Optimizing Strategies to Enhance the Analgesia, Quality and Safety of Maternal Fetal Care During Labor and Delivery

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<table>
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<th>Citation</th>
<th>Chau, Anthony. 2016. Optimizing Strategies to Enhance the Analgesia, Quality and Safety of Maternal Fetal Care During Labor and Delivery. Master’s thesis, Harvard Medical School.</th>
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Introduction

The labor and delivery unit is a unique environment where anesthesiologists interact and collaborate with multiple professional groups to provide care for parturients and their fetuses; the delivery process is also a dramatic and unique experience for women, which can result in significant pain, morbidity and mortality. The focus of this thesis is to determine strategies to optimize existing processes and techniques to enhance the analgesia, quality and safety of maternal fetal care during labor and delivery.

Limitations in communication and teamwork processes have been cited as the most common contributors to maternal and perinatal mortality and morbidity. For example, more than one-third of anesthesia-related cases of newborn death or brain damage involved poor communication between the obstetricians and anesthesiologists. In 2005, labor and delivery (L&D) physician and nursing leaders at the Brigham and Women’s Hospital instituted structured interprofessional rounds (SIPRs) as a mechanism to improve team communication and teamwork. Although the implementation of SIPRs physically brings teams together, poor perceptions of the value of such rounds can affect attendance, hinder teamwork, and affect patient outcomes. A number of studies have demonstrated that anesthesiologists share differing perceptions of the quality of communication in the operating room environment with other providers. Thus, understanding providers’ perceptions of SIPR can further optimize communication and teamwork, ultimately leading to improved patient safety.
In addition to optimizing existing teamwork processes, providing safe, high quality analgesia without harm to mother and fetus is an important mission of the anesthesiologist. Currently, epidural techniques are the most effective form of analgesia during labor and are used in approximately 70% of parturients undergoing labor and delivery in the United States. Two types of epidural analgesia techniques are available – the standard epidural analgesia technique and the combined-spinal epidural analgesia technique; each technique has its own benefits and risks. For example, the standard epidural analgesia technique has a long history of use and safety profile, however, it is slow in onset, making it an unsuitable choice for a patient with rapidly progressing labor; by contrast, combined-spinal anesthesia technique provides analgesia that has significantly faster onset and improved bilateral and sacral coverage, but is also associated with a few maternal side effects and fetal bradycardia. As such, there is a clinical need to optimize neuraxial techniques to provide more effective and safe labor analgesia.

In our first study, we explored whether the perceptions of SIPRs improve teamwork among a multidisciplinary labor and delivery team at the Brigham and Women’s Hospital. We demonstrated that although all providers perceive SIPRs favorably, higher mean scores were given by obstetricians and nurses (versus anesthesiologists and midwives), and providers with greater than 10 years of practice (versus less than 10 years). These observations provide a foundation for the development of educational strategies to target specific groups as a method of improving teamwork.
In our second study, we explored the use of a novel method of neuraxial analgesia called the dural-puncture epidural technique and compared it to two conventional forms of neuraxial analgesia on maternal and fetal efficacy and safety outcomes. We demonstrated that dural-puncture epidural technique has significantly higher incidence of analgesia that is faster onset, with greater bilateral and sacral spread when compared to standard epidural technique, and a significantly lower incidence of pruritus, need for supplemental analgesia and combined uterine tachysystole and hypertonus compared to the combined-spinal epidural technique. These findings demonstrate that the dural-puncture epidural technique offers greater maternal and fetal advantages compared to existing techniques, providing an ideal combination of safe and high quality labor analgesia.
Cross-disciplinary Perceptions of Structured Interprofessional Rounds in Promoting Teamwork within an Academic, Tertiary Care Obstetric Unit

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Conflicts of Interest: None
**Funding:** Departmental

**Conflict of interests:** None of the authors have any conflict of interests to declare.

**Word counts:**
Abstract: 278
Main text without reference: 2869

**Clinical trial number and registry URL:** NCT02368535  
[https://clinicaltrials.gov/ct2/show/NCT02368535](https://clinicaltrials.gov/ct2/show/NCT02368535)

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Abstract

Background: In 2005, physician and nursing leaders at Brigham and Women’s Hospital initiated structured interprofessional rounds (SIPRs) on the labor and delivery (L&D) suite to improve team communication.

Objective: The purpose of this study was to assess providers’ perceptions of SIPRs and their effectiveness in improving teamwork. We hypothesized that all providers would perceive SIPRs as being effective in promoting teamwork but ratings would differ among professional groups.

Study Design: After a factor analysis and reliability check, a 19-item questionnaire was used to evaluate perceptions of SIPRs on promoting teamwork using a five-point Likert scale. Respondents included L&D nurses, midwives, obstetricians, and anesthesiologists who participate in SIPRs. Intergroup differences were assessed by ANOVA with Bonferroni correction. The primary outcome was provider groups’ perception of the effectiveness of SIPRs in promoting teamwork as measured by mean total response scores. Higher mean total response scores indicated stronger agreement that SIPRs are effective in promoting teamwork.

Results: A total of 234 practitioners responded (100% response rate). Obstetricians had significantly higher mean total response scores than anesthesia (p<0.001) and midwife providers (p=0.039). Nursing providers had significantly higher mean total response scores than anesthesia providers (p<0.001). Providers gave higher mean total response
scores if they had >10 years of professional practice (p=0.003) and worked >10 years on L&D (p=0.025), but significantly lower scores if they had worked >60 clinical hours per week (p=0.001).

**Conclusion:** All providers perceived SIPRs as being effective in promoting teamwork. Greater ratings of SIPRs were associated with four provider characteristics: 1) obstetric and nurse providers, 2) >10 years of practice in their profession, 3) >10 years of experience on L&D and 4) working <60 clinical hours per week.

**Key Words:** Interprofessional rounds, communications, teamwork, patient safety, labor and delivery unit.
Introduction

The Institute of Medicine (IOM), through the publication of two landmark position papers in 2001, indicated a crisis in health care quality resulting from medical mistakes and communication problems.\textsuperscript{1, 2} In response, the Joint Commission on Accreditation of Healthcare Organizations (JACHO), the National Quality Forum (NQF) and the Agency for Healthcare Research and Quality (AHRQ) advocated for the development and implementation of methods to improve interprofessional communication, programs for team-based training, and metrics for evaluating performance quality.\textsuperscript{3-5}

Limitations in communication and teamwork have been cited as the most common contributors to maternal and perinatal mortality and morbidity.\textsuperscript{6-8} In 2005, labor and delivery (L&D) physician and nursing leaders at the Brigham and Women’s Hospital, a 798-bed tertiary care hospital, instituted structured interprofessional rounds (SIPRs) to improve team communication and patient safety. The SIPRs were named “Safon Rounds” to commemorate an obstetrician who focused on improving patient outcomes; the rounds emphasize a non-hierarchical environment where providers initially communicate information in a structured way followed by open dialogue period to share patient care concerns. Since their inception, the SIPRs occur twice a day, seven days a week, in front of a board displaying all patients; multidisciplinary providers from nursing, obstetrics, midwifery, and anesthesia services including attending faculty, fellows and residents are involved. Nursing staff lead the discussion of each patient using an “SBAR” (situation, background, assessment, recommendation) approach,\textsuperscript{9} followed by a discussion of concerns and care plans among providers. Unique elements of the SIPRs are outlined in Table 1.
Although the implementation of SIPRs creates an opportunity for multidisciplinary communication,\textsuperscript{10} the resulting collaboration can be marked by poor attendance and limited perceived value to teamwork and subsequent patient safety.\textsuperscript{11,12} The purpose of this study was to assess the effectiveness of SIPRs in promoting teamwork. Using a 19-item questionnaire developed to evaluate specific knowledge, skill and attitude domains important to teamwork, we hypothesized that our providers would perceive SIPRs as being effective in promoting teamwork. The primary outcome was the perception of SIPRs by each provider group as measured by mean total response scores. Secondary outcomes included the difference in mean total response scores based on duration of professional experience, duration of L&D experience, number of clinical work hours worked per week and for nurses, the principle shift assignment (e.g., day, evening, night), and four knowledge, skill and attitude domains. In addition, we compared the mean total response scores on eight items present in the current questionnaire and a quality assurance questionnaire administered in 2008.

**Material and Methods**

**Design and Setting**

Our Institutional Research Board (IRB) approved the present study with a waiver for written informed consent; the study was registered with ClinicalTrials.gov (NCT02368535). In 2008, three years following the implementation of the SIPRs at the Brigham and Women’s Hospital L&D suite, a questionnaire containing 11 items was distributed to all L&D providers; the current 19-item questionnaire included eight items from the survey completed in 2008 (see appendix).
Study Population

From January to April 2015, all providers who actively participate in and/or supervise direct patient care on the L&D suite were surveyed; attendance at SIPRs is mandated for all providers (including fellows and senior residents) involved in clinical patient care. Leaders from nursing, midwifery, obstetric, and anesthesia submitted membership lists and these were used to identify all eligible providers. The list for nursing staff also contained shift assignments (i.e., day (7am-7pm), evening (3pm-11pm), and night (7pm-7am)). Subjects were invited to complete the questionnaire immediately following participation in the SIPRs; questionnaires were completed anonymously, however, participant names were removed from membership lists upon survey completion to eliminate duplicate sampling. No incentives were offered for questionnaire completion.

Survey Content and Weight

Demographic information included academic training, professional role, number of years and working hours per week on the L&D suite, and number of years in current profession defined as the time from professional credential completion to time of survey for Medical Doctor (MD), Doctor of Osteopathy (DO), Registered Nurse (RN) or Certified Nurse Midwife (CNM).

A five-point Likert scale was assigned to each of the items (1=strongly disagree 2=disagree 3=neutral 4=agree 5=strongly agree). An opt-out choice, “not sure,” was also
provided for each item to minimize incomplete responses; providers were also encouraged to include written comments at the end of the questionnaire.

Survey Reliability and Validity

A 25-item questionnaire was developed based on selected knowledge, skill and attitude domains; the definition and examples of these domains have been outlined previously.\cite{12} The face validity of the survey questions was assessed through a focus group amongst three anesthesiology and two nursing providers. The initial questionnaire included 8 items that used the same methodology and Likert scale from a 2008 pilot survey, the results of which were retained as an internal document for quality improvement. An exploratory factor analysis allowed all 25 questions to be efficiently distributed into four latent constructs that were labelled with the corresponding knowledge, skill and attitude domains: 1) Adaptability and Communication; 2) Backup Behavior; 3) Shared Mental Model; and 4) Team/Collective Orientation. Six items exhibited lower factor loading scores (<0.40) indicative of being redundant or ambiguous and were removed. All study investigators and a group of senior L&D suite administrators then evaluated the revised 19-item questionnaire for content validity, with all items being approved.

