II , dichotomous variables. Parturients with prior caesarean birth, Vaginal birth after caesarean birth (VBAC) | 10 studies identified Cochrane Pregnancy and Childbirth Group Trial Registry | Fixed-effect model meta-analysis, revman manager software to analyze data | Recommendations for further studies to support the benefits and risks associated with labor induction after caesarean birth. No RCT`s identified and insufficient data available to validity of studies reviewed. 95% CI | Limited evidence to support conclusions and outcomes, generalizability low |
| Bradbury, Singh, Badder, Wakley, & Jones (2013). Prevention of post-dural puncture headache (PDPH) in parturients: A systematic review and meta-analysis. Acta Anaesthesiologica Scandinavica | Determine techniques to reduce incidence of post-dural puncture headache after labor epidurals | Systematic review and meta-analysis level I , 40 RCT, PRISMA Variables, parturients labor epidurals dependent variables; Combined spinal – epidural, loss of resistance medium, epidural blood patch, needle bevel , epidural morphine, ultra-sound guided insertion. | n=11,536 Laboring parturients with epidural analgesia | Median quality score range between 2-5 CI 95%, Data analysis Stata 12.0, Forest plot. | Jadad scores low for quality assessment, inadequate double blinding & power, randomization, weak. No specific intervention significantly reduced incidence of PDPH, 5 techniques reduced incidence of PDPH, sprotte needle bevel position, morphine, and cosyntropin. | Heterogeneity high, validity questionable, further studies indicated to support techniques to reduce PDPH & prophylactic use of epidural blood patch. |

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|---|---|---|---|---|---|---|
| Shobary, Kaufman, & Schricker (2011). Anesthetic management of a morbidly obese parturient undergoing cesarean section. Middle East Journal of Anesthesiology | Summarize risks associated with obesity and potential complications in a case study of a parturient undergoing cesarean delivery | Case study reporting clinicians experience with obese parturient. Level VII | 42 year old Afro-American woman BMI=73kg/m 2 Montreal, Canada | No method for selection of case study reported, 35 references indicated | No data analysis | Potential for publication bias and inappropriate generalizations (Melnyk & Fineout-Overholt, 2011). Epidural placement recommended |
| McKinney, D. (2009). Morbid obesity and pregnancy; A . case study. International Student Journal of Nurse Anesthesia | Review of clinical case involving obese parturient and conversion of epidural to general anesthesia | Case Study, lower hierarchy Level VIII | One case report 25 yr old gravida 3, Para 2, Lincoln Memorial University | No statistical analysis | Reliability of case report low, further reports indicated to support recommendations | Objectivity questionable, Strong clinical focus related to adverse event and obesity. Limited evidence |
| Ellinas, E, Eastwood,D., Patel, S., Maitra-D`Cruze, A., Ebert, T ( 2009). The effect of obesity on neuraxial technique difficulty in pregnant patients: A prospective, observational study | Examined obese parturients to determine factors that predict difficult epidural insertion. Recommend intermittent evaluation of functioning epidural related to potential for caesarean delivery. | Perspective observational study systematic review Level III. Placement time & number of needle passes, | n=427 parturients. Medical College of Wisconsin over 8 month period | Generalized linear model utilized, bias addressed by survival model, univariate analysis SAS 9.1 version indicated, negative binomial | The ability of practitioner to palpate landmarks significant factor in determining difficulty in epidural placement. Degree of obesity not indicator of technical difficulty. 4 anesthesia providers collected data, experience of practitioner noted P<.01 consolidation of groups to increase power. CI=95% | Position of patient during epidural placement correlates with outcomes, including ability for back flexion, spinal deformity and landmark palpitation. Significant study strong reliability based on analysis. Only 14 study patients with BMI>50kg/m2 |
| **Body Mass Index (BMI) Classifications, Correlation, Significance** | | | | | | |
| Barclay, L. (2014). Epidural prolongs second stage of labor by more than two hours. Obstetrics and Gynecology | Compared the duration of the second stage of labor with and without epidural analgesia | Retrospective Cohort study Level IV | n=42,268 parturients University of California San Francisco | Kruskal-Wallis test and Kaplan –Meir utilized for statistical analysis. P>.001 | Epidurals extend the length of second stage labor between 2 hrs and 54 minutes compared to 81 minutes without epidural analgesia | Limitations missing data, bias, ,analysis of data from a single academic institution, generalizability questionable |

