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Original contribution

Preprocedural ultrasound assessment does not improve trainee performance of spinal anesthesia for obstetrical patients: a randomized controlled trial☆

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ABSTRACT

Study objective: This randomized controlled trial was designed to evaluate the efficacy of additional information from preprocedure ultrasound examination to aid anesthesiology trainees performing spinal anesthesia for obstetric patients.
Design: Trainee residents were randomly allocated to landmark technique and anatomy demonstration via ultrasound examination or landmark technique only for spinal anesthetic placement.
Setting: Obstetric delivery suite.
Patients: Eighty healthy obstetric patients undergoing elective cesarean delivery.
Intervention: Ultrasound examination prior to spinal anesthetic placement.
Measurements: The primary outcome was the number of attempts for the spinal anesthetic. Secondary outcomes included placement duration; block height; and the incidence of need for staff intervention, paresthesia, and bloody tap. Subjective ease of placement was rated on a 100-mm visual analog scale.
Main results: Baseline demographic data were similar between the patient groups. The median number of attempts with preprocedure ultrasound and landmark was 3 (interquartile range, 2-7). This was not significantly different from the number of attempts with landmark technique only of 3 (1-60) ($P = .69$). The median duration of spinal placement with ultrasound and landmark was 92 (51-140) seconds vs 75 (53-126) seconds with landmark only ($P = .57$). There was no statistical difference between the groups in spinal placement duration, need for staff intervention, paresthesia, bloody tap, lumbar interspace, or block height. There was no difference in subjective ease of spinal placement by the resident.
Conclusions: In this study of junior anesthesia trainees performing obstetrical spinal anesthesia with preprocedure ultrasound and landmark technique or landmark technique only, no significant difference was observed in the number of attempts, duration of spinal placement, subjective ease of spinal placement, or any other measured secondary outcome.

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1. Introduction

Spinal anesthesia is one of the most commonly used techniques in obstetric patients undergoing elective cesarean delivery. It can be challenging because of poorly palpable surface landmarks and positioning challenges due to pregnancy-related changes [1]. Spinal ultrasound can provide effective information to perform spinal anesthesia [2], be used as a preoperative assessment tool predicting the feasibility/difficulty of neuraxial blockade [3,4], and assist with difficult spinal patients [5].

When learning to place spinal anesthesia, junior residents are encouraged to conceptualize the anatomy based on previous didactic teaching, models, and palpation and then direct the needle blindly to the intrathecal space. The sources of anatomical knowledge may include anatomy laboratory sessions, didactic learning, physical and virtual spinal models, anatomy text books, videos presentations, Internet resources, and others. The educational benefits of ultrasound imaging for teaching regional anesthesia have been validated [6]; for anesthesiology trainees placing *epidural* catheters, preprocedure ultrasound

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examination has been shown to reduce the number of attempts and the number of failures [7].

Neuraxial ultrasound studies in obstetric patients have shown that ultrasound can assist epidural placement [8] and have been reviewed [9] and led to National Institute for Health and Care Excellence guidelines [10], but for intrathecal anesthetic placement, the benefits are less clear [11]. Spinal ultrasound allows more accurate identification of axial anatomical structures and intervertebral spaces than palpation [9,11-14], but the ergonomic challenges with needle angulation and depth have limited real-time utilization to a few practitioners. A meta-analysis [15] of epidural anesthesia, spinal anesthesia, combined spinal-epidural anesthesia, and lumbar puncture found benefit with ultrasound, although only 1 contributory study [5] featured spinal anesthesia. A recent study of residents performing epidurals did not demonstrate a benefit using ultrasound assistance [16], and a recent study of ultrasound assistance for spinal anesthesia for nonobstetric patients also did not demonstrate benefit [17]. Although supportive of this technology, the literature has been limited to small studies by a limited number of centers/experts [11].

This randomized controlled trial was designed to evaluate the impact of additional information provided by preprocedure ultrasound examination among trainee anesthesiologists performing spinal anesthesia for obstetric patients undergoing elective cesarean deliveries. We hypothesized that trainees would require fewer attempts for successful spinal placement with the addition of a preprocedural ultrasound examination to demonstrate the spinal anatomy.

2. Materials and methods

This randomized clinical trial took place at the 2 obstetrical teaching hospitals in London, Ontario, Canada. The trial was registered at clinicaltrials.gov (NCT01444638), and institutional research ethics board approval was obtained. Written informed consent was obtained from all patients and residents.

Anesthesia residents in their first or second postgraduate year were invited to participate when they had experience of at least 3 and no more than 25 obstetric spinal anesthetics. English-speaking adult patients scheduled for elective cesarean delivery under spinal anesthesia were invited to participate. Exclusion criteria included parturient body mass index >40 kg/m^2, emergency cesarean delivery, multiple gestations, significant scoliosis, previous spinal surgery, or previous failed spinal anesthetic.