The final questionnaire was distributed to all L&D providers and a confirmatory factor analyses was performed for construct validity. Comparative fit index and standardized root mean square residual were used to evaluate the model fit of confirmatory factor analysis. The internal consistency (reliability) of the questionnaire and each latent factor were examined using Cronbach’s coefficient $\alpha$ and Guttman's Lambda 4. (Table 2)
**Statistical analysis**

ANOVA test was used to examine differences in mean total response scores by professional roles, years in current profession, years worked on L&D, weekly working hours, and shift hours. Post-hoc pair-wise comparisons with Bonferroni correction were used to assess the intergroup differences in mean total response scores. The median score of each question was used to impute cases where a response was missing. The eight items on the prior and current survey were compared using equal variance t-test. Data were analyzed using the R software (version 3.1.2).

**Results**

A total of 234 providers were approached; all providers completed the questionnaire producing a response rate of 100%. Six providers were not approached, consisting of two obstetric senior residents who were completing off-site rotations, one midwife who was on maternity leave, and three nurses who were not scheduled to work during the sampling timeframe. A total of 0.8% and 1.2% of responses were missing or marked as ‘not sure’, respectively. The comparative fit index and standardized root mean square residual for the questionnaire were 0.94 and 0.050, respectively. The Cronbach’s coefficient $\alpha$ and Guttman's Lambda 4 were 0.94 and 0.97.

Baseline demographics by professional roles are summarized in Table 3. A greater percentage of physician providers (obstetricians and anesthesiologists) practiced in their profession and worked on the L&D for $\leq$10 years, reflecting the fellow and senior
resident component. In contrast, a greater percentage of nurses practiced in their profession and worked on L&D for >10 years.

With higher mean total response scores indicating more favorable perceptions of SIPRs, the mean score (SD) for all provider groups was 73.3(9.5). Obstetricians had the highest mean score of 78.8(10.4), with anesthesiologists [68.9(13.0), p<0.001] and midwives [70.4(5.7), p=0.032] having significantly lower scores. Nursing providers had a significantly higher mean score [76.3(9.6), p<0.001] compared to anesthesiologists. Providers had higher mean scores if they had >10, compared to ≤10 years of professional practice [76.5(9.6) vs. 72.0(12.5), p=0.002] and worked >10, compared to ≤10 years on L&D [76.4(9.5) vs. 73.1(9.5) p=0.022]. Providers who worked ≤20 hours weekly had the highest mean scores [81.5(8.0)]. Mean scores were lower, but no different, for those who worked 21-40 hours [75.4(9.5)] or 41-60 hours [77.7(9.6)] weekly; the mean score was lowest for providers who worked >60 hours per week [69.3(14.1), p<0.005]. (Figure 1)

When the mean scores for knowledge, skill and attitude domains were compared between professional roles, anesthesiologists scored significantly lower except for the shared mental model element. Midwives responded significantly lower compared to nursing and obstetricians in the category of team/collective orientation (p<0.001). Providers who worked >10 versus ≤10 years in their professions had greater mean scores in all domains except the shared mental model element (p=0.56); providers who had practiced >10 versus ≤10 years on L&D had similar patterns. Finally, providers who worked >60 hours weekly had significantly lower mean scores across all four domains; no significant differences were found between those who worked ≤20, 21-40 or 41-60 hours weekly. (Tables 4 and 5)
A significantly higher mean score (SD) was obtained in the current study for the eight questions originating from the 2008 survey [30.4 (2.9) vs. 28.4(3.4) p <0.00001].

**Comment**

In this prospective cross-sectional analysis, all providers perceived SIPRs to be effective in promoting teamwork. Greater total response mean scores were associated with four provider characteristics: 1) obstetrician and nurses, 2) >10 years of practice in their profession, 3) >10 years of experience on L&D, and 4) working <60 hours per week on L&D.

Our findings are consistent with studies demonstrating that SIPR implementation enhances perceptions of collaboration and teamwork in a variety of hospital settings across a wide spectrum of providers.\(^{13-16}\) Investigations evaluating the mechanism by which SIPRs improve teamwork appear to highlight the creation of opportunities for different disciplines to jointly share and solve problems.\(^{13-16}\) However, the teamwork demonstrated within SIPRs can be altered by elements in the workplace environment, professional role held within a team, and seniority in the profession.\(^{17}\)

Discrepancies in the perceived effectiveness of interdisciplinary teamwork often stem from dissatisfaction with the quality of the physician-nurse relationship among nursing providers.\(^{18,19}\) Nurse dissatisfaction can originate from perceptions of being relegated to a subordinate role, having few opportunities to offer perspectives, and possessing limited input in decision-making.\(^{19}\) In our study, physicians and nurses gave similar, high mean scores for SIPR effectiveness in promoting teamwork; we believe the elemental framework of our SIPRs to be at least partially responsible for these results.
We disrupt traditional, physician-nurse patterns by having nursing leaders coordinate SIPR conduct and staff nurses initiate the presentations on each patient. In addition, the SIPR timing (i.e., 2 hrs after nursing work shift transitions) facilitates consistent, robust attendance by nursing staff, which likely explains the similarity in nursing scores regardless of work shift.

Among obstetric providers, midwives found SIPRs significantly less effective in promoting teamwork compared to obstetricians; more specifically, midwives provided lower mean scores for the team/collective orientation construct compared to obstetricians. These findings may reflect subtle, often poorly defined boundaries in philosophies, hierarchy, jurisdictions, and roles between the two groups; perceptions of trust, respect and autonomy likely vary among individual obstetric providers as well as obstetrician/midwife dyads. 20-22

Among physicians, anesthesiologists provided significantly lower mean scores for SIPRs promoting teamwork compared to obstetricians, with the lowest mean scores being given by those with \( \leq 10 \) years experience or working \( >60 \) work hours per week. Despite finding enjoyment in working on teams, 23 anesthesiologists frequently perceive the quality of teamwork present within perioperative interactions to be lower than other providers. 24 In a survey of 1033 operating room providers who provided assessments of errors, stress and teamwork, 62% of surgeons reported high levels of teamwork with anesthesiologists, but only 41% of anesthesiologists held a similar impression of surgeons. 24 These discrepancies may stem from differences in communication styles and the frequency of individual providers to work as a team member. Minehart et al. 25 found that anesthesiologists were more likely than obstetricians to make statements,
observations or opinions (i.e., advocate) and less likely to elicit information from other team members (i.e., inquire). Anesthesiologists, particularly residents, also provide care in diverse units throughout the hospital, resulting in fewer opportunities to form consistent, strong social core relationships as a team member (i.e., “team coreness”) with most other L&D providers who regularly provide clinical services on a single unit.\textsuperscript{26}

It was not surprising that the providers with greater than 10 years of professional practice and greater than 10 years on L&D gave higher scores the effectiveness of SIPRs in promoting teamwork; the particularly robust association with nursing providers may reflect the higher proportion with greater years of service (Table 3). Team coreness and culture familiarity are linked with higher productivity, greater efficiency and better decision making.\textsuperscript{27} For example, knowing the names of colleagues, and being able to predict his or her actions during crisis can affect the dynamics and perception of good teamwork.\textsuperscript{28,29}

In contrast to higher scores associated with increased years of service, lower scores were reported by providers working >60 clinical hours weekly (translating to >12 hours/day). Our findings are consistent with Kalisch et al.\textsuperscript{30}, who reported significantly lower teamwork scores in nursing staff working greater, versus less than, 30 hours weekly. Similarly, in a study evaluating teamwork in the United States, Japan and Taiwan, Wu et al.\textsuperscript{31} found significantly lower teamwork scores in nursing staff working ≥60 hours/week, compared to those working <40 hours/week. These perceptions have been attributed to longer hours being associated with greater fatigue and opportunities for miscommunication; Griffiths et al.\textsuperscript{32} found that nurses working ≥12 hours were more likely to perceive care as being of lesser quality and of greater concern to patient safety.
Similarly, studies performed on resident physician providers have demonstrated that shifts exceeding 12 to 16 hours increase miscommunication.\textsuperscript{33}

The presence of teamwork knowledge, skill and attribute domains within SIPRs has improved since our 2008 study, when a subset of identical questions was posed. Reasons for this change were not queried and thus remain speculative; however, ongoing positive experiences with interprofessional rounds have been observed to benefit overall communication and the culture of patient safety.\textsuperscript{34} The written comments indicated a number of issues that provide an opportunity for further improvements. First, the inability of all participants to reliably participate in SIPRs due to unpredictable clinical demands is a common sentiment that has been associated with lower teamwork scores.\textsuperscript{35} This issue should invoke specific provider-based plans about who can optimally translate information to and from the team (often times not the most senior practitioner), as well as identifying backup coverage; this underscores the importance of having the SIPRs at specific, consistent times (in our case at 10 am and 10 pm), so plans can be made.

Second, the presence of certain individual providers at SIPRs can positively or negatively influence the openness and quality of discussions; this stems from practitioners possessing and expressing significantly different values on team behaviors, information sharing and interprofessional socialization.\textsuperscript{36} Strategies and training methods should be developed to provide evaluation and feedback, promote positive role-modeling, improve leadership quality, and de-emphasize institutional hierarchical structures.\textsuperscript{37} Finally, practitioners are often observed to be profession-focused, rather than team- or patient-focused, with interactions based on stereotyped roles and behaviors.\textsuperscript{38-40} These discipline-specific expectations, roles and priorities have been attributed to the independent training
each professional group receives\textsuperscript{41}; the Institute of Medicine acknowledges that dismantling silo-based practices will require significant investment in joint curricula, experiences and evaluation processes that promote training team-, population- and patient-centered care. \textsuperscript{42}

Improvement in workplace communication, relationships, and teamwork require acceptance and attention to these issues.\textsuperscript{43} Hospitals, health care organizations, and regulatory agencies are beginning to focus on teamwork as a strategy and tool to enhance patient safety (e.g., TeamSTEPPS); such efforts emphasize three distinct teamwork competencies: shared mental models, mutual trust and closed-loop communication.\textsuperscript{44} We propose that twice-daily SIPRs are a simple, inexpensive, and practical clinical method to assess, foster, and implement a culture of teamwork. Attention to key knowledge, skill and attitude domains within SIPRs should further enable the growth of team- and patient-based care.

Strengths of our study include the robust 100% response rate with full representation of all the providers on our labor and delivery suite, the high internal consistency of our survey instrument and the use of knowledge, skill and attitude domains previously identified as being relevant to teamwork.\textsuperscript{12} However, we acknowledge a few limitations. First, the study was performed within a single, academic institution with a 10-year history of conducting SIPRs, which may limit the generalizability of our findings. Second, the study questions were constructed with scoring in a single direction, fixed pattern Likert scale, which may introduce acquiescence bias.\textsuperscript{45} Third, we were only able to assess certain knowledge, skill and attitude domains known to improve teamwork; other domains such as closed-loop
communications are better measured using other methods such as simulation studies.\textsuperscript{12} Finally, we did not specifically examine our findings in relation to specific patient outcomes; such correlation studies would require discrete interventions, specific patient outcome measures, and a larger epidemiologic analyses.\textsuperscript{46}

Effective teamwork on the labor and delivery suite requires effective interprofessional communication and collaboration. SIPRs offer a distinct opportunity for professionals to enhance their work together. Measurement of the knowledge, skill and attribute domains present in SIPRs that promote good teamwork can allow providers to develop strategies for improvement. We conclude that provider factors, including their specific profession, the numbers of years worked in the field and in labor and delivery, as well as the number of hours worked per week, can alter perceptions of teamwork. Future studies should ultimately link provider and patient perceptions of SIPRs to patient outcomes.

