

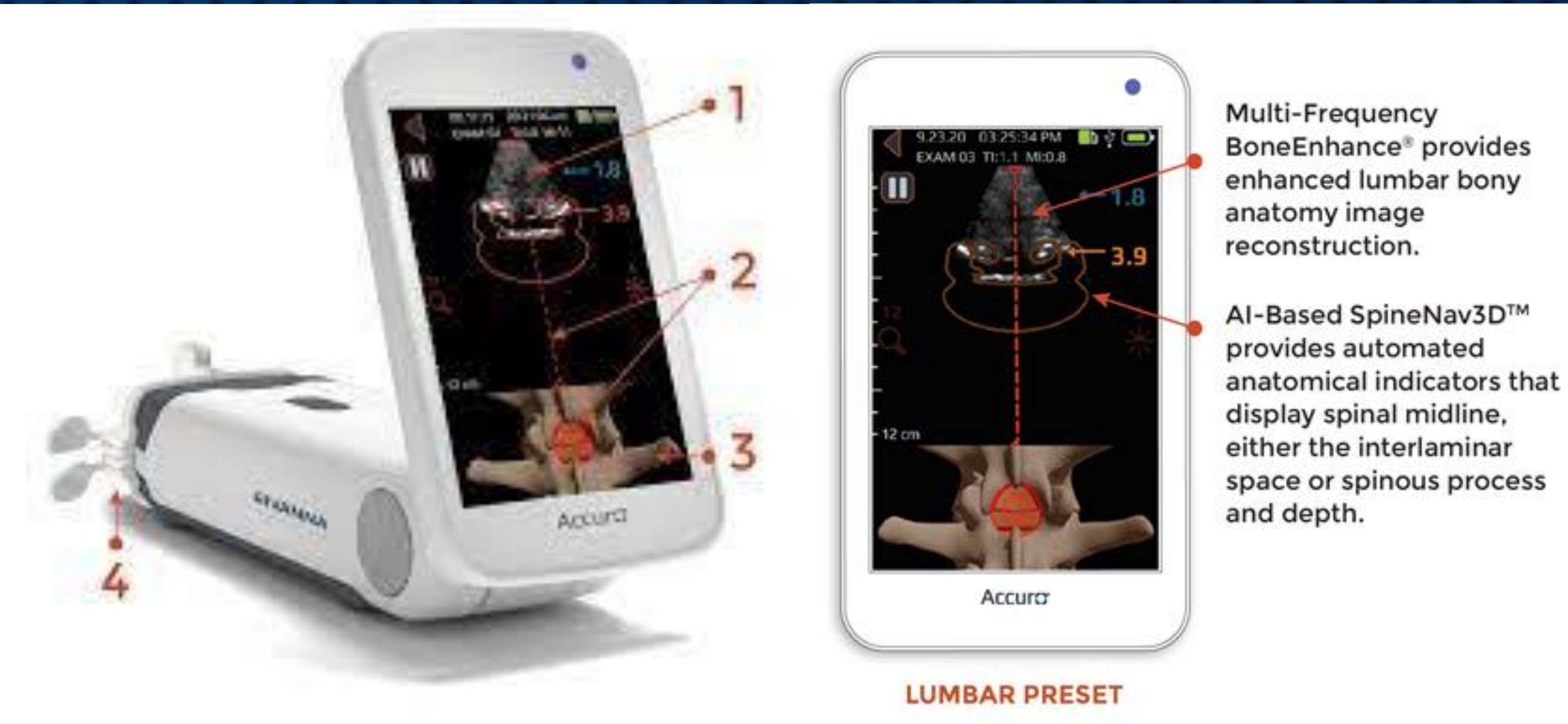
Pilot Study: Using Handheld Ultrasound for Epidural Placement in the Obese Laboring Patient

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Introduction

Placement of neuraxial blocks is usually achieved by palpating surface landmarks. This blind technique is more difficult in obese patients. Application of conventional ultrasound for neuraxial blocks has been limited by bulkiness and poor imaging due to bony structures. A pocket-size ultrasound addresses these limitations by providing 3D overlay for recognition of midline and intervertebral space using an automated artificial intelligence algorithm. We hypothesize that ultrasound guidance will reduce time to epidural placement and reduce number of passes in obese patients.