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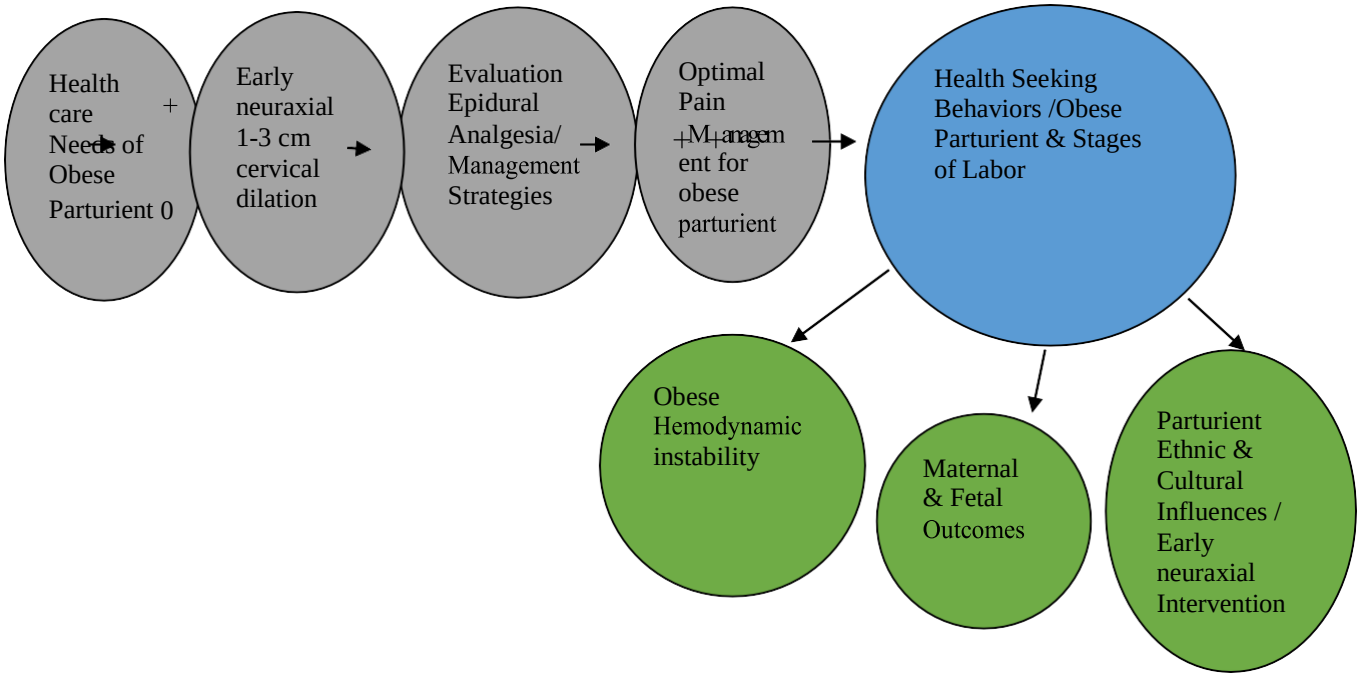
|---|---|---|---|---|---|---|
| Rao & Rao. (2010). Morbidly obese parturient: Challenges for the anaesthesiologists, including managing the difficult airway in obstetrics. What is new? Indian Journal of Anaesthesia | Review of aspects of obesity and pregnancy including pathological clinical issues, technical challenges, and pharmacological issues. Difficult airway management was addressed | Systematic review Level V WHO classifications of obesity, Physiological changes with pregnancy, maternal complications, placement of epidural , CSE, airway | Number of studies to support review of inclusion and exclusion criteria not indicated. 92 references including RCTS, meta-analysis, surveys, population based screening studies | No methods or statistical analysis indicated | Formulation of guidelines for obese parturient is essential to optimize outcomes | Regional anesthesia is optimal choice for obese parturients, emergency caesarean delivery spinal recommended due to time factor. Experienced anesthesia provider essential to manage difficult airway algorithm. |
| Shah & Latoo (2008).Anesthetic management of obese parturient. British Journal of Medical Practitioners | Review of the comorbidities associated with the obese parturient, management, and recommendations for early anesthetic intervention, WHO classification of obesity | Systematic review of obese parturients, technical challenges, with neuraxial and general anesthesia Level V | 94 references, systematic reviews, case studies, qualitative and quantitative studies, committee opinions | Selection criteria for systematic review not indicated. Cochrane review noted in references, methods not indicated | Classifications of obesity gynecoid (thigh and buttock fat distribution) and android (trunchal distribution of fat associated with cardiovascular disorders. BMI > 30 in 27% of maternal deaths (2003-2005). Perinatal deaths 30% | Recommend early epidural placement to reduce risks associated with general anesthesia, potential difficult airway. Anesthesia consult indicated as early as 28weeks. |
| Heslehurst, Simpson, Batterham, Wilkinson, & Summerbell (2006). Trends in maternal obesity incidence rates, demographic predictors, and health inequalities in 36,821 women over a 15 year period. | Identify risks and trends in maternal obesity including ethnic groups, age, parity, and socio-economic status | Longitudinal database study from January 1990-December 2004. Level III | n=36,821 women, England | Socio-economic factors increase the incidence of obesity in the parturient, multivariate logistics for confounding variables. No correlation with BMI & ethnicity. | P>0.01, for increased number of obese parturients during implementation of the study. CI=95% , chi square utilized | Health inequalities socio-economic factors influence the prevalence of obesity in the parturient. Obesity rates in parturients expected to increase . Potential data entry errors. |