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Figure Legend:

Figure 1. Providers’ perceptions of SIPRs on promoting teamwork. Mean total response score with standard deviations obtained from the 25-item questionnaire are presented. All p values are adjusted based on Bonferroni correction. All p values are adjusted based on Bonferroni correction.
Table 1. Elements of SIPRs at Brigham and Women’s Hospital L&D Suite

<table>
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<th>Unique Characteristics:</th>
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<tr>
<td>• Established for over ten years with regular internal quality assurance projects to refine system.</td>
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<td>• Communication of information in a structured way by nursing providers.</td>
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<td>• De-hierarchical and sharing leadership – charge nurse moderate session, trainees present patient information, nursing staff lead the discussion, obstetric and anesthesia providers generate patient plans.</td>
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<td>• Rounds occur in two parts, at two central nursing stations (East side, West side), maximum 12 patients on each side.</td>
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<th>Structures:</th>
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<td>• Structured time: hour-long (half-hour on each nursing station), twice daily (10 am, 10 pm), seven days a week.</td>
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<td>• Structured teams: multidisciplinary participation from nursing, obstetrics, midwifery, anesthesia.</td>
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<td>• Structured language (e.g. National Institute of Child Health and Human Development nomenclature for fetal monitoring interpretation, standardized measurement units and drug names) used by all team members.</td>
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<td>• Structured location: teams meet at the central nursing stations in front of electronic patient display board with summary of clinical information.</td>
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<tr>
<td>• Structured communication: discussion of concerns by nursing followed by care plans from obstetric, midwifery and anesthesia providers.</td>
<td></td>
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<tr>
<td>• Structured presentation: use of “SBAR” (situation, background, assessment, recommendation) approach by all nursing providers.</td>
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<th>Participants and Clinical Coverage during Rounds:</th>
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<tr>
<td>• Anesthesia providers: one fellowship-trained obstetric anesthesiologist and one fellow/senior resident are identified as the “team leaders” for all patients on the unit. Clinical coverage during rounds offered by a team of 6-8 anesthesia providers.</td>
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<tr>
<td>• Obstetric and midwifery providers: mixed academic and private providers; mixed individual and group practices. Clinical coverage during rounds offered by a team of 6-8 obstetric providers for the academic, but not private providers.</td>
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<tr>
<td>• Nursing providers: one-to-one nursing provider with charge nurse and nurse administrators. Clinical coverage during rounds organized by charge nurse to allow direct nurse providers to attend rounds.</td>
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<th>Attendance Scheme:</th>
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<tr>
<td>• Overhead, individual and group reminder paging to encourage attendance.</td>
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<tr>
<td>• Mandatory attendance by clinical attending, fellows and senior residents.</td>
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</table>
• Invited attendance by neonatal care providers and other consultants (e.g. cardiology, infectious diseases, neurology) as required.
• Attendance in full duration by nursing and physician leaders and administrators, charge nurse and anesthesia providers.
• Obstetric and nursing providers are always present for their own patient(s) but may not stay for the entire duration due to shared backup coverage to enable attendance at rounds.

Opportunities and Barriers:
• The robust use of checklists to guide patient discussions can limit informal, but important commentary or insights.
• The incorporation and value of clinical teaching often determined by the individual providers in attendance.
• Private obstetric providers with limited clinical backup coverage can have greater difficulty participating in rounds.
• The large number of providers in each profession can create significant variation in team composition and dynamics.
• Presence of intra-professional hierarchy may result in certain providers (i.e. new providers or junior trainees) feeling less comfortable sharing insights.
Table 2. Confirmatory factor analysis and internal consistency of final questionnaire.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Knowledge, Skill and Attitude Domains</th>
<th>Cronbach’s Coefficient $\alpha$</th>
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<td>1</td>
<td>Adaptability and Communication</td>
<td>0.89</td>
<td>0.92</td>
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<tr>
<td>2</td>
<td>Backup Behavior</td>
<td>0.80</td>
<td>0.82</td>
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<td>3</td>
<td>Shared Mental Model</td>
<td>0.84</td>
<td>0.77</td>
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<tr>
<td>4</td>
<td>Team / Collective Orientation</td>
<td>0.88</td>
<td>0.91</td>
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Table 3. Demographics by professional roles.

<table>
<thead>
<tr>
<th></th>
<th>Obstetrics (n=47)</th>
<th>Anesthesia (n=56)</th>
<th>Nursing (n=115)</th>
<th>Midwifery (n=16)</th>
<th>All Groups (n=234)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of academic training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor</td>
<td>1 (2.1)</td>
<td>1 (1.8)</td>
<td>59 (51.3)</td>
<td>1 (6.3)</td>
<td>62 (26.5)</td>
</tr>
<tr>
<td>Masters</td>
<td>1 (2.1)</td>
<td>2 (3.6)</td>
<td>16 (13.9)</td>
<td>13 (81.3)</td>
<td>32 (13.7)</td>
</tr>
<tr>
<td>PhD</td>
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<td>2 (3.6)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>5 (2.1)</td>
</tr>
<tr>
<td>MD/DO</td>
<td>42 (89.4)</td>
<td>50 (89.3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>92 (39.3)</td>
</tr>
<tr>
<td>RN</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>41 (35.7)</td>
<td>2 (12.5)</td>
<td>43 (18.4)</td>
</tr>
<tr>
<td>CNM</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>16 (100)</td>
<td>16 (6.8)</td>
</tr>
<tr>
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<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Years in Profession</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤10 years</td>
<td>25 (53.2)</td>
<td>45 (80.4)</td>
<td>19 (16.5)</td>
<td>3 (18.8)</td>
<td>92 (39.3)</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>22 (46.8)</td>
<td>10 (17.9)</td>
<td>96 (83.4)</td>
<td>12 (75.0)</td>
<td>140 (59.8)</td>
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<tr>
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<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (0.8)</td>
<td>1 (6.3)</td>
<td>2 (0.9)</td>
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<tr>
<td><strong>Years on L&amp;D unit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤10 years</td>
<td>28 (59.6)</td>
<td>46 (82.1)</td>
<td>29 (12.4)</td>
<td>7 (43.8)</td>
<td>110 (47.0)</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>18 (38.3)</td>
<td>9 (16.1)</td>
<td>86 (36.8)</td>
<td>8 (50.0)</td>
<td>121 (51.7)</td>
</tr>
<tr>
<td>Not sure</td>
<td>1 (2.1)</td>
<td>0 (0)</td>
<td>1 (0.4)</td>
<td>1 (6.3)</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td><strong>Clinical hours/week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤20</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
<td>11 (9.6)</td>
<td>0 (0)</td>
<td>12 (5.1)</td>
</tr>
<tr>
<td>21-40</td>
<td>6 (12.8)</td>
<td>8 (14.3)</td>
<td>98 (85.2)</td>
<td>14 (87.5)</td>
<td>126 (53.8)</td>
</tr>
<tr>
<td>41-60</td>
<td>18 (38.3)</td>
<td>18 (32.1)</td>
<td>5 (4.3)</td>
<td>1 (6.3)</td>
<td>42 (17.9)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>22 (46.8)</td>
<td>27 (48.2)</td>
<td>1 (0.8)</td>
<td>0 (0)</td>
<td>50 (21.4)</td>
</tr>
<tr>
<td>Not sure</td>
<td>1 (2.1)</td>
<td>1 (1.8)</td>
<td>1 (0.8)</td>
<td>1 (6.3)</td>
<td>4 (1.7)</td>
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<tr>
<td><strong>Shift Assignment</strong>b</td>
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<tr>
<td>Day</td>
<td>-</td>
<td>-</td>
<td>16 (13.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Swing</td>
<td>-</td>
<td>-</td>
<td>10 (8.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Night</td>
<td>-</td>
<td>-</td>
<td>31 (27.0)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>No fixed assignment</td>
<td>-</td>
<td>-</td>
<td>41 (35.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Not sure</td>
<td>-</td>
<td>-</td>
<td>17 (14.8)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Values are n (percentage of all participants). aSubjects may indicate more than one response. bNurses only. L&D = labor and delivery.
Table 4. Mean total response scores by knowledge, skill and attitude domains. Values are mean (SD).

<table>
<thead>
<tr>
<th>Total response score range</th>
<th>Adaptability and Communication</th>
<th>Backup Behavior</th>
<th>Shared Mental Model</th>
<th>Team / Collective Orientation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-40</td>
<td>14.92 (2.83)</td>
<td>12.75 (1.92)</td>
<td>17.47 (2.59)</td>
<td>78.78 (10.42)</td>
<td></td>
</tr>
<tr>
<td>4-20</td>
<td>12.79 (3.33)</td>
<td>12.04 (1.89)</td>
<td>15.1 (3.32)</td>
<td>68.87 (13.04)</td>
<td></td>
</tr>
<tr>
<td>3-15</td>
<td>14.71 (2.62)</td>
<td>12.22 (1.82)</td>
<td>16.97 (2.53)</td>
<td>76.30 (9.57)</td>
<td></td>
</tr>
<tr>
<td>4-20</td>
<td>11.62 (1.02)</td>
<td>14.19 (2.26)</td>
<td></td>
<td>70.38 (5.71)</td>
<td></td>
</tr>
<tr>
<td>19-95</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Professional Roles

- Obstetric: 33.65 (4.42), 14.92 (2.83), 12.75 (1.92), 17.47 (2.59), 78.78 (10.42)
- Anesthesia: 28.94 (5.76), 12.79 (3.33), 12.04 (1.89), 15.1 (3.32), 68.87 (13.04)
- Nursing: 32.40 (4.37), 14.71 (2.62), 12.22 (1.82), 16.97 (2.53), 76.30 (9.57)
- Midwifery: 30.38 (3.12), 14.19 (2.04), 11.62 (1.02), 14.19 (2.26), 70.38 (5.71)

### Years in Profession

- ≤10 years: 30.54 (5.60), 13.53 (3.17), 12.16 (1.92), 15.78 (3.21), 72.02 (12.53)
- >10 years: 32.54 (4.30), 14.77 (2.62), 12.31 (1.79), 16.93 (2.61), 76.54 (9.57)

### Years on L&D unit

- ≤10 years: 30.89 (5.57), 13.73 (3.25), 12.35 (1.87), 16.08 (3.15), 73.05 (12.41)
- >10 years: 32.53 (4.18), 14.81 (2.49), 12.18 (1.81), 16.87 (2.64), 76.39 (9.46)

### Clinical hours/week

- ≤20: 34.17 (3.83), 15.67 (1.97), 13.50 (1.68), 18.17 (2.59), 81.5 (7.97)
- 21-40: 32.06 (4.40), 14.60 (2.65), 12.10 (1.71), 16.67 (2.58), 75.44 (9.52)
- 41-60: 33.02 (4.23), 14.76 (2.79), 12.83 (1.65), 17.10 (2.54), 77.71 (9.67)
- >60: 29.38 (6.19), 12.88 (3.38), 11.88 (2.16), 15.14 (3.61), 69.28 (14.12)

Values are mean (SD). L&D = labor and delivery.
Table 5. Differences in mean total responses scores between professional roles by knowledge, skill and attitude domains.

