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Ultrasonography Versus Palpation for Spinal Anesthesia in Obese Parturients Undergoing Cesarean Delivery

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Introduction:

Neuraxial blocks (including single shot spinal, epidural, and combined spinal-epidural) are the most commonly used techniques for uncomplicated cesarean delivery to avoid the complications of general anesthesia such as airway and pulmonary complications.[1]

Neuraxial anesthesia relies primarily on the visualization and palpation of the surface landmarks, which can be difficult in the setting of obesity, edema, and anatomical variation.[2]

Obesity causes difficulty in the detection of anatomical landmarks during neuraxial blocks resulting in increased number of attempts, longer procedure time, higher incidence of vascular puncture, and higher failure rate.[3]

Ultrasonography has been used to guide neuraxial blocks either as a prepuncture procedure or less commonly as a real-time technique. Ultrasonography is readily available, relatively safe, and has now been familiar for anesthesiologists being used in vascular access and various regional anesthetic techniques.[4,5]

Prepuncture ultrasound scan has been utilized to identify the midline, locate the appropriate intervertebral space, detect the optimal angle for needle insertion, and measure the distance to the epidural space. This added information has increased the success rate of neuraxial block on the first attempt, increased patient comfort and satisfaction, and decreased the incidence of complications such as vascular puncture and backache.[6,7] However, the use of ultrasonography for identification of spinal structures is complicated because the epidural and intrathecal spaces are a thin and deep structure and surrounded by bony structures

which impede the ultrasound beam. It also needs additional training and adds cost and time to the procedure.[8]

In obese patients, there are multiple factors that affect image quality because of deep anatomic location of structures, the ultrasound beam travels a greater distance, resulting in beam attenuation. Also phase aberration of the sound field occurs because of uneven speed of sound in the irregularly-shaped adipose layers. This is due to differing speeds of sound in the overlying nonhomogeneous tissues above the focus of the transducer. Another factor that can affect the quality of the ultrasound image is reflection which is due to mismatch of acoustic impedance at the fat/muscle interface. When the ultrasound beam crosses a boundary between muscle layer and fat, a portion of energy is reflected back to the transducer because of different acoustic velocity between the two tissues.[9]

Moreover, the real-time ultrasound guidance seems difficult and may need two physicians; one to hold the ultrasound probe and the other to perform the neuraxial block. Therefore, real-time ultrasound guided neuraxial blocks are not currently recommended for routine use.[5] The first report of ultrasound utilization for epidural catheterization in the English literature was published by Cork et al. in 1980. There were very few reports on the topic until the last decade when increasing number of studies were performed due to the great innovation in ultrasound technology.[2] Most of these studies were designed to validate the prepuncture technique and they used inconsistent imaging strategies and were not blinded.

Several studies have examined the use of preprocedural ultrasonography for spinal anesthesia and compared it with the conventional landmark technique. Creaney et al have used ultrasonography to identify the lumbar spaces in parturients with poorly

defined landmarks presenting for cesarean delivery under spinal anesthesia and demonstrated that ultrasonography reduced the number of needle passes and did not prolong the whole procedure time.[10] Ekinci et al compared ultrasonography with conventional landmark technique in parturients with impalpable anatomical landmarks.[11] Real- time ultrasonography also was used to guide spinal anesthesia in patients with predicted difficult anatomy.[12]

Aim of the study:

The aim of this study is to evaluate the efficacy of prepuncture ultrasonography to facilitate spinal anesthesia in obese parturients undergoing elective cesarean delivery compared with the conventional palpation technique.

Outcomes of the study:

The primary outcome will be the number of needle passes required to obtain free CSF flow. Secondary outcomes will be the number of skin punctures required to obtain free CSF flow, the success rate at the first needle pass, the success rate at the first skin puncture, the duration of the spinal procedure, patient satisfaction from the procedure, and the incidence of vascular puncture, paresthesia, failure to obtain CSF flow, and failed spinal block.

Anticipated Duration of the study:

18 months

Type of the study:

Prospective, randomized controlled, double-blind, 2-arm study.

The study subjects and the investigators assessing the outcomes will be blinded to the study group.

Patients:

The study will be conducted on parturients scheduled for elective cesarean delivery under spinal anesthesia at the Obstetric department of Mansoura University Hospitals.

Inclusion Criteria:

- American Society of Anesthesiologists physical status II-III parturients
- Full term, singleton pregnancy
- Body Mass Index ≥ 35 Kg/m^2

Exclusion Criteria:

- Age < 19
- Women presenting in labor
- Contraindications to neuraxial anesthesia (Coagulopathy, increased intracranial pressure, or local skin infection)
- Significant spinal deformities or previous spinal surgery
- Preeclampsia

Methods:

After obtaining written informed consent, the study subjects will be randomly assigned to 2 equal groups (ultrasonography and palpation groups) according to computer-generated codes using the permuted block randomization method with randomly selected block sizes of 4 and 6. The group allocation will be concealed in sequentially numbered, sealed opaque envelopes.