Appendix D: Theory to Application Diagram




Adapted from "Comfort Theory and Practice: A vision for holistic health care and research by Kolcaba (2003).

# Appendix E: Logic Model for DNP Diagram

PICOT Question: Does early neuraxial intervention in the obese parturient affect maternal and fetal outcomes.

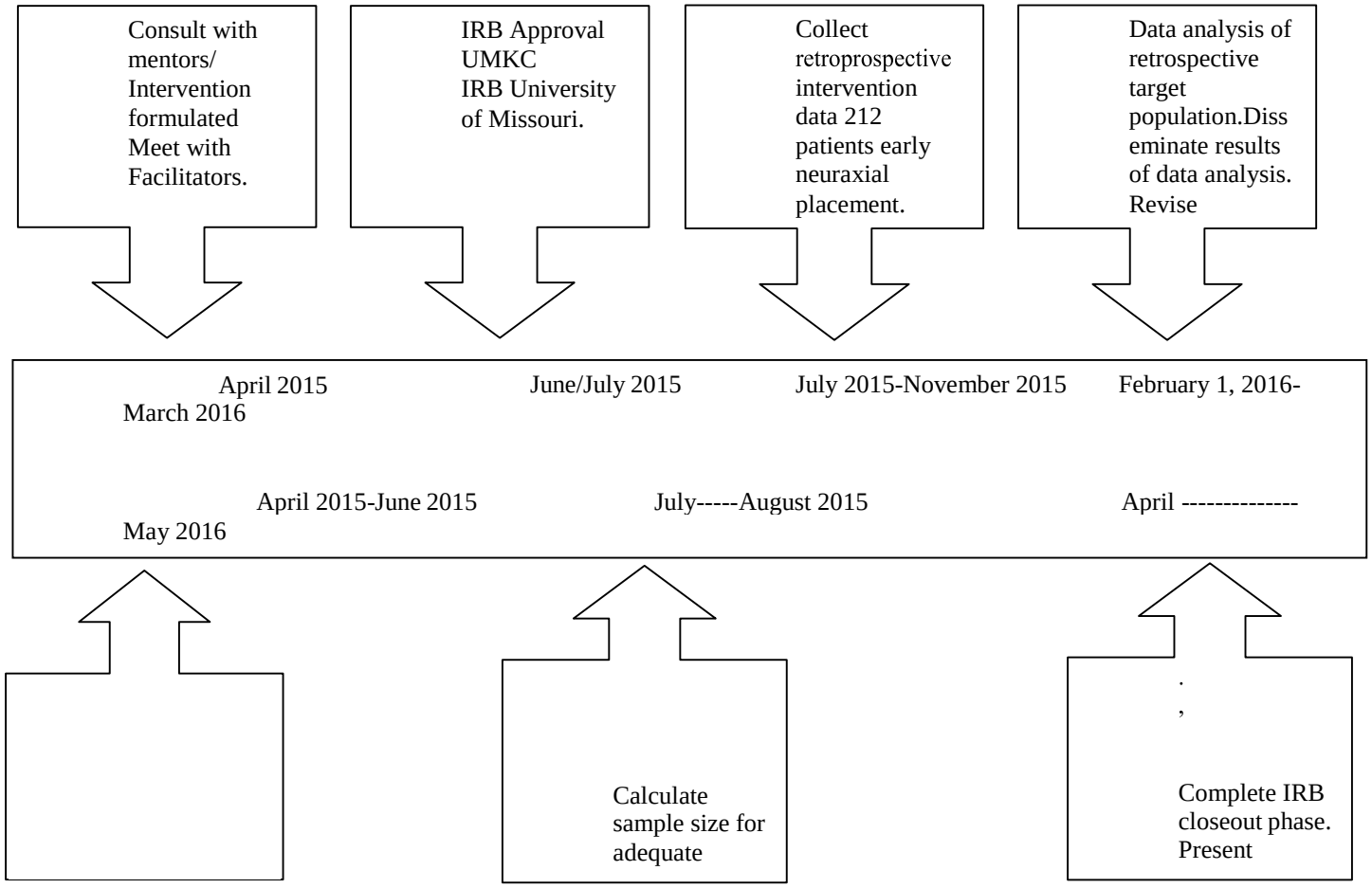
| Inputs | Intervention(s) | Outputs | Outcomes -- Impact | | |
|---|---|---|---|---|---|
| | *Activities* | *Participants* | *Short* | | *Long* |
| (1)BMI (Body mass index), correlation, & significance<br>(2)Early neuraxial placement in the obese parturient<br>(3) Anesthesia techniques to facilitate epidural placement<br>(4) Adverse events associated with the obese parturient<br><br>Major Facilitators or Contributors<br>Nurse Anesthestists/ Anesthesiologists<br>Obstetricians, Chairman of Anesthesia Department, Labor and Delivery Nurses<br><br>Major Barriers or Challenges<br>Denial of consent from IRB, lack of support from colleagues, , low interventionalists | The EBP intervention which is supported by the evidence in the Input column<br>Early neuraxial placement in the laboring obese parturient (BMI 30kg/$m^2$ or greater), 1 to 2 cm cervical dilation.<br>Major steps of the intervention<br>(1)Develop inclusion / exclusion criteria for target population<br>(2)Communication with facilitators, patient & obtain informed consent.<br>(3)Epidural placement by anesthesia providers<br>(4) Measuring outcomes, document method of delivery, timeline.<br>From initial epidural placement until hospital discharge, adverse events, and outliers for exclusion | The participants Laboring obese parturients with BMI =/> than 30/$m^2$, projected sample size n=212<br><br>Site University of Missouri Healthcare system, Women & Children`s Hospital<br><br>Time Frame<br>3-6 month interval<br>August 2015-January 2016<br><br>Consent Needed or other<br>IRB & Informed Consent<br>Person(s) collecting data<br>(5) Nurse anesthestists<br>Others directly involved.<br>Labor & Delivery | (Completed as a student).<br><br>Method of delivery, Adverse events, regional versus general anesthesia, maternal pain scores, apgar scores, length of hospitalization<br><br>Statistical analysis to be used.<br>Descriptive statistics, Power analysis, ANOVA, Chi square | Outcomes to be measured (past DNP student time).<br>Development of protocals, practice guidelines for early neuraxial intervention for the obese parturient.<br>Further studies to support intervention findings and conclusions | Outcomes that are potentials (past DNP student)<br>Influence and develop practice guidelines regional and national level, supported by the American Society of Anesthesiologists(ASA)<br>National Patient Safety Foundation , American Association of Nurse Anesthetists (AANA)<br>Grant funding for extension research to replicate intervention with larger sample size |