<table>
<thead>
<tr>
<th>Professional Roles</th>
<th>Adaptability and Communication</th>
<th>$P$</th>
<th>Backup Behavior</th>
<th>$P$</th>
<th>Shared Mental Model</th>
<th>$P$</th>
<th>Team / Collective Orientation</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td>0.001</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Anesthesia</td>
<td>-4.7 [-7.13,-2.28]</td>
<td>&lt;0.001</td>
<td>-2.13 [-3.59,-0.68]</td>
<td>0.001</td>
<td>-0.71 [-1.65,0.24]</td>
<td>0.298</td>
<td>-2.37 [-3.79,-0.96]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nursing</td>
<td>-1.25 [-3.32,0.82]</td>
<td>0.678</td>
<td>-0.21 [-1.45,1.04]</td>
<td>1</td>
<td>-0.53 [-1.33,0.28]</td>
<td>0.513</td>
<td>-0.51 [-1.71,0.7]</td>
<td>1</td>
</tr>
<tr>
<td>Midwifery</td>
<td>-3.27 [-6.79,0.25]</td>
<td>0.09</td>
<td>-0.73 [-2.85,1.39]</td>
<td>1</td>
<td>-1.12 [-2.49,0.25]</td>
<td>0.195</td>
<td>-3.28 [-5.34,1.23]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td>&lt;0.001</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Nursing</td>
<td>3.46 [1.45,5.51]</td>
<td>&lt;0.001</td>
<td>1.92 [0.69,3.16]</td>
<td>&lt;0.001</td>
<td>0.18 [-0.62,0.98]</td>
<td>1</td>
<td>1.87 [0.67,3.07]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Midwifery</td>
<td>1.43 [-2.08,4.95]</td>
<td>1</td>
<td>1.4 [-0.72,3.51]</td>
<td>0.494</td>
<td>-0.41 [-1.78,0.96]</td>
<td>1</td>
<td>-0.91 [-2.96,1.14]</td>
<td>1</td>
</tr>
<tr>
<td>Nursing</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Midwifery</td>
<td>-2.02 [-5.31,1.26]</td>
<td>0.628</td>
<td>-0.53 [-2.5,1.45]</td>
<td>1</td>
<td>-0.59 [-1.87,0.69]</td>
<td>1</td>
<td>-2.78 [-4.69,0.86]</td>
<td>0.001</td>
</tr>
</tbody>
</table>

### Years in Profession

<table>
<thead>
<tr>
<th>Years in Profession</th>
<th>Adaptability and Communication</th>
<th>$P$</th>
<th>Backup Behavior</th>
<th>$P$</th>
<th>Shared Mental Model</th>
<th>$P$</th>
<th>Team / Collective Orientation</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 10</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td>1.99 [0.71,3.27]</td>
<td>0.003</td>
<td>1.24 [0.49,1.99]</td>
<td>0.001</td>
<td>0.14 [-0.34,0.63]</td>
<td>0.56</td>
<td>1.15 [0.39,1.9]</td>
<td>0.003</td>
</tr>
</tbody>
</table>

### Years on L&D unit

<table>
<thead>
<tr>
<th>Years on L&amp;D unit</th>
<th>Adaptability and Communication</th>
<th>$P$</th>
<th>Backup Behavior</th>
<th>$P$</th>
<th>Shared Mental Model</th>
<th>$P$</th>
<th>Team / Collective Orientation</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 10</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td>1.64 [0.37,2.9]</td>
<td>0.012</td>
<td>1.08 [0.34,1.83]</td>
<td>0.005</td>
<td>-0.16 [-0.64,0.31]</td>
<td>0.501</td>
<td>0.79 [0.04,1.53]</td>
<td>0.04</td>
</tr>
</tbody>
</table>

### Clinical hours/week

<table>
<thead>
<tr>
<th>Clinical hours/week</th>
<th>Adaptability and Communication</th>
<th>$P$</th>
<th>Backup Behavior</th>
<th>$P$</th>
<th>Shared Mental Model</th>
<th>$P$</th>
<th>Team / Collective Orientation</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 20</td>
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<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>21-40</td>
<td>-2.1 [-5.92,1.72]</td>
<td>0.886</td>
<td>-1.06 [-3.31,1.19]</td>
<td>1</td>
<td>-1.4 [-2.83,0.04]</td>
<td>0.066</td>
<td>-1.49 [-3.75,0.76]</td>
<td>0.493</td>
</tr>
<tr>
<td>41-60</td>
<td>-1.14 [-5.28,-3]</td>
<td>1</td>
<td>-0.9 [-3.34,1.53]</td>
<td>1</td>
<td>-0.67 [-2.22,0.89]</td>
<td>1</td>
<td>-1.07 [-3.51,1.37]</td>
<td>1</td>
</tr>
<tr>
<td>&gt;60</td>
<td>-4.79 [-8.85,-0.72]</td>
<td>0.013</td>
<td>-2.79 [5.18,-0.39]</td>
<td>0.014</td>
<td>-1.62 [-3.15,-0.09]</td>
<td>0.034</td>
<td>-3.03 [-5.43,-0.63]</td>
<td>0.006</td>
</tr>
<tr>
<td>21-40 hrs</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>41-60</td>
<td>0.96 [-1.29,3.21]</td>
<td>1</td>
<td>0.16 [-1.17,1.49]</td>
<td>1</td>
<td>0.73 [-0.12,1.58]</td>
<td>0.144</td>
<td>0.42 [-0.91,1.75]</td>
<td>1</td>
</tr>
<tr>
<td>&gt;60</td>
<td>-2.68 [-4.8,-0.57]</td>
<td>0.006</td>
<td>-1.72 [-2.97,-0.48]</td>
<td>0.002</td>
<td>-0.22 [-1.02,0.57]</td>
<td>1</td>
<td>-1.53 [-2.78,0.29]</td>
<td>0.008</td>
</tr>
<tr>
<td>41-60 hrs</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>&gt;60</td>
<td>-3.64 [-6.29,-1]</td>
<td>0.002</td>
<td>-1.88 [-3.44,-0.32]</td>
<td>0.01</td>
<td>-0.95 [-1.95,0.04]</td>
<td>0.074</td>
<td>-0.95 [-1.95,0.04]</td>
<td>0.074</td>
</tr>
</tbody>
</table>

Values are Δ mean [CI]. All $p$ values are adjusted based on Bonferroni correction.
Figure 1.
Appendix A – 2015 Questionnaire

†Questions included in 2008 questionnaire

Demographics

• What is your level of academic training? Circle all relevant. Please write in others.
  o Bachelor
  o Masters
  o PhD
  o MD / DO
  o RN
  o Others:

• What is your professional role?
  o Obstetrician/Gynecologist
  o Anesthesiologist
  o Nursing Staff
  o Midwifery Staff

• How many years have you been in your current profession?
  o ≤10 years
  o >10 years

• How many years have you worked on L&D at BWH?
  o ≤10 years
  o >10 years

• How many clinical hours a week do you work?
  o ≤20 hrs
  o 21-40 hrs
  o 41-60 hrs
  o >60

Adaptability and Communication

1. Safon rounds help develop plans to respond to patient changes
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
2. Safon rounds creates opportunities for improvement of habitual or routine practices
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

3. †As a result of Safon rounds, I have changed my clinical practice
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

4. †As a result of Safon rounds, I have gained new clinical insight
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

5. †As a result of Safon rounds, I have learned something new about myself
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

6. Safon rounds help facilitate team problem solving
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure
7. †I have made professional contributions to Safon rounds
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

8. †Safon rounds have improved my communication with other team members
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

Backup Behavior

9. Safon rounds assist in the distribution of tasks to under-utilized team members
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

10. Safon rounds assist in the evaluation of how well the team functions
    a. Strongly Disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly Agree
    f. Not Sure

11. Safon rounds create an environment that fosters self-evaluation
    a. Strongly Disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly Agree
    f. Not Sure
12. Safon rounds help improve decision making by consultants (e.g., cardiologists, hematologists, intensive care specialists, etc.)
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

**Shared Mental Model**

13. Safon rounds enable me to anticipate the needs of other team members
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

14. Safon rounds allow for the adjustment of strategies based on team member changes
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

15. Safon rounds help identify the considerations and priorities of other team members
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

**Team / Collective Orientation**

16. Safon rounds assist in providing team-based feedback
   a. Strongly Disagree
   b. Disagree
   c. Neutral
d. Agree
e. Strongly Agree
f. Not Sure

17. †I am able to speak openly and freely
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

18. †My opinion is valued
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

19. †Safon rounds have improved teamwork
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

**Eliminated Questions**

20. Safon rounds have altered patient management plans based on team discussions
    a. Strongly Disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly Agree
    f. Not Sure

21. †Overall, patients are safer on L&D as a result of Safon rounds
    a. Strongly Disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly Agree
    f. Not Sure
22. Safon rounds allows an evaluation of how people in your role interact with team members with different roles
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

23. Safon rounds help identify clinical errors
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

24. Safon rounds help clarify team member roles
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

25. Nurse in charge, Anesthesia / OB Attendings are consistently present at Safon rounds
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure
2008 Questionnaire

1. What is your professional role?
   a. Obstetrician/Gynecologist
   b. Anesthesiologist
   c. Neonatologist
   d. Nursing Staff
   e. Midwifery Staff
   f. Others

2. What clinical hours do you work?
   a. 12 hours
   b. 8 hours
   c. Day
   d. Evening
   e. Night
   f. Rotate
   g. Other

3. As a result of Safon rounds, I have changed my clinical practice
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

4. As a result of Safon rounds, I have noticed an improvement in teamwork
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

5. As a result of Safon rounds, I have learned something new about myself
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure
6. As a result of Safon rounds, I have gained new clinical insight
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

7. I have made professional contribution to Safon rounds
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

8. My opinion is valued
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

9. I am able to speak openly and freely
   a. Strongly Disagree
   b. Disagree
   c. Neutral
   d. Agree
   e. Strongly Agree
   f. Not Sure

10. Overall patients are safer on L&D as a result of Safon rounds
    a. Strongly Disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly Agree
    f. Not Sure

11. Nurse in charge, Anesthesia / OB Attendings are consistently present at Safon rounds
    a. Strongly Disagree
    b. Disagree
    c. Neutral
d. Agree
e. Strongly Agree
f. Not Sure
Dural Puncture Epidural (DPE) Technique Improves Block Quality and Minimizes Side Effects for Parturients Requesting Early Labor Analgesia when Compared with Combined Spinal Epidural and Standard Epidural Techniques.

