Does Pre-Procedure Neuraxial Ultrasound Using the GE Logiq® Improve Midline Placement of Combined Spinal Epidural when Compared to a Palpation Technique Performed by Experienced Anesthesiologists? A Prospective Randomized Study

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ABSTRACT

Background: Neuraxial placement relies on palpation of anatomical landmarks, sometimes challenging to identify. Ultrasound (US) has helped facilitate those procedure. We wanted to assess efficacy of the US compared to landmark techniques when used by experienced obstetric anesthesiologists.

Methods: We conducted a randomized prospective trial of healthy parturients requesting neuraxial labor analgesia. Positive CSF through the 27 G Pencan spinal needle at the first interspace attempted was the primary outcome. Secondary outcomes were the number of attempts and the number of needle adjustments within a space, presence of symmetrical analgesia 2 hours after placement, and need for epidural replacement. The procedures were performed by practitioners experienced in obstetric anesthesia, including obstetric anesthesiology fellows, and attending physicians who received a video training of the US technique prior to the study [1].

Results: Forty-eight patients were randomized to either the US or landmark group. Two patients (one in each group) were excluded from the study due to delivery within 2 hours of CSE (Combined Spinal Epidural) placement. One patient in the landmark group was excluded due to a wet tap. No statistical difference was found regarding positive CSF flow on first attempt at CSE (p = 0.6). All secondary outcomes were statistically insignificant as well: number of spaces attempted (p = 0.71 95% CI –0.30 to 0.21), number of needle adjustments (p = 0.09, 95% CI –0.10 to 1.28), presence of symmetrical anesthesia at 2 hours (p = 1) and need for epidural replacement (p = 0.48).

Conclusions: When placed by an experienced obstetric anesthesiology fellow or attending physician, there is no difference in the successful placement of CSE with US versus landmark technique.

KEY POINTS SUMMARY

Question: Does the use of an US machine (GE Logiq®) by experienced obstetric anesthesiology providers increase the success of neuraxial placement compared to the 'traditional' landmark technique.

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Findings: Our results did not show any statistical difference between the US and the landmark techniques when done by skilled anesthesiologists in term of the number of interspaces attempted, number of adjustments or redirections of the needle in the same interspace, the presence/absence of CSF flow upon dural puncture or the adequacy of the block 2 hours after placement.

Meaning: We concluded that the use of US does not confer any benefits for neuraxial placement in this specific subgroup of practitioners.

INTRODUCTION

Neuraxial analgesia has become the gold standard for pain control during labor over the past 30 years [2]. Epidural placements using the landmark technique, which is the most widespread, can be challenging in obstetrical patients due to edema, obesity and pain. These factors increase the difficulty for the anesthesiologists as the time it takes to successfully place the labor analgesia can be prolonged due to need to redirect needles or reposition patients, all which may increase anxiety and discomfort of parturients. Failure rate for epidural analgesia without the use of ultrasound, can be as high as 20%. In 1998, Eappen et al, published a large retrospective chart review in IJOA, showing a 13.1% failure rate of lumbar epidural based on "need to replace it" [3]. Another large retrospective analysis of almost 20,000 deliveries, published in 2004, found an incidence of neuraxial analgesia use in labor of 75% with an overall failure rate of 12% [4].

Ultrasound guided placement (US) could be a method of improving speed of placement of neuraxial analgesia as it provides an opportunity to directly visualize landmarks which have traditionally been located by palpation. US guidance for regional anesthesia has gained tremendous popularity over the past 15 years [5–8]. In a literature review published in 2016 by Soni et al., 20 randomized trials and 2 meta-analysis comparing landmark-based versus ultrasound-guided techniques for lumbar puncture or epidural/spinal anesthesia, showed a large advantage of the US technique in different patient populations, using different outcomes (see *Table 1*) [9]. Different methods of using US have been described: real-time ultrasound guidance like the technique used for peripheral nerve blocks, or pre procedure US identification of landmarks. A study done by Tran et al showed the successful use of real-time paramedian ultrasound-guidance for needle insertion in a small cohort of patients undergoing elective cesarean delivery [10]. Another study conducted by Karmakar et al. in the adult non-pregnant population, demonstrated the successful use of real-time US guidance in combination with LOR to saline for paramedian epidural access with the epidural needle inserted in the plane of the US beam [11]. Both studies used a para-median approach for the neuraxial placement, likely due to the technical challenges linked to the real-time use of US during this procedure when utilizing a midline approach. The paramedian approach is less popular than the midline approach, especially in obstetrics. In clinical practice, the use of US is still more sporadically used in obstetrical patients, and not yet as widespread as the landmark technique. One of the reasons might be that in patients with more challenging anatomy, such as parturients, the use of ultrasonography can be more challenging, impacting its feasibility, especially when time is of the essence in a patient experiencing pain. US has been used as an epidural placement teaching tool and current studies have looked at residents' performance rather than obstetric (OB) anesthesia trained attendings. There is limited information comparing US guided labor epidural placement in practicing anesthesiologists.