| | | | | | |
|---|---|---|---|---|---|
| | | Nurses, Obstetricians, Statistician | | | |

http://www.uwex.edu/ces/lmcourse/interface/coop_M1_Overview.htm

Logic-Model Worksheet content revisions by Lyla Lindholm, Applied to DNP EBP Project. Not to be placed on web for public used. For UMKC DNP coursework only.

Appendix F:
Early Neuraxial Intervention in Obese Parturients to Determine Maternal and Fetal Outcomes
Retrospective Analysis




Adapted from R. Endicott DNP. Intervention Implementation Plan Flow Diagram (2013).

# Appendix G: IRB Approval

August 24, 2015
Principal Investigator: Sheila Barrett Ray
Department: Anesthesiology
Your Data Analysis Application to project entitled Maternal and Fetal Outcomes with Early Neuraxial Engagement in the Obese Parturient was reviewed and approved by the MU Institutional Review Board according to the terms and conditions described below:
IRB Project Number 2003357
IRB Review Number 207231
Initial Application Approval Date August 24, 2015
IRB Expiration Date August 24, 2016
Level of Review Expedited
Project Status Record Review
Expedited Categories 45 CFR 46.110.a(f)(5)
Risk Level Minimal Risk
Type of Consent Waiver of Consent
The principal investigator (PI) is responsible for all aspects and conduct of this study. The PI must comply with the following conditions of the approval:
1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date.
2. All unanticipated problems, adverse events, and deviations must be reported to the IRB within 5 days.
3. All changes must be IRB approved prior to implementation unless they are intended to reduce immediate risk.
4. All recruitment materials and methods must be approved by the IRB prior to being used.
5. The Continuing Review Report (CRR) must be submitted to the IRB for review and approval at least 30 days prior to the project expiration date. If the study is complete, the Completion/Withdrawal Form may be submitted in lieu of the CRR.
6. Maintain all research records for a period of seven years from the project completion date.
7. Utilize the IRB stamped consent documents and other approved research documents located within the document storage section of eCompliance. These documents are highlighted green.