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Funding: This project was supported in part by the Clinician Investigator Program, University of British Columbia

Key Words: Obstetric Anesthesia, Dural-Puncture Epidural, Epidural, Combined-Spinal Epidural, Labor Analgesia

Abstract word count: 448

Manuscript word count: 4165

Clinical Trial Registration URL: https://clinicaltrials.gov/ct2/show/NCT02008591

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Abstract

Introduction: The dural puncture epidural technique (DPE) is a modification of the combined spinal epidural technique (CSE), where a dural perforation is created but intrathecal medication administration is withheld. DPE offers unique labor analgesia advantages over a standard epidural technique (EPL), but to date, direct comparison of all three techniques have not been performed. We designed this prospective randomized double blind study to determine if DPE would result in faster onset in pain relief compared to EPL, with fewer maternal and fetal side effects compared to CSE.

Methods: Upon patient consent, 120 parturients in early labor (≤5cm cervical dilation) were randomized to EPL, DPE or CSE groups. Attending and fellow anesthesiologists performed all placements. Initial dosing for EPL and DPE consisted of epidural 20mL of 0.125% bupivacaine plus fentanyl 2 mcg/mL over 5 min, and for CSE, 1 of 1.5 mL premixed solution of intrathecal 0.25% bupivacaine 2.5 mg and fentanyl 25 mcg. Upon block completion, an independent blinded co-investigator assessed the outcomes. Two blinded obstetricians independently interpreted uterine contractions and fetal heart rate (FHR) tracings one hour before and after neuraxial placement. The primary outcome was time to achieving numeric pain rating scale (NPRS) ≤1 analyzed using log rank test. Secondary outcomes included neuraxial block quality, maternal adverse effects, uterine contractions and fetal heart rate changes analyzed by logistic regression.

Results: The time to achieving NPRS ≤1 was significantly faster for CSE and similar between EPL and DPE. Compared to EPL, DPE had significantly greater incidence of bilateral S2 block at 10 mins (OR 6.67; 95%CI 2.44-18.21; p<0.001) and 20 mins (OR +∞; 95% CI 5.04-∞; p<0.001) after initial bolus dosing, lower incidence of asymmetric block 30 mins after initial
dosing (OR 0.10; 95% CI 0.03-0.34; P<0.001), lower incidence of first top-up bolus intervention (OR 0.29; 95% CI 0.11-0.76; P=0.012) and lower incidence of motor block on the right side (OR 0.29; 95% CI 0.10-0.86; P=0.03). Compared to CSE, DPE had significantly lower incidence of patients requiring first top-up bolus intervention (OR 0.29; 95% CI 0.11-0.76; P=0.012), lower incidence of pruritus during the first 30 min (OR 0.05; 95% CI 0.02-0.18; P<0.001), lower incidence of hypotension during the first 30 min (OR 0.30; 95% CI 0.09-0.93; P=0.038), lower incidence of combined uterine tachysystole and hypertonus (OR 0.14; 95% CI 0.04-0.45; P=0.001) and lower incidence of conversion from National Institute of Child Health and Development category I to II FHR tracings (OR 0.30; 95% CI 0.09-0.93; P=0.038).

**Conclusions:** Time to NRPS≤1 following initial dosing was fastest with CSE and similar between DPE and EPL. However, the DPE technique offers improved block quality and safety compared to EPL and CSE techniques for parturients requesting early labor analgesia.
Introduction

The dural puncture epidural (DPE) technique creates a single dural perforation via a spinal needle placed through the shaft of an epidural needle, followed by placement of a catheter into the epidural space. However, unlike a combined-spinal epidural (CSE) technique, where medications are directly administered through the spinal needle, all medications for analgesia or anesthesia are introduced through the epidural catheter.

When compared to a standard epidural (EPL) technique, the DPE technique offers the dural puncture as an additional confirmatory tool for the correct placement of the epidural needle [e.g., the spinal needle, if too shallow or off the midline tangent, would otherwise have difficulty obtaining cerebrospinal fluid (CSF)], and as a conduit for the indirect translocation of medications from the epidural to subarachnoid spaces; the technique also allows an epidural catheter to be tested at the time of placement.

For laboring parturients, the DPE technique offers improved onset, sacral spread and bilateral sensory blockade when compared to a standard EPL technique;[4] there may also be ongoing advantages in the functioning of the epidural catheters. When compared to to a CSE technique, the DPE technique may also have advantages. The intrathecal medications used to initiate a CSE technique have been associated with a higher incidence of maternal pruritus, hypotension and fetal bradycardia. [3] Furthermore, the ability to confirm functional status of the epidural catheter can be delayed with CSE. To date, all three techniques have not been compared.

We designed this prospective, randomized, double-blinded study to compare the onset of labor analgesia, as well as the maternal and fetal side effects, of DPE CSE, and EPL techniques. We
hypothesized that the order of most rapid onset of labor analgesia would be CSE, DPE, and EPL techniques; however, we also hypothesized that overall analgesia characteristics and side effects would favor the DPE technique.

**Methods**

**Study population**

This study was approved by the Institutional Research Ethics Board of Partners Healthcare, Brigham and Women’s Hospital and registered with the www.clinicaltrials.gov protocol registration system (NCT02008591). All participants provided written informed consent. Healthy pregnant women with singleton, vertex presentation fetuses at 38-42 weeks’ gestation in active labor with cervical dilatation less than 5.0 cm and desiring labor epidural analgesia at Brigham and Women’s Hospital from January 2014 to November 2015 were eligible. We excluded subjects with diseases of pregnancy (e.g. gestational hypertension, preeclampsia or gestational diabetes), subjects with contraindications to neuraxial analgesia techniques, known fetal anomalies, conditions associated with an increased risk of cesarean delivery (e.g. vaginal birth after cesarean section, history of uterine rupture).

**Randomization and concealment of group assignments**

Once subjects have made the decision to receive labor epidural analgesia, the clinical anesthesiologist and study co-investigator were notified. The clinical anesthesiologists were experienced (attending or fellow) anesthesiologists who performed the epidural placement and
were not part of the study. Prior to entering the patient room, the clinical anesthesiologist was informed on the study protocols, then opened a sealed envelope containing the random assignment according to a computer-generated randomization list to one of three groups (DPE, CSE, or EPL) and retrieved the appropriate medications as per study protocol. The clinical anesthesiologist was instructed along with the bedside nurse to not reveal the randomization arm to the patient or study co-investigators. The study co-investigator waited outside the patient room and only entered upon notification from the nurse, at the request of the clinical anesthesiologist.

**Epidural placement protocol**

Prior to the epidural placement, all subjects received sodium citrate and had an 18-G IV catheter placed with automated noninvasive blood pressure, pulse oximetry, and external tocodynamometry monitors applied. All subjects received 500-1000 mL bolus of lactated Ringer’s solution infused over 15 min immediately before the initiation of neuraxial analgesia.

The epidural space was identified in seated position at the L2-3 or L3-4 interspace via the midline approach with a 17-G, 8.5 cm Weiss epidural needle using a loss of resistance to saline technique. In subjects randomized to DPE and CSE, a needle-through-needle technique was performed using a 25-G, 12cm Whitacre spinal needle placed into the shaft of the previously sited epidural to create a single dural puncture with confirmation of free flow cerebrospinal fluid (CSF). The spinal needle protruded 15 mm beyond the epidural needle tip when fully inserted. A 20-G multi-port polyamide catheter (Portex, Kent, UK) was placed 5 cm into the epidural space. After a negative aspiration for blood and CSF, initial dosing regimens based on the current
institutional practice were administered. A lidocaine test dose was not used. Initial dosing for EPL and DPE consisted of 20 mL of 0.125% bupivacaine with fentanyl 2 mcg/mL fractionated into four 5mL boluses given over 5 min through the catheter; for CSE, it consisted of 1 of 1.5 mL premixed solution of 0.25% bupivacaine 2.5 mg and fentanyl 25 mcg (i.e. bupivacaine 1.7 mg and fentanyl 17 mcg). Upon completion of initial dosing, patient-controlled epidural analgesia (PCEA) was initiated immediately using the following parameters: bupivacaine 1.25 mg/mL with fentanyl 2 mcg/mL, background infusion at 6 mL/h, demand dose of 6 mL, lockout interval of 15 min, and no hourly limits.

All procedural complications that occurred during epidural placement or postpartum including no analgesia within the first 30 min, accidental dural puncture by the epidural needle, dural puncture by the spinal needle without return of CSF, intravascular or intrathecal catheter insertion, post-dural puncture headache, persistent paresthesia or persistent back pain were documented by the clinical anesthesiologist or non-study anesthesia provider and transferred to the study database after the delivery of the infant. All study subjects were visited post-partum day one by an independent anesthesia provider not involved in the study who assessed the presence of headache, back pain, paresthesia or other complications. Outcomes for subjects who experienced these complications were recorded and analyzed according to the intention-to-treat principle.

Outcome assessments
After initial dosing completion, while the epidural catheter was being secured in a seating position, the study co-investigator entered the room at $t=0$ and assessed the outcomes immediately, and then at $t=2,4,6,8,10,12,14,16,18,20$ and 30 min. Following the first 30 min, assessments continued at every 90-min intervals until delivery.

For CSE, the time immediately after intrathecal dosing was completed and epidural catheter had been threaded in position was designated as $t=0$. To minimize the time to thread the catheter, the clinical anesthesiologists were instructed to ensure ease of catheter threading prior to making a dural puncture. For EPL and DPE, $t=0$ was immediately after completion of all 20 mL of epidural medication given over 5 min. (Fig 1)

Analgesia was evaluated using the verbal numeric pain rating scale (NPRS) during every uterine contraction. Sensory blockade was evaluated using a non-traumatic pinprick stimulus starting at the S2 dermatome and moving caudad to cephalad. The highest segment at which the patient perceived the stimulus as identical to the ipsilateral deltoid was recorded. In the lower extremity, dermatomal levels were assessed by stimulating the inguinal crease (L1), anterior thigh (L2), medial knee (L3), medial malleolus (L4), dorsum web between great and second toe (L5), the lateral heel (S1), and the medial popliteal fossa (S2). On the torso, dermatomal levels were assessed in the mid-clavicular line. Motor strength was assessed with a modified Bromage score ($0 = \text{full flexion of knees and ankles}$, $1 = \text{partial flexion of knees, full flexion of ankles}$, $2 = \text{inability to flex knees, partial flexion of ankles}$; $3 = \text{inability to flex knees and ankles}$). Presence of motor block was defined as modified Bromage scale score $\geq 1$. Pruritus and nausea were evaluated by directly asking the subject for presence and severity graded on a scale ranging from
0 = none, 1 = mild, 2 = moderate, and 3 = severe. Temperature were taken orally using an automated temperature probe. Hypotension was defined as a 20% reduction in the systolic blood pressure from the admission blood pressure. Hypotension was treated with a fluid bolus of 250-500 mL in addition to IV phenylephrine 80 mcg bolus every 2 min as required. Rescue bolus of IV phenylephrine 40 mcg bolus every min was administered as required.