Each patient was allocated to either preprocedure ultrasound with landmark technique or landmark technique only by a computer-generated random code enclosed within a sealed opaque envelope (www.random.org). Two anesthesiologists (an “investigator” and an “attending”) were present during this study, in addition to the resident.

The patient was positioned in sitting position to the satisfaction of the attending anesthesiologist prior to randomization to avoid bias in patient positioning based on group assignment, and standard monitors were applied. The ultrasound machine (Sonosite M-Turbo with C60x 2-5 MHz probe; Sonosite Inc., Bothell, WA) was brought into the room and prepared. The attending anesthesiologist then left the room so as to remain blinded to group assignment. The group randomization envelope was then opened, and the patient was allocated to either preprocedure ultrasound with landmark technique or the landmark-only technique.

If the patient was randomized to the landmark-only technique group, the resident palpated surface anatomical landmarks (iliac crests, lumbar spinous processes, and interspinous spaces) with guidance from a study investigator. The palpated spines and lumbar interspinous spaces were marked. The interspinous space for spinal anesthesia was chosen based on the ease with which it was palpated. If the patient was assigned to the landmark technique with ultrasound group, the resident palpated the anatomical landmarks as described above, and then the investigator anesthesiologist performed the preprocedure ultrasound examination for the anesthesia resident, demonstrating both paramedian and midline views of the lumbar spine. The paramedian view was used to count upward from the sacrum and view the lamina, posterior longitudinal ligament, and lumbar interlaminar spaces. The midline transverse view was then used to show the spinous processes, tranverse processes, laminae, vertebral bodies, as well as the interspinous processes and ligamentum flavum–dura complexes. The distance from skin to the dura and potential angle of needle insertion were discussed with the resident. The spines and interspinous spaces based on ultrasound examination were marked. The interspinous space for the initial attempt was chosen based on the ease with which it was visualized in the transverse view.

For both groups, the residents, nurses, and patient were requested not to discuss the ultrasound examination, or lack thereof, to preserve blinding of the attending anesthesiologist. Once the marking was completed, the attending anesthesiologist blinded to group assignment then returned to the room to observe the placement of the intrathecal anesthetic by the junior resident. Patients received 0.75% bupivacaine (10-12 mg), fentanyl (0-15 μg), and preservative-free morphine (100-200 μg). All residents used a #25 Whitacre spinal needle through a #20 introducer with a midline approach.

The blinded attending anesthesiologist recorded all of the outcomes [18]. The primary outcome was the number of attempts for the spinal anesthetic. The number of attempts was defined as 1 if the introducer was placed and the spinal needle was advanced to the intrathecal space in 1 continuous movement. Each time the spinal needle or introducer was partially or completely withdrawn or repositioned, an additional attempt was counted.

The placement duration was defined from when the introducer needle punctured the skin for the first time until cerebrospinal fluid was observed at the needle hub. Presence of bloody tap was categorized as none, trace, or significant. The block height was measured using ice testing 5 and 10 minutes after injection of the spinal medications. After the case was completed, the investigator anesthesiologist reviewed the anesthetic record to determine if any supplemental intravenous analgesics had been administered during the case.

Other prespecified secondary outcomes included need for staff intervention (staff completion of the spinal anesthetic), spinal anesthetic failure, incidence of paresthesia, block level, and resident subjective ease of spinal placement scored on a 100-mm visual analogue scale (VAS) with 0 mm = difficult and 100 mm = easy.

2.1. Statistical analysis

The null hypothesis was that there would be no difference in the number of attempts at spinal anesthesia with or without preprocedure ultrasound examination prior to palpation.

All data were analyzed by a statistician blinded to group allocation [19] (Dr Larry Stitt, Western University). SAS version 9.3 (SAS Institute Inc, Cary, NC) was used for all statistical tests and for sample size calculation. Sample size calculation was based on parametric analysis even though nonparametric analysis was anticipated for the outcomes in the study [20]. For the sample size calculation, the consensus of the investigators was that a reduction of 1 attempt would be clinically relevant. An estimation of standard deviation (SD) of 1.5 was based conservatively on the finding of Grau et al [1] of an SD of 1.0 for epidural anesthesia. Standard type I and type II error rates ($\alpha = .05$, $\beta = .20$) were used. The calculated sample size was 36 per group; a total sample size of 80 patients was selected to allow for patient dropout or missing data.

The primary outcome of number of attempts and other discrete variables were assumed to be nonparametric and described with median and interquartile range and compared between groups using the Mann-Whitney U or log-rank tests. Categorical variables were compared between groups using Fisher exact test or χ^2 analysis as appropriate. There was no correction for multiple comparisons [21]. Results were considered statistically significant when $P < .05$.

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