If you have any questions, please contact the IRB at 573-882-3181 or

irb@missouri.edu.

# Appendix H:
# Measurement Tools/ Permission for Tools

1.Numerical Rating Score (NRS): Permission to utilize the NRS in research and clinical practice is granted by the author, Jean Solodiuk PHD.
2. Donabedian Model: Permission to utilize the model is requested by publisher JohnWiley and Sons. 111 River Street, Hoboken, N.J.07030 Phone: 201-748-6000 Contacted Permissions Department 3/20/2016,

Appendix I:
Table 1 Data Collection Template/ Retrospective Analysis

| **Date** | **Entry** | **Admission (Days)** | **Insurance** | **Neuraxial** | **BMI** | **Gravida** | **Age (Years)** | **Dilation (cm)** | **Vaginal (Y) (N)** | Caesarean (Y) (N) | NPS Scores |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

| Continued | **Umbilical PH** | **Apgar Scores** | **Post neuraxial pain scores** | **Anesthesia CS (Type)** | **Complications** | **Comments** |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

# Appendix J:
# Statistical Analysis Tables

**Table 1**. Sample description, N=212. Maternal and Fetal Obstetric Characteristics

| | **N** | **Mean(sd)** | **Median (Range)** |
|---|---|---|---|
| Patient Characteristics | | | |
| Age | 212 | 27.48(5.65) | 28.00(18-42) |
| BMI | 212 | 34.63(4.69) | 33.50(30-62) |
| Gravida | 212 | 2.70(1.78) | 2.00(1-10) |
| Insurance Type (N;%) | | | |
| Government | 133 | (62.7%) | |
| Self | 3 | (1.4%) | |
| Private | 72 | (34.0%) | |
| Not Insured | 4 | (1.9%) | |
| Delivery Characteristics | | | |
| Vaginal delivery (N;%) | 169 | 79.7% | |
| Cesarean delivery | 41 | 19.3% | |
| No delivery | 2 | .9% | |
| Type of Anesthesia Received (N;%) | | | |
| CSE | 138 | 65.1% | |
| No Anesthesia | 25 | 11.8% | |
| Failed Epidural | 1 | .5% | |
| Epidural | 45 | 21.2% | |
| General | 1 | .5% | |
| Did not give birth | 2 | .9% | |
| Placement Timing | | | |
| Early Placement | 75 | 35.4% | |
| Late Placement | 111 | 52.4% | |
| No Epidural | 25 | 11.8% | |
| Dilation | | | |
| Dilation (CM) | 211 | 3.86(1.66) | 4.00(0-9) |
| Dilation (Categorical) | | | |
| 0-3 cm | 80 | 37.7% | |
| 4+ cm | 131 | 61.8% | |
| Umbilical PH | 18 | 7.42(.63) | 7.30(7.09-9.90) |
| Pain Score (1-minute) | 206 | 7.46(2.42) | 8.00(0-10) |
| Pain Score (5-minutes) | 86 | .84(1.86) | 0(0-10) |
| Length of Hospitalization | 212 | 2.00(3.12) | 2.80(1-32) |

**Table 1**. Sample description, N=212. Maternal and Fetal Obstetric Characteristics (Continued)

| | | | |
|---|---|---|---|
| Fetal Health | | | |
| Apgar 1-minute | 207 | 7.19(1.99) | 8.00(0-9) |
| Apgar 5-minute | 202 | 8.37(1.35) | 9.00(0-10) |
| Apgar 1-minute (Twins) | 3 | 6.00(2.00) | 6.00(4-8) |
| Apgar 5-minute (Twins) | 3 | 7.67(1.53) | 8.00(6-9) |
| Complications (N;%) | | | |
| VBAC | 10 | 4.7% | |
| TOLAC | 2 | .9% | |
| VBAC or TOLAC | 12 | 5.7% | |
| Hemorrhage | 11 | 5.2% | |
| Shoulder Dystocia | 12 | 5.7% | |
| Forceps or Vacuum assisted delivery | 6 | 2.8% | |
| Fetal intolerance/ Caesarean delivery | 5 | 2.4% | |
| Difficult epidural placement | 7 | 3.3% | |
| Discharged (did not deliver) | 2 | .9% | |
| NICU Admission | 2 | .9% | |
| 1+ Complications | 50 | 23.6% | |
| NOTE: Twins counted only once – first twin | | | |