Asymmetric blockade was defined as difference in sensory blockade greater than two dermatomal levels between the left and right side of the patient anytime during labor after the initial dose measured from the cephalad or caudad direction.

Inadequate analgesia protocol

For subjects who experienced unilateral discomfort due to asymmetric blockade, a protocol was followed for administering bolus doses for inadequate analgesia. Starting 30 min from the epidural placement, if analgesia was inadequate (defined as patient request for a supplemental analgesia beyond boluses self-administered by PCEA), an assessment was made by an anesthesia provider blinded to group assignment and administer top-up doses. At patient’s initial request, top-up intervention consisted of 6 mL of bupivacaine 1.25 mg/mL with fentanyl 2 mcg/mL administered as clinician bolus through the PCEA infusion pump. After 10 min, if this did not provide sufficient analgesia (NPRS<3) then 10 mL of bupivacaine 1.25 mg/mL with fentanyl 2mcg/mL was administered as a manual bolus over a period of 5 min. After 10 min, if patient remained uncomfortable, 10 mL of 2.5 mg/mL was administered as a manual bolus over a period
of 5 min. In the event of failed block (defined as no change in NPRS response after 30 min), catheter replacement would be discussed with the patient. All catheter adjustments and boluses were recorded.

Analysis of uterine contractions and fetal heart tracings

Continuous uterine contractions and fetal heart tracings were stored on the hospital patient electronic system and retrospectively interpreted by two independent obstetricians blinded to patient assignment and study outcomes. If there was any disagreement in their evaluation, tracings were reviewed until consensus was obtained.

Using an approach previously described,[5] uterine contraction and fetal heart rate monitoring patterns were extracted in 10 min epochs, starting one hour before and up to one hour after completion of initial dosing of epidural analgesia. Baselines were mean values of the six 10-min epochs before and after epidural placement.

All classifications of uterine contraction and fetal heart rate frequencies and abnormalities were based on definitions developed by the National Institute of Child Health and Human Development (NICHD).[6] Quantitative assessment of uterine contractions included contraction frequency, presence of uterine tachysystole and hypertonus. Uterine tachysystole was defined as >5 contractions in 10 min, averaged over a 30-min window. Uterine hypertonus was defined as a single contraction lasting longer than 2 min.[6, 7] Presence of uterine tachysystole and
hypertonus were further qualified as to the presence or absence of associated fetal heart rate decelerations.

Quantitative assessment of fetal heart tracings included baseline heart rate, variability, accelerations and decelerations. Each type of deceleration (early, late or variable) was described and listed as mean number present. Finally, the obstetricians assigned a category to the fetal heart tracings before and after the epidural placement based on the three-tiered NICHD system.

Statistical analysis

The primary outcome of the study was time to achieving NPRS ≤1. The choice of this outcome was based on prior study demonstrating that very few patients with NPRS 0 or 1 would desire more medication for labor epidural analgesia compared to those with NPRS >1. [5] We estimated 75% and 95% of subjects in EPL and DPE, respectively, achieve numeric pain rating scale ≤1 at 30 min based on our previous study. Based on this, we need a sample size of 35 subjects per group to have 80% power (two-tailed) to detect a different survival curve between group using a log-rank test with alpha=0.05. In keeping with the total of subjects enrolled in our prior study, the sample size was arbitrarily increased to 40 per group. Kaplan–Meier curve and log-rank tests (LR test) was used to analyze the primary outcome. Logistic regression was used to analyze the secondary outcomes. All analyses were performed with statistical software R version 3.1.2.
Results

Participant flow and baseline characteristics are summarized on Figure 2 and Table 1, respectively. The groups were similar at baseline. Two patients in the DPE group failed to have CSF return on dural puncture. There were no other procedural complications.

The median times (25-75% quantiles) to NPRS ≤1 were 2 (0.5-6) min for CSE, 11 (4-120) min for DPE and 18 (10-120) mins for EPL. The times to achieving NPRS ≤1 were similar between EPL and DPE (LR test; p=0.183) and significantly faster for CSE than EPL (LR test; p<0.001) and DPE (LR test; p<0.001) (Figure 3).

Block characteristics and maternal adverse effects, uterine contraction assessment and fetal heart tracing assessment are summarized in Tables 2-4.

Compared to EPL, DPE had significantly greater incidence of bilateral S2 block at 10 mins (OR 6.67; 95%CI 2.44-18.21; p<0.001) and 20 mins (OR +∞; 95% CI 5.04-∞; p<0.001) after initial bolus dosing, lower incidence of asymmetric block 30 mins after initial dosing (OR 0.10; 95% CI 0.03-0.34; P<0.001), lower incidence of first top-up bolus intervention (OR 0.29; 95% CI 0.11-0.76; P=0.012) and lower incidence of motor block on the right side (OR 0.29; 95% CI 0.10-0.86; P=0.03). (see Table 5)

Compared to CSE, DPE had significantly lower incidence of patients requiring first top-up bolus intervention (OR 0.29; 95% CI 0.11-0.76; P=0.012), lower incidence of pruritus during the first
30 min (OR 0.05; 95% CI 0.02-0.18; P<0.001), lower incidence of hypotension during the first 30 min (OR 0.30; 95% CI 0.09-0.93; P=0.038), lower incidence of combined uterine tachysystole and hypertonus (OR 0.14; 95% CI 0.04-0.45; P=0.001) and lower incidence of conversion from NICHD category I to II FHR tracings (OR 0.30; 95% CI 0.09-0.93; P=0.038). (see Table 5)

Discussion:

In this first prospective RCT comparing three neuraxial labor analgesia techniques, we found CSE had the most rapid onset of analgesia and no significant difference between DPE and EPL in time to NPRS $\leq 1$ during the first 30 min following initial epidural bolus dosing. Compared to EPL, DPE had earlier and greater incidence of bilateral sacral coverage with less incidence of asymmetric block, first top-up bolus intervention and motor block on the right side. Compared to CSE, DPE had fewer maternal pruritus, hypotension, combined uterine tachysystole and hypertonus and NICHD category 1 to 2 fetal heart tracing. Together, these results indicate that while NPRS $\leq 1$ was most rapidly achieved with CSE, DPE has improved block quality over EPL and improved maternal-fetal side effect profile over CSE for parturients in early labor requesting epidural analgesia.

In the presence of a dural perforation, solution administered into the epidural space can translocate into the subarachnoid space. This phenomenon had been demonstrated radiologically through contrast dye study in a pregnant patient with unusually fast onset of hypotension,
profound motor and sensory blockade following inadvertent dural puncture by a Touhy needle.[9] Subsequent to this report, in vitro study of cadaver dura from monkeys demonstrated that the flux of lidocaine was significantly increased with dura punctured with 24-G Sprotte or 18-G Tuohy but not 27-G Whitacre needles, indicating that flux across the dura is directly proportional to the diameter of the punctured hole.[1] Consistent with these in vitro observations, a randomized clinical trial (RCT) in healthy laboring patients by Thomas et al. found DPE using a 27-G needle did not improve epidural labor analgesia quality including block symmetry, sacral spread and number of top-up boluses required compared to EPL. Using the DPE technique via a 26-G Whitacre needle, Suzuki et al. observed in non-pregnant subjects there was significant sacral, but not thoracic, spread at 15 and 20 mins following initial bolus dosing compared to EPL. Using a larger gauge needle, Cappiello et al. [4] demonstrated reported a significantly greater proportion of patients with S1 but not S2 blockade in laboring patients receiving DPE using a 25-G Whitacre compared to EPL (92.3% vs. 70.0%, p=0.02) but there was no difference in proportion of patients with visual analogue score (VAS) < 10 mm obtained at 20 mins, block symmetry or number of top-up boluses required between the two groups. [4, 10]. Similar to the Suzuki., et al. study, we were able to demonstrate that a single dural perforation generated a difference in time to caudal but not cranial spread in vivo compared to intact dura; the low lumbar location of the dural perforation preferentially resulted in more rapid spread to the sacral versus the thoracic dermatomes following initial bolus dose. However, unlike the Cappiello et al. study, we were able to demonstrate significant differences in time to S2 block and other improved block quality endpoints in favor of DPE despite using the same 25-G perforation. This suggests that other factors must be present to account for the ability to provide early sacral
spread found in the Suzuki et al. study and the current study that were not detected in trials using a similar-sized perforation. [4] [11]

The surface area of the dural perforation exposed to the drug and thus having high initial bolus volume in the epidural space is likely a responsible factor for a number of important outcome differences between DPE and EPL.[1] A higher volume may increase the pressure gradient to help drive higher net flux across the dural perforation into the subarachnoid space. Cappiello et al. [4] used a 25-G perforation with moderate volume and less concentrated solution (12 mL of 2.5 mg/mL plain bupivacaine) as an initial bolus dose. Suzuki et al.[2] used 26-G perforation with a higher volume (total of 18 mL of plain 2% mepivacaine without epinephrine) as an initial bolus dose. We selected a 25-G perforation with high volume, less concentrated solution (20 mL of bupivacaine 1.25 mg/mL with fentanyl 2mcg/mL) for the initial loading dose, providing the greatest surface area that the dural perforation was exposed to the drug. In this regard, whether a smaller perforation such as a 27-G perforation with a high volume solution would replicate our sacral spread findings require further investigation. In the study by Thomas et al. [3], where a 27-G perforation was made, a low volume and concentrated solution (10 mL of 2% lidocaine) was used and the investigators did not examine sacral spread. The study by Bernards et al.[1] suggests that a 27-G hole would not produce adequate flux, however, the in vitro model used may not accurately reproduce the epidural pressure gradient in vivo.

Beyond the initial bolus, we found that dural perforation in the DPE and CSE groups continued to exert benefits for the duration of labor beyond the first 30 min following initial bolus. There
was a low incidence of motor block and asymmetric block 30 min after the initial bolus in both DPE and CSE groups.

The literature is inconsistent on motor block differences between neuraxial analgesia techniques, likely due to different regimens being compared. Hepner et al. [12] found no difference in motor blockade between EPL and CSE using a low dose epidural analgesia infusion of 0.0625% bupivacaine and fentanyl 0.0002% for EPL and intrathecal fentanyl 25 mcg and bupivacaine 2.5 mg for CSE. A 2012 Cochrane review found that women receiving epidural analgesia were more likely to experience motor blockade compared to CSE. [13] Thomas et al. and Cappiello et al. did not report motor block data for DPE.