Some previous studies of epidural placement in pregnant populations have demonstrated reduced number of needle passes with pre-procedural ultrasound. Perna et al found mean identification of the epidural spaces in parturients being managed with labor epidural anesthesia to range from 1.7 ± 0.87 passes in the ultrasound group and 3.43 ± 3.80 passes in the palpation group ($P=0.019$) (2017). In obese patients ($>33 \text{ kg/m}^2$), being managed with combined spinal and epidural anesthesia, puncture attempts were 1.5 ± 0.9 in ultrasound group and 2.6 ± 1.4 in control group ($P < 0.001$) (Grau et al 2001). This study also found significant advantages in the ultrasound group regarding number of puncture sites, catheter advancement attempts, maximum visual analog scale (VAS), and patient’s satisfaction (Grau et al 2001). Rate of first pass success in parturients requiring labor epidurals, was 67.3% for ultrasound group and 40% for the palpation group ($P=0.037$) (Nassar et al 2014). Other studies have not shown a clear advantage of using ultrasound. Tawfik et al. found the rate of successful epidural catheterization in parturients with first needle pass undergoing cesarean delivery to be 60% in the palpation group and 58.5% in the ultrasound group (2017).



Objectives

1. To determine the study **power** needed to answer the research questions.
2. To investigate if using handheld ultrasound for neuraxial block placement in parturients with BMI=35-59.9 reduces **time** to placement.
3. To investigate if using handheld ultrasound for neuraxial block placement in parturients with BMI=35-59.9 reduces number of **passes**.

Study Design

We performed a pilot prospective randomized study of full- term non-emergent obese parturients with BMI 35-59.9 who requested epidural labor analgesia at UK HealthCare Labor & Delivery from October 2021 to December 2022. 25 patients were randomized to palpation or ultrasound groups with stratification into WHO Group II (BMI 35-39.9)& III (BMI above 40) classes of obesity. Subjects who met all study criteria were randomized to the study interventions using the REDCap randomization module. All procedures were performed in the sitting position using a LOR technique with identical epidural kits. For patients randomized to the ultrasound group, the anesthesiologist performed the ultrasound and marked the L3/4 location. They then performed the epidural procedure, without palpation, inserting into the horizontal plane at the location marked. For palpation group, normal palpation was performed before epidural placement. In both groups a test dose was given, followed by 8-12cc bolus with 0.125% bupivacaine in a multi-orifice catheter. Analgesia was maintained with PIEB (8-12cc every 45 mins) and PCEA (5cc every 15 mins) protocol of 0.1% bupivacaine with 2mcg/cc fentanyl.

Inclusion and Exclusion Criteria

- Inclusion

 1. Subject requesting and consenting for a labor epidural, aged 18-45 BMI between 35-59.9 at admission for labor.
 2. Subject with American Society of Anesthesiologists score < /= III.
 3. Subject with singleton gestation at >/= 37 weeks.
 4. Subjects with planned labor epidural in sitting position.
- Exclusion

 1. Patients with urgent or emergent diagnosis involving the health of the patient or child, such as abnormal fetal heart tracing.
 2. Patients with major back abnormalities (back surgery, significant scoliosis).
 3. Patients with contra-indication to neuraxial block (bleeding risk, local anesthetic allergy).
 4. Patients having cesarean section or combined spinal epidural.
 5. Patients whose epidurals are performed by residents in first month of obstetric rotation and/or have performed <20 labor epidurals.
 6. Patient needing translator for procedure.
 7. Patients who are prisoners.
 8. Patients with BMIs of 60 or greater.

Data Collected

1. Preparation Time
 - a. Ultrasound group, defined as placing ultrasound probe on skin to inserting local anesthetic needle
 - b. Palpation group, defined as touching patient back to palpate until inserting local anesthetic needle
2. Time to placement (from local anesthetic to skin to removal of Tuohy needle from skin after catheter placement) is recorded.
3. Number of passes (epidural needle removed from skin and re-entered)
4. Number of needle redirections (epidural needle direction is changed without removal from the body)
5. Number of interspaces attempted.
6. Complications, including dural puncture and clinician bolus requirements.
7. Visual Analogue Scale Pain Scores (before placement and 30 minutes after dosing epidural).