**Table 2.** Bivariate assessment of the relationship between early neuraxial placement in obese parturients and maternal and fetal health outcomes. (ANOVA`s)

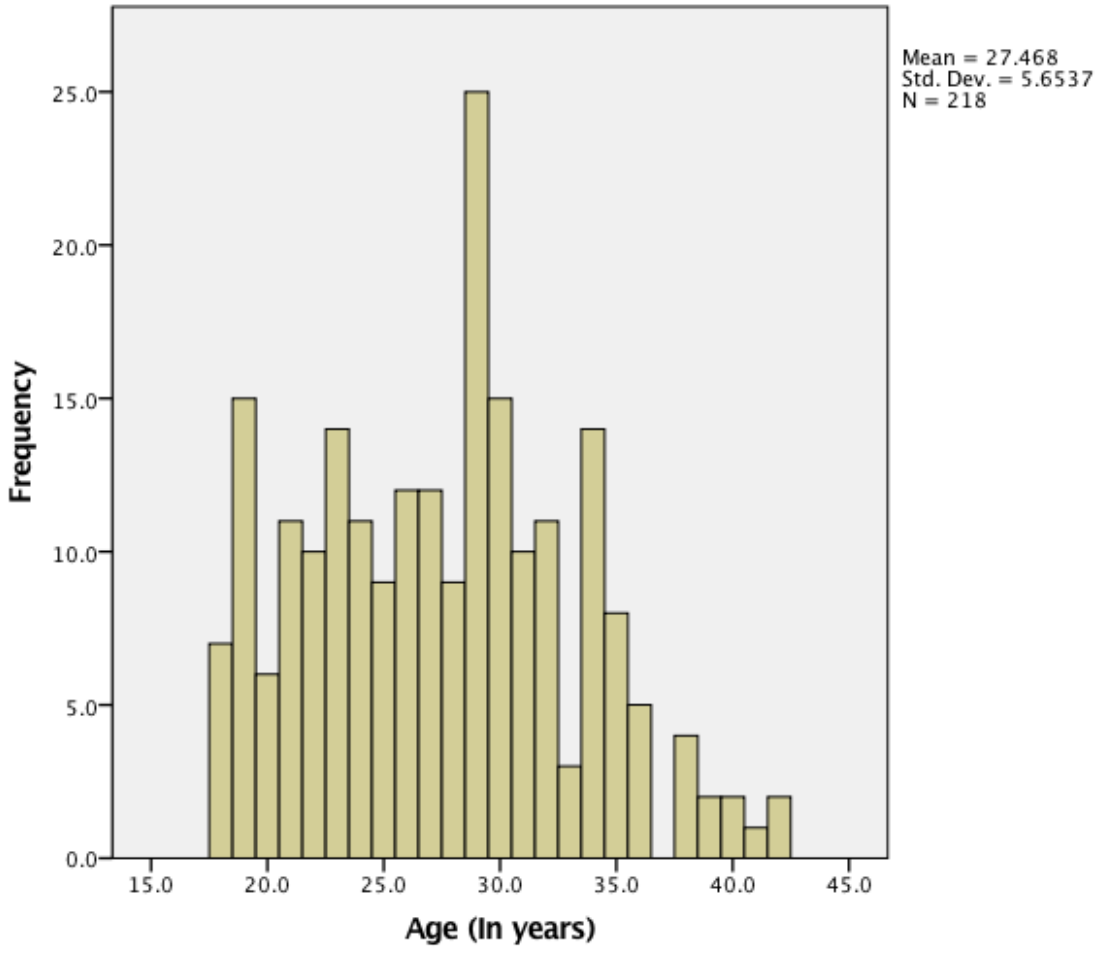
| | Early Placement N=75 N(%) | Late Placement N=111 N(%) | No Epidural N=25 N(%) | $x^2$ | *p* |
|---|---|---|---|---|---|
| Fetal Complications | | | | | |
| VBAC | 1(1.3%) | 8(7.2%) | 1(4.0%) | 3.321 | .170 |
| TOLAC | 1(1.3%) | 1(.9%) | 0(0%) | .724 | 1.000 |
| Hemorrhage | 3(4.0%) | 4(3.6%) | 4(16.0%) | 5.309 | .062 |
| Shoulder Dystocia | 4(5.3%) | 5(4.5%) | 3(12.0%) | 2.274 | .333 |
| Forceps or Vacuum assisted delivery | 4(5.3%) | 2(1.8%) | 0(0%) | 2.073 | .315 |
| Fetal intolerance | 5(6.7%) | 0(0%) | 0(0%) | 7.483 | .012 |
| Difficult epidural placement | 3(4.0%) | 4(3.6%) | 0(0%) | .533 | .876 |
| NICU Admission | 0(0%) | 0(0%) | 2(8.0%) | 7.371 | .014 |
| Number of Complications | | | | | |
| 0 | 53(70.7%) | 93(83.8%) | 15(60.0%) | 12.455 | .007 |
| 1 | 21(28.0%) | 18(16.2%) | 8(32.0%) | | |
| 2 | 1(1.3%) | 0(0%) | 2(8.0%) | | |
| | Mean(SD) | Mean(SD) | Mean(SD) | ***F*** | ***p*** |
| Fetal Health | | | | | |
| Apgar 1-minute | 7.19(1.84) | 7.18(2.04) | 7.21(2.30) | .002 | .998 |
| Apgar 5-minute | 8.37(1.17) | 8.43(1.28) | 8.08(2.02) | .657 | .519 |
| Umbilical PH | 7.24(.11) | 7.26(.10) | 7.75(1.06) | 1.299 | .302 |
| Maternal Health | | | | | |
| Length of Hospitalization | 2.87(1.52) | 2.98(4.09) | 1.80(.87) | 1.487 | .228 |
| Pain (Pre) | 7.45(2.69) | 7.45(2.38) | 7.50(1.75) | .004 | .996 |
| Pain (Post) | .85(2.06) | .74(1.60) | .00(0) | .134 | .875 |