The available literature is also inconsistent on whether there is a difference in block asymmetry between CSE, DPE and EPL. For example, large retrospective studies by Eappen et al [14], and Norris et al. [15], found that CSE using 25-G and 27-G Whitacre needles, respectively, were more likely to produce bilateral sensory changes compared to EPL. However, prospective RCTs by Cappiello et al. [4] and Thomas et al.[3] using dural perforations from 25-G and 27-G Whitacre needles, respectively, were unable to demonstrate a significant difference in unilateral blocks between DPE and EPL. The definition of unilateral block may be one factor to this discrepancy, which was defined as sensory block >3 dermatome levels between left and right in studies by Cappiello et al., and Thomas et al., and >2 dermatome levels in the current study, which we adopted from a more recent publication.[16] A recent meta-analysis of 10 RCTs comparing CSE and EPL in 1722 parturients and found the relative risk of unilateral block was
significantly reduced after CSE vs. EPL (RR 0.48, 95% CI 0.24-0.7) but there was presence of significant between-study heterogeneity.[17]

In a large RCT of 800 patients, Gambling et al.[18] found fewer patients required top-up boluses with CSE using a 26-G Gertie-Marx needle compared to EPL (16.4% vs. 25.6%, p=0.002), however, the study did not maintain consistent blinding and control for supplemental analgesia using a strict protocol. In a smaller RCT of 100 patients by Goodman et al. [19] a strict supplemental analgesia protocol was used and the study found no difference in top-up requirements between CSE using a 27-G Whitacre and EPL. A meta-analysis by Heesen et al also found that the rates of epidural-tops were not significantly different between CSE and EPL. Our study also used a strict protocol and found no difference between top-up bolus requirement between CSE and EPL. Our results were consistent with these findings, but in addition, we observed a significantly fewer number of patients in the DPE group required first top-up boluses. While a difference between CSE and DPE would not be anticipated as both techniques are anatomically similar beyond the first hour, functionally they may be different. First, unlike CSE, there is a lack of analgesia transition phase from spinal to epidural analgesia in those who received DPE. Second, when administered in early labor, intrathecal analgesia by CSE have been found to be associated with faster cervical dilatation. [20] [21] The hastened cervical dilation in patients receiving CSE may in part, contribute to greater bolus interventions required.

Concerns about the fetal bradycardia have limited the widespread use of the CSE technique. A clinically important finding of the current study is that there was no difference in fetal bradycardia before and after performance of EPL, DPE or CSE; however, we observed a
significantly higher incidence of combined tachysystole and hypertonus and conversion of NICHD category I to category II FHR tracings within the first hour following CSE. However, the increased incidence in uterine tachysystole and hypertonus did not result in an increased need for tocolysis or emergent delivery. The incidence of hypotension was also significantly higher following CSE, and might have contributed to FHR tracing category changes. On the other hand, similar associations with uterine contraction changes have not been documented for EPL and DPE techniques. It should be noted that this study only involved healthy parturients with no anticipated fetal abnormalities. Therefore, the fetal tolerance for transient uterine tachysystole and hypertonus was high within our defined population; the choice of neuraxial technique may be more important in situations when fetal blood flow is limited or compromised.

Other studies have also observed similar findings of increased uterine tone and FHR changes after neuraxial analgesia. Van de Velde et al. [22] reported a significant increase in the incidence of uterine hyperactivity and nonreassuring FHR in the high-dose opioid CSE group that used 7.5 mcg intrathecal sufentanil alone but not in the low-dose opioid CSE group that used 1.5 mcg sufentanil with bupivacaine or DPE with a 29-G perforation. Similarly, a recent RCT by Patel et al. found no difference in FHR changes in low-dose opioid CSE that used 5 mcg intrathecal fentanyl when compared to EPL. The intrathecal opioid dosing for CSE in our study is most similar to the RCTs by Abrao et al.,[23] which found CSE using 2.5 mcg intrathecal sufentanil (approximately 11 mcg intrathecal fentanyl using a relative potency ratio of 4.4:1 [24]) was associated with greater elevation of uterine tone and FHR abnormalities vs EPL. Although an intrauterine pressure catheter was used in the Abrao et al. study, FHR tracings were only assessed for 15 mins before and after the initiation of analgesia. Our findings provided a stronger
evidence as we extended the assessment periods to 60 mins before and after in an attempt to capture the effect of peak analgesia following EPL or DPE.

This study has several limitations. First, the NPRS scores were only obtainable when patient experienced uterine contractions. As such, some patients might in fact have achieved NRPS≤1 sooner than reported. Although every effort was done to maintain blinding of the arms, the co-investigator assessing the outcomes was also an anesthesiologist and could recognize the rapid onset of analgesia or side effect (e.g. intense pruritus) typically associated with CSE that are not as conspicuous in other techniques. Assessment of outcomes based on objective measurements, standardized timing and direct response from the patients, thus minimizing the impact of potential bias. Our low adjustment and replacement rates are much lower than other studies and most likely due to our restriction of placements to only experienced providers (attending and fellows) because all anesthesiology provider who perform placement had to be equally skillful at placing all three techniques. This may also explain the absence of accidental dural puncture and other complications.

In summary, the results of this randomized trial suggest that comparing to EPL and CSE, the DPE technique offers improved block characteristics and maternal-fetal safety profile for pregnant patients requesting early labor analgesia.
Acknowledgement

This study was supported in part by the Clinician Investigator Program, University of British Columbia.

We are indebted to our obstetrics, nursing, midwifery and anesthesiology colleagues for their support and assistance during this study.

References


10. Duzenmas D: Are the conclusions supported by the statistics? Anesthesia and analgesia 2010, 110(3):969; author reply 969.
Figure 1. Timing of initial dose and commencement of primary outcome measure (t=0). EPL = Standard Epidural Analgesia; DPE = Dural Puncture Epidural Analgesia; CSE = Combined Spinal Epidural Analgesia
Figure 2. Consort diagram.
Figure 3. Kaplan-Meier curves for time to achieving NPRS≤1 following initial bolus dosing by standard epidural (EPL), dural-puncture epidural (DPE) or combined-spinal epidural (CSE) analgesia techniques.
<table>
<thead>
<tr>
<th></th>
<th>EPL</th>
<th>DPE</th>
<th>CSE</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>32.3 (4.0)</td>
<td>32.9 (4.7)</td>
<td>32.8 (5.0)</td>
<td>0.83</td>
</tr>
<tr>
<td><strong>Height (cm)</strong></td>
<td>164.1 (7.1)</td>
<td>166.6 (5.8)</td>
<td>164.8 (5.8)</td>
<td>0.86</td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td>81.0 (18.6)</td>
<td>81.5 (10.7)</td>
<td>79.5 (14.2)</td>
<td>0.83</td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td>30.0 (6.1)</td>
<td>29.4 (3.9)</td>
<td>29.3 (5.5)</td>
<td>0.67</td>
</tr>
<tr>
<td><strong>Gestational weeks</strong></td>
<td>39.5 (1)</td>
<td>39.2 (1)</td>
<td>39.3 (1)</td>
<td>0.30</td>
</tr>
<tr>
<td><strong>Primipara, n</strong></td>
<td>23</td>
<td>19</td>
<td>17</td>
<td>0.35</td>
</tr>
<tr>
<td><strong>Induction of labor, n</strong></td>
<td>28</td>
<td>31</td>
<td>31</td>
<td>0.67</td>
</tr>
<tr>
<td><strong>Total IVF received during labor (L)</strong></td>
<td>3.4 (2.0)</td>
<td>3.2 (1.6)</td>
<td>2.7 (1.5)</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>Oxytocin at time of epidural Placement, mIU/min</strong></td>
<td>6 [0-24]</td>
<td>6 [0-21]</td>
<td>6 [0-23]</td>
<td>0.86</td>
</tr>
<tr>
<td><strong>Initial NPRS score</strong></td>
<td>8 [3-10]</td>
<td>8 [4-10]</td>
<td>8 [5-10]</td>
<td>0.41</td>
</tr>
</tbody>
</table>

Values are mean(SD) or median [range]. IVF = intravenous fluids; NPRS = numeric pain rating scale
Table 2. Neuraxial Block Quality Parameters and Maternal Adverse Effects Groups

<table>
<thead>
<tr>
<th>Block Type</th>
<th>EPL (n=40)</th>
<th>DPE (n=40)</th>
<th>CSE (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic Sensory block</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Highest level any time</td>
<td>T4 [T2-T8]</td>
<td>T4 [T2-T8]</td>
<td>T4 [T2-T6]</td>
</tr>
<tr>
<td>Bilateral T10 at 0.5 min, %</td>
<td>15</td>
<td>15</td>
<td>50</td>
</tr>
<tr>
<td>Bilateral T10 at 10 min, %</td>
<td>75</td>
<td>95</td>
<td>100</td>
</tr>
<tr>
<td>Sacral Sensory block, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral S2 at 0.5 min, %</td>
<td>0</td>
<td>7.5</td>
<td>27.5</td>
</tr>
<tr>
<td>Bilateral S2 at 10 min, %</td>
<td>37.5</td>
<td>80</td>
<td>95</td>
</tr>
<tr>
<td>Bilateral S2 at 20 min, %</td>
<td>62.5</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Bilateral S2 at 30 min, %</td>
<td>85</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>No S2 block entire duration, %</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asymmetric blocks, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>within 30 min, %</td>
<td>57.5</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>after 30 min, %</td>
<td>52.5</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Top-up Bolus Interventions, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st bolus (10 cc via PCEA), %</td>
<td>50</td>
<td>22.5</td>
<td>50</td>
</tr>
<tr>
<td>2nd bolus (10 cc 0.125%), %</td>
<td>27.5</td>
<td>15</td>
<td>12.5</td>
</tr>
<tr>
<td>3rd bolus (10 cc 0.25%), %</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Intervention, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter adjustment, %</td>
<td>10</td>
<td>5</td>
<td>7.5</td>
</tr>
<tr>
<td>Catheter replacement, %</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Motor Block, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bromage score, median (range)</td>
<td>0 (0-3)</td>
<td>0 (0-2)</td>
<td>0 (0-3)</td>
</tr>
<tr>
<td>Motor block (left), %</td>
<td>30</td>
<td>12.5</td>
<td>17.5</td>
</tr>
<tr>
<td>Motor block (right), %</td>
<td>37.5</td>
<td>15</td>
<td>7.5</td>
</tr>
<tr>
<td>Adverse effects, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea first 30 min, %</td>
<td>10</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Pruritus first 30 min, %</td>
<td>10</td>
<td>10</td>
<td>67.5</td>
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<tr>
<td>Hypotension first 30 min, %</td>
<td>12.5</td>
<td>12.5</td>
<td>32.5</td>
</tr>
<tr>
<td>Post-dural puncture headache, %</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Duration of epidural infusion, min</td>
<td>450 (200)</td>
<td>407 (275)</td>
<td>314 (189)</td>
</tr>
</tbody>
</table>

Values are mean(SD) or median [range]. PCEA = patient-controlled epidural analgesia.
Table 3. Uterine Contraction Assessment