Results

Ultrasound-guided vs. Palpation Technique Data

Demographic Data

	US Group (N=10)	Palpation Group (N=11)	p-value
Age	25.6 (7.5)	25.9 (5.4)	0.92
Height	165.6 (10.5)	164.2 (7.1)	0.72
Weight	117.0 (26.9)	111.6 (15.8)	0.58
BMI	42.2 (5.7)	41.2 (4.0)	0.64
BMI Group (Group=1)	4 (40.0%)	3 (27.3%)	0.66

Of the 25 subjects, there were 4 drop-outs – one delivering without epidural placement after randomization and the other 3 consented patients having epidurals placed with no co-investigator present (after hours) for timing and data collection.

The average BMI of patients was 41.7 overall for the study

Table 1

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Results cont.

Epidural Placement Data			
	US Group (N=10)	Palpation Group (N=11)	p-value
ASA PS Classification (ASA =1)	5 (50.0%)	5 (45.5%)	1.00
Resident Level – Ultrasound (PGY-2)	8 (80.0%)	10 (90.9%)	0.59
Resident Level – Procedure (PGY-2)	8 (80.0%)	10 (90.9%)	0.59
Experienced Procedure Resident (Yes)	10 (100.0%)	11 (100.0%)	1.00
Number of passes	1.6 (1.1)	1.3 (0.5)	0.42
Number of redirections	1.8 (1.9)	2.4 (2.2)	0.51
Subjects with additional spaces attempts	3 (30.0%)	1 (9.1%)	0.31
Time to skin anesthetic	151.4 (46.7)	113.9 (43.1)	0.07
Time from skin anesthetic to epidural placement	382.9 (338.5)	266.0 (127.3)	0.30

Table 2

Ultrasound-guided vs. Palpation VAS Pain scores and clinician bolus requirements			
	US Group (N=10)	Palpation Group (N=11)	p-value
Pain level before epidural	7.6 (1.8)	8.5 (1.5)	0.23
Pain level after epidural	1.0 (1.8)	0.5 (1.0)	0.44
Pain level improvement	5.3 (3.2)	8.0 (1.5)	0.02
PCA provided relief (yes)	0 (0%)	2 (18.2%)	0.48
Additional clinician boluses needed (yes)	1 (10%)	6 (54.5%)	0.06

Table 3

- Our results were not statistically significant due to this being a pilot study. A larger study would be needed to show definitive results.
- We did see a trend of **shorter preparation time for the palpation group** vs the ultrasound group (113.9 vs 151.4 secs, p=0.07), in Table 2.
- As seen in Table 2, there was a trend toward **shorter placement time in the palpation group** vs the ultrasound group (266 vs 338.5 secs, p=0.30), although we found no great differences in the number of passes (1.3 for palpation, 1.6 for ultrasound, p = 0.42) and redirections (2.4 for palpation, 1.8 for ultrasound p=0.51). There were 1 vs 3 subjects with additional interspaces attempted in the palpation vs ultrasound group (p=0.31).
- The VAS pain scores decreased in both groups after epidural placement, with the mean decrease slightly more in the palpation group (Table 3).
- The number of patients requiring **clinician boluses** was 1 (10%) in the ultrasound group vs 6 (54.5%) in palpation group, with p=0.06 (Table 3).

Sample size Calculation

Our power calculation showed that to find a statistically significant difference (alpha = 0.05, power = 0.8) between the ultrasound and palpation groups:

- Time from skin anesthetic to epidural placement = 38 subjects per group (to show palpation quicker)
- Number of passes = 44 subjects per group (to show palpation is fewer)
- Additional boluses needed = 16 subjects per group (to show US is fewer).

Conclusion

This pilot study was undertaken to determine how many patients should be enrolled to compare palpation and ultrasound techniques for epidural placement in obese parturients. While the trend we found was that palpation had a shorter preparation and placement time as well as less passes, there were less clinician boluses and redirections required in the ultrasound group. With the power calculation performed with these pilot study results, we plan to perform a larger, definitive study comparing these techniques in obese patients.

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