**Table 3.** Bivariate assessment of the relationship between cervical dilation in obese parturients and maternal and fetal health outcomes.

| | Dilated 0-3cm N=80 N(%) | Dilated 4+cm N=131 N(%) | $x^2$ | *p* |
|---|---|---|---|---|
| Complications | | | | |
| VBAC | 2(2.5%) | 8(6.1%) | 1.565 | .325 |
| TOLAC | 1(1.3%) | 1(.8%) | .122 | .727 |
| VBAC or TOLAC | 3(3.8%) | 9(6.9%) | .954 | .329 |
| Hemorrhage | 4(5.0%) | 7(5.3%) | .012 | 1.00 |
| Shoulder Dystocia | 4(5.0%) | 8(6.1%) | .115 | .734 |
| Forceps or Vacuum assisted delivery | 4(5.0%) | 2(1.5%) | 2.089 | .148 |
| Fetal intolerance to labor | 5(6.3%) | 0(0%) | 9.898 | .007 |
| Preeclampsia | 4(5.0%) | 2(1.5%) | 2.089 | .203 |
| Difficult epidural placement | 3(3.8%) | 4(3.1%) | .074 | 1.00 |
| Fetal mortality | 0(0%) | 2(1.5%) | 1.918 | .527 |
| NICU Admission | 0(0%) | 2(1.5%) | 1.918 | .527 |
| Number of Complications | | | | |
| 0 | 56(60.0%) | 106(80.9%) | 3.741 | .142 |
| 1 | 23(28.7%) | 23(17.6%) | | |
| 2 | 1(1.3%) | 2(1.5%) | | |
| Fetal Health | Mean(SD) | Mean(SD) | *t* | *p* |
| Apgar 1-minute | 7.20(1.81) | 7.19(2.10) | .058 | .957 |
| Apgar 5-minute | 8.36(1.17) | 8.38(1.45) | -.131 | .896 |
| Umbilical PH | 7.24(.10) | 7.48(.73) | -.739 | .471 |
| Maternal Health | | | | |
| Length of Hospitalization | 2.85(1.15) | 2.77(3.80) | .143 | .886 |
| Pain (Pre) | 7.42(2.62) | 7.50(2.30) | -.232 | .817 |
| Pain (Post) | .97(2.18) | .74(1.60) | .569 | .571 |