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<thead>
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<th>Groups</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>EPL (n=40)</td>
<td>DPE (n=40)</td>
</tr>
<tr>
<td><strong>Baseline - Before Neuraxial Analgesia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of contraction, contractions/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowest frequency</td>
<td>2.0 (1.3)</td>
<td>2.1 (1.2)</td>
</tr>
<tr>
<td>Highest frequency</td>
<td>3.8 (1.5)</td>
<td>3.9 (1.3)</td>
</tr>
<tr>
<td>Tachysystole, hypertonus, or both, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertonus without bradycardia</td>
<td>17.5</td>
<td>5</td>
</tr>
<tr>
<td>Hypertonus with bradycardia</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Tachysystole without bradycardia</td>
<td>2.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Tachysystole with bradycardia</td>
<td>0</td>
<td>2.5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>After Neuraxial Analgesia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of contraction, contractions/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowest frequency</td>
<td>2.0 (1.0)</td>
<td>2.1 (1.1)</td>
</tr>
<tr>
<td>Highest frequency</td>
<td>3.9 (1.0)</td>
<td>4.1 (1.1)</td>
</tr>
<tr>
<td>Tachysystole, hypertonus, or both, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertonus without bradycardia</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Hypertonus with bradycardia</td>
<td>2.5</td>
<td>0</td>
</tr>
<tr>
<td>Tachysystole without bradycardia</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Tachysystole with bradycardia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>12.5</td>
<td>10</td>
</tr>
<tr>
<td>Received Tocolysis</td>
<td>2.5</td>
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Values are mean(SD) or median [range]
Table 4. Fetal Heart Tracing Assessment

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<tr>
<th>Groups</th>
<th>EPL (n=40)</th>
<th>DPE (n=40)</th>
<th>CSE (n=40)</th>
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</thead>
<tbody>
<tr>
<td><strong>Before Neuraxial Analgesia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fetal heart rate, beats/min</td>
<td>137 (9.2)</td>
<td>133 (9.7)</td>
<td>136 (8.2)</td>
</tr>
<tr>
<td>Fetal decelerations, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early</td>
<td>2.5</td>
<td>7.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Late</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
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<tr>
<td>Variable</td>
<td>12.5</td>
<td>12.5</td>
<td>10</td>
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<tr>
<td>Total</td>
<td>22.5</td>
<td>27.5</td>
<td>20</td>
</tr>
<tr>
<td>Variability, %</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
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<tr>
<td>Minimal</td>
<td>12.5</td>
<td>12.5</td>
<td>12.5</td>
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<tr>
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<td>75</td>
<td>82.5</td>
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<td>10</td>
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<td>5</td>
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<tr>
<td>NICHD classification, %</td>
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<td>Category I</td>
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<td>72.5</td>
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<td>Category II</td>
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<td>30</td>
<td>22.5</td>
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<tr>
<td>Category III</td>
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<tr>
<td>Uninterpretable due to missing data</td>
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<td>10</td>
<td>5</td>
</tr>
<tr>
<td><strong>After Neuraxial Analgesia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fetal heart rate, beats/min</td>
<td>134 (9)</td>
<td>132 (9.4)</td>
<td>131 (12)</td>
</tr>
<tr>
<td>Fetal decelerations, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early</td>
<td>7.5</td>
<td>2.5</td>
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</tr>
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<td>Late</td>
<td>20</td>
<td>27.5</td>
<td>30</td>
</tr>
<tr>
<td>Variable</td>
<td>20</td>
<td>20</td>
<td>22.5</td>
</tr>
<tr>
<td>Total</td>
<td>47.5</td>
<td>50</td>
<td>52.5</td>
</tr>
<tr>
<td>Variability, %</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Absent</td>
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<td>0</td>
<td>0</td>
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<tr>
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<td>5</td>
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<td>5 minute &lt; 7</td>
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<td>Emergency cesarean delivery due to fetal decelerations, n</td>
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Values are mean(SD) or median [range]. NICHD = National Institute of Child Health and Human Development
Table 5. Results of Logistic Regression Models for Secondary Outcomes and Respective Odds Ratios and 95% Confidence Intervals.

<table>
<thead>
<tr>
<th>Block Quality</th>
<th>DPE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>DPE CSE as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>CSE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Bilateral S2 block at 0.5 min</td>
<td>Inf</td>
<td>0.42-Inf</td>
<td>0.25</td>
<td>0.21</td>
<td>0.05-0.84</td>
<td><strong>0.037</strong></td>
<td>Inf</td>
<td>3.09-Inf</td>
<td>&lt;0.001</td>
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<tr>
<td>Bilateral S2 block at 10 min</td>
<td>6.67</td>
<td>2.44-18.21</td>
<td>&lt;0.001</td>
<td>0.21</td>
<td>0.04-1.6</td>
<td>0.059</td>
<td>31.67</td>
<td>6.66-150.59</td>
<td>&lt;0.001</td>
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<tr>
<td>Bilateral S2 block at 20 min</td>
<td>Inf</td>
<td>5.04-Inf</td>
<td>&lt;0.001</td>
<td>0</td>
<td>0-Inf</td>
<td>1</td>
<td>Inf</td>
<td>5.04-Inf</td>
<td>&lt;0.001</td>
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<tr>
<td>1st top-up bolus (10 cc via PCEA)</td>
<td>0.29</td>
<td>0.11-0.76</td>
<td><strong>0.012</strong></td>
<td>0.29</td>
<td>0.11-0.76</td>
<td><strong>0.012</strong></td>
<td>1.00</td>
<td>0.42-2.40</td>
<td>1</td>
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<tr>
<td>Asymmetric block within 30 min</td>
<td>0.49</td>
<td>0.20-1.20</td>
<td>0.12</td>
<td>2.67</td>
<td>0.98-7.25</td>
<td>0.06</td>
<td>0.18</td>
<td>0.07-0.50</td>
<td><strong>0.001</strong></td>
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<tr>
<td>Asymmetric block after 30 min</td>
<td>0.10</td>
<td>0.03-0.34</td>
<td>&lt;0.001</td>
<td>1.00</td>
<td>0.23-4.31</td>
<td>1</td>
<td>0.10</td>
<td>0.03-0.34</td>
<td>&lt;0.001</td>
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<table>
<thead>
<tr>
<th>Maternal Adverse Effects</th>
<th>DPE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>DPE CSE as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>CSE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Nausea first 30 min</td>
<td>0.23</td>
<td>0.02-2.16</td>
<td>0.20</td>
<td>1.00</td>
<td>0.06-16.56</td>
<td>1</td>
<td>0.23</td>
<td>0.02-2.16</td>
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<tr>
<td>Pruritus first 30 min</td>
<td>1.00</td>
<td>0.23-4.31</td>
<td>1</td>
<td>0.05</td>
<td>0.02-0.18</td>
<td>&lt;0.001</td>
<td>18.69</td>
<td>5.48-63.74</td>
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<tr>
<td>Hypotension first 30 min</td>
<td>1.00</td>
<td>0.27-3.76</td>
<td>1</td>
<td>0.30</td>
<td>0.09-0.93</td>
<td><strong>0.038</strong></td>
<td>3.37</td>
<td>1.07-10.61</td>
<td><strong>0.038</strong></td>
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<tr>
<td>Motor block (left)</td>
<td>0.33</td>
<td>0.10-1.06</td>
<td>0.06</td>
<td>0.67</td>
<td>0.19-2.33</td>
<td>0.53</td>
<td>0.49</td>
<td>0.17-1.43</td>
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<tr>
<td>Motor block (right)</td>
<td>0.29</td>
<td>0.10-0.86</td>
<td><strong>0.03</strong></td>
<td>2.18</td>
<td>0.50-9.39</td>
<td>0.30</td>
<td>0.14</td>
<td>0.04-0.52</td>
<td><strong>0.003</strong></td>
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<table>
<thead>
<tr>
<th>Uterine Contractions</th>
<th>DPE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>DPE CSE as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>CSE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
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<tbody>
<tr>
<td>Before NA</td>
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<tr>
<td>Tachysystole, hypertonus or both</td>
<td>1.00</td>
<td>0.33-2.99</td>
<td>1</td>
<td>1.42</td>
<td>0.44-4.53</td>
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<td>0.71</td>
<td>0.22-2.26</td>
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<tr>
<td>After NA</td>
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<tr>
<td>Tachysystole, hypertonus or both</td>
<td>0.78</td>
<td>0.19-3.14</td>
<td>0.72</td>
<td>0.14</td>
<td>0.04-0.45</td>
<td><strong>0.001</strong></td>
<td>5.73</td>
<td>1.86-17.65</td>
<td><strong>0.002</strong></td>
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<table>
<thead>
<tr>
<th>Fetal Heart Tracing</th>
<th>DPE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>DPE CSE as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
<th>CSE EPL as reference group</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Before NA FHR Deceleration*</td>
<td>0.73</td>
<td>0.24-2.20</td>
<td>0.58</td>
<td>0.85</td>
<td>0.28-2.61</td>
<td>0.78</td>
<td>0.86</td>
<td>0.29-2.52</td>
<td>0.79</td>
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<tr>
<td>After NA FHR Deceleration*</td>
<td>0.90</td>
<td>0.36-2.23</td>
<td>0.82</td>
<td>0.90</td>
<td>0.36-2.23</td>
<td>0.82</td>
<td>1.00</td>
<td>0.40-2.47</td>
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<tr>
<td>NICHD Category I to II After Neuraxial Analgesia</td>
<td>1.00</td>
<td>0.27-3.76</td>
<td>1</td>
<td>0.30</td>
<td>0.09-0.93</td>
<td><strong>0.038</strong></td>
<td>3.37</td>
<td>1.07-10.61</td>
<td><strong>0.038</strong></td>
<td></td>
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</tbody>
</table>

*Combined early, variable or late decelerations. Inf = infinity; NA=Neuraxial Analgesia; NICHD = National Institute of Child Health and Human Development
Acknowledgment

Brigham and Women’s Obstetric Anesthesia Clinical Research Team
- Lawrence Tsen
- Chuan-Chin Huang
- Alice Vijjeswarapu
- Kelly Elterman
- Eric Cappiello
- Margaret Hickey
- David Acker

Harvard Medical School MPCTI Program
- Jonathan Williams
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- Paul Colin
- Anthony Hollenberg
- Lauren Dewey Platt

Brigham and Women’s Obstetrics Clinical Research Team
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- Julian Robinson

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University of British Columbia Clinician-Investigator Program
- Sian Spacey
- Tessa Feuchuk

Division of Obstetric Anesthesia, Brigham and Women’s Hospital
- William Camann
- Bhavani Kodali
- Arvind Palanisamy
- Lawrence Tsen
- Michaela Farber
- Andrew Miller
- Ronald Hurley
- David Hepner
- Jean Marie Carabuena
- Jay Zhou
- Eric Cappiello
- Angelina Mavropoulos
- Dirk Varelmann
- Mihaela Podovei
- Vesela Kovacheva

Special Thanks
- Siu-Ling Chau
- Chun-Wu Chau
- Ada Chau-Ngai
- Stanley Chau
- Evan O’Loughlin
- Elaine Lee
- Ricky Li
- Mieke Soens
- Laura Chang
- Jamie Bell