Vascular access will be obtained then the subjects will be placed in the sitting position and standard monitors (electrocardiography, non-invasive blood pressure, and pulse oximetry) will be applied. The subjects will be kept in the same position during identification of landmarks and during the spinal anesthesia procedure. The subjects will be examined for the ease of landmark palpation using a 4-point scale (1 = the spinous processes and the interspaces can be identified by light palpation; 2 = the spinous processes and the interspaces can be identified by deep palpation; 3 = the spinous processes only can be identified by deep palpation, and the interspaces cannot be identified; 4 = neither the spinous processes nor the interspaces can be identified). The difficulty grade for each patient will be recorded.

In the palpation group, a sham procedure will be performed to blind the subjects by sliding the ultrasound probe on the patient`s back while the ultrasound machine is in the freeze position. Conventional palpation technique will be performed: The midline will be identified by palpation of the spinous processes and the line connecting the iliac crests (Tuffier`s line) will be assumed to cross the L4 spine or L3-L4 interspace. Identification of 2 intervertebral spaces (L3-L4 and L2-L3) will be done and the widest/most easily palpable interspace will be chosen for needle puncture. In women with impalpable spines, the iliac crest or the crease at

the bottom of the spine will be used to determine the needle insertion point.

In the ultrasonography group, a systematic 7–step approach will be performed using an 8-2 MHz curved array transducer (SonoAceR3®, Samsung Medison; Seoul, South Korea):

1. The probe will be longitudinally placed on the bottom of the spine, with the probe mark pointing cephalad, to obtain the longitudinal view of the sacrum and the paramedian sagittal oblique view of the L5–S1 interspace.

2. The operator will count up the intervertebral levels to obtain the paramedian sagittal oblique view of theL3–L4 interspace.

3. The probe will be rotated 90ºanticlockwise to obtain the transverse interlaminar view of the L3–L4 interspace, which will be used in the next steps.

4. The skin will be marked with horizontal and vertical lines at the midpoints of the probe's short and long sides, respectively; the intersection point of the 2 lines represents the needle insertion point.

5. The angle of the probe obtaining the best sonographic image will be observed.

6. The distance from the skin surface to the ventral aspect of the ligamentum flavum-dura mater complex will be measured; this will correspond to the depth of the epidural space.

7. The probe will be moved 1 interspace cephalad to obtain the transverse interlaminar view of the L2–L3 interspace and steps 4 to 6 will be repeated.

The interspace with the best sonographic image or the widest/ most easily palpable interspace will be chosen for the first attempt in the

ultrasonography and palpation groups, respectively. If the 2 spaces are of equal image quality or width/ease of palpation, the L3-L4 interspace will be first attempted. The puncture site will be infiltrated with 1-2 mL of 2% lidocaine. Spinal anesthesia will be performed with a 25- or 22-gauge spinal needle (a 22-gauge needle will be only used after a failed first attempt in subjects with tough ligaments) using a midline or paramedian approach according to the preference of the operator. The paramedian approach will be used in women having difficulty in flexing their spines and/or difficult interspaces; the puncture site is 1 cm lateral to and 0.5 cm below the midpoint of the interspace. After obtaining free cerebrospinal fluid (CSF) flow, 2.5 mL of 0.5% hyperbaric bupivacaine (12.5 mg) and fentanyl 15 μg will be intrathecally administered. After intrathecal injection, women will be placed supine with slight left lateral table tilt.

A maximum of 11 passes (the first attempt and 10 redirections) of the spinal needle will be allowed for each skin puncture and a maximum of 6 skin punctures will be allowed to obtain free CSF flow.

The number of performed needle passes (defined as any forward introduction of the spinal needle after its incomplete withdrawal, including the primary attempt) and skin punctures (defined as any separate skin puncture by the needle after its complete withdrawal, including the primary attempt) will be recorded.

The occurrence of unintentional vascular puncture will be recorded. The actual duration of the procedure (from the start of the first skin puncture by the spinal needle to obtaining free CSF flow) will be recorded.

Patient satisfaction from the procedure will be assessed immediately after intrathecal injection using a five-point scale (1 = very unsatisfied, 2 = unsatisfied, 3 = fair, 4 = satisfied, 5 = very satisfied).

The upper sensory level will be assessed using pin prick and surgery will start after attaining a level of T6 or higher. The level after 20 minutes of intrathecal injection will be recorded; a level below T6 will be considered a failed spinal block and the patient will be managed as appropriate.

Sample Size Calculation:

The primary outcome will be the number of needle passes required to obtain free CSF flow. In a pilot study performed on 20 obese parturients using the palpation technique, 8 ± 5 needle passes were required to successfully obtain free CSF flow. Assuming alpha = 0.05 and beta = 0.1 (power = 90%) and using the 2-tailed Student *t* test, 133 subjects will be required in each group to detect a difference of 2 needle passes between groups which is considered to be the minimal clinically important difference. To allow for subject dropouts, 140 subjects will be assigned to each group.

Statistical analysis:

Data will be analyzed using the R software (R Core Team; R Foundation for Statistical Computing, Vienna, Austria). Continuous data will be tested for normality using the histogram and the Kolmogorov-Smirnov test. Normally distributed data will be presented as mean ± standard deviation and compared using the Student`s *t* test. Non-normally distributed data will be presented as median (range) and compared using the Mann-Whitney U test. Categorical data will be presented as number (percentage) and compared using the chi-square test or Fisher`s exact test. A P-value < 0.05 will be considered statistically significant.

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