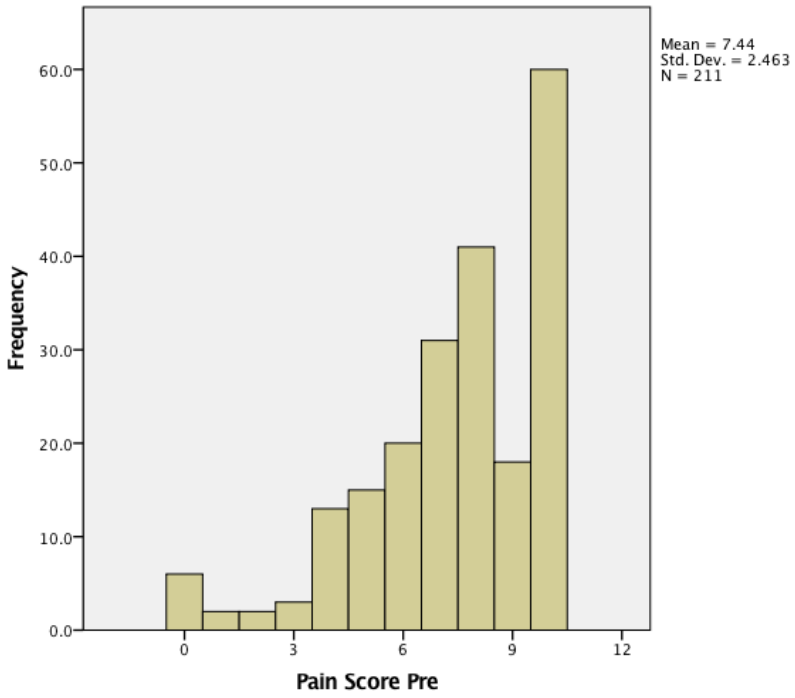
Those dilated 0-3cm were more likely to have fetal intolerance than expected by chance. Those dilated 4+cm were less likely to have fetal intolerance that would be expected by random chance.

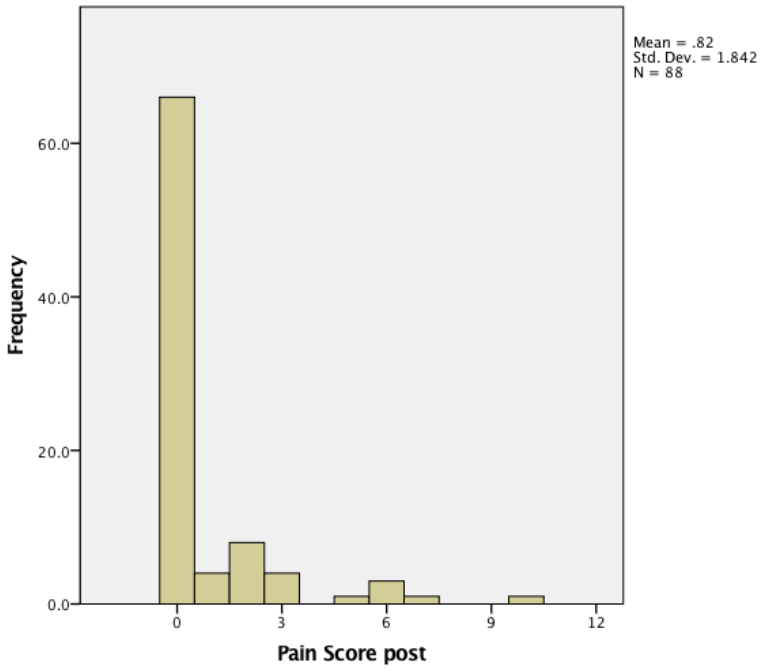
Appendix K
Age Demographics



Appendix L

Pain Scores



# Appendix M:
# UMKC IRB

## NOTICE OF EXEMPT DETERMINATION

Principal Investigator: Lyla Lindholm
UMKC Health Sciences Building
Kansas City, MO 64108
Protocol Number: 15-338
Protocol Title: Maternal and Fetal Outcomes with Early Neuraxial Engagement in Obese Parturients
Type of Review: Exempt
**Date of Determination: 09/09/2015**

Dear Dr. Lindholm,

The above referenced study was reviewed and determined to be exempt from IRB review and approval in accordance with the Federal Regulations 45 CFR Part
46.101(b).

This study was classified as exempt in accordance with exemption criteria #4 in the Federal Guidelines 45 CFR Part 46 as follows: "Research involving the collection or
study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by
the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects."

This determination includes the following documents:

**Attachments**

irb_approval_letter_aug-08-2015 (1)
Proposal Approval Committe Letter, Ray, 07 17 2015
2003357hipaa_waiver_of_authorization approval
Data Collection Template 09 03 2015
DNP Methods, Ray, 09 03 2015
HIPAA_Waiver_of_Authorization (2)
SUB PART B UMKC, 08 31 2015

You are required to submit an amendment request for all changes to the study, to prevent withdrawal of the exempt determination for your study. When the study is
complete, you are required to submit a Final Report.

Please contact the Research Compliance Office (email: umkcirb@umkc.edu; phone: (816)235-5927) if you have questions or require further information.

Thank you,
Simon MacNeill
UMKC IRB

**UMKC**
**5319 Rockhill Road**
**Kansas City Missouri**
**TEL: 816 235-5927**
**FAX: 816 235-5602**