Consequently, most of the studies show an advantage of the use of US for epidural placement, but whether this holds for experienced providers has not been clearly delineated. To address this dilemma, we performed a randomized controlled trial of landmark and US placement of labor epidurals. We hypothesized that the use of US for labor analgesia placement in patients without known spinal pathology, would be superior to the use of landmark technique when performed by obstetric anesthesiologists.

METHODS

This study was approved by the University's Institutional Review Board (IRB #12-172) and written informed consent was obtained from all subjects participating in the trial. The trial was registered prior to patient enrollment at *clinicaltrial.gov https://register.clinicaltrials.gov* with NCT number 0220792, 07/31/2014.

REFERENCE NO.	STUDY TYPE	STUDY POPULATION		RATE OF SUCCESSFUL PROCEDURE			MEAN NO. OF ATTEMPTS[a] (SUCCESS ON FIRST PASS, %)			ADDITIONAL FINDINGS
		NO.	POPULATION	US	NO US	P VALUE	US	NO US	P VALUE	
9	RCT	66	ED patients needing LP	—	—	NS	—	—	—	Decreased procedure time
10	RCT	46	ED patients needing LP	95%	73%	<0.05	2	2	NS	Increased ease of procedure in obese patients
11	RCT	61	ED patients needing LP	97%	71%	0.07	1.6 ± 1.1 (97%)	2.3 ± 1.8 (71%)	0.66 (0.07)	Fewer failed procedures in elderly patients
12	RCT	60	ED patients age >60 y needing LP	100%	83%	<0.05	1.5 ± 0.8	3.3 ± 2.4	<0.05	Decreased procedure time; decreased pain scores; fewer traumatic taps
13	RCT	80	ED patients needing LP, ages 18–60 y	100%	100%	1	1 ± 0.5	2 ± 1	<0.047	Decreased procedure time; fewer traumatic taps; decreased pain scores
14	RCT	78	ED patients needing LP	—	—	—	1 (0–2)	2 (1–3)	0.57	Fewer traumatic taps
15	RCT	100	ED patients needing LP	78%	76%	0.81	3 (1–5)	5 (1–10)	0.24	
16[b]	Meta	1,334	14 RCTs	Risk ratio 0.21[c] (95% CI 0.10–0.43)		<0.001	Mean difference −0.44 (95% CI −0.64 to −0.24)		<0.001	Fewer traumatic taps; fewer needle redirections[d]
17[b]	Meta	1,678	13 RCTs	Risk ratio 0.51[c] (95% CI 0.32–0.80)		0.003	Mean difference −0.75 (95% CI −1.07 to −0.44)		<0.00001	Fewer traumatic taps

Table 1 Summary of literature review done by Soni et al [9].

Abbreviations: CI = confidence interval; ED = emergency department; l_P = lumbar puncture; meta = meta-analysis; NS = not significant; RCT = randomized controlled trial; US = ultrasound.

[a] Refers to withdrawing the needle completely out of the skin and then reinserting.

[b] Contains studies with both LPs and epidural anesthesia.

[c] Risk of failed LP or epidural anesthesia procedure (risk ratio <1 favors US; risk ratio >1 favors non-US).

[d] Refers to withdrawing needle back without completely removing it from body prior to reinsertion.

Inclusion criteria were term pregnant women, gestational age >37 weeks, vertex presentation, singleton pregnancy, ability to provide English informed consent, and request for labor analgesia. Exclusion criteria included women for whom a cesarean section was planned, fetal presentation other than vertex, history of active drug/alcohol dependence, history of previous spinal surgeries, known spinal deformities or prior back surgeries, or cervical dilation greater than 9 cm.

 After obtaining informed consent to participate in the study, patients were randomized into 2 groups for CSE placement. The randomization was done by blindly choosing a paper in an envelope, prepared in advance by the research team to be evenly divided. Group 1 received US guided placement of CSE, and group 2 received use of palpation of landmarks. All blocks were placed by 1 of 3 experienced practitioners who were participating in the study. All patients received CSE for labor analgesia with 1 cc of intrathecal 0.25% bupivacaine and were immediately started on a continuous epidural infusion of 0.0625% bupivacaine plus fentanyl 2mcg/cc, at 12 cc/hr with demand doses of 8cc at 10-minute intervals, per our standard unit protocol.

To train for the ultrasound technique, each participant was asked to watch tutorial videos prior to the beginning of the study, as well as to practice image acquisition to become more acquainted with this technique. In our study, we used a 2.5 MHz curvilinear transducer (US GE Logiq®) (*Figure 1*). The patient's back was briefly assessed by hand to position the probe and the lumbar spine was scanned in the longitudinal approach to obtain an interspace with visualization of a "saw-like" image, (*Figure 2*) and in the transverse approach to locate the midline of the neuraxial structures including the ligamentum flavum and the dura with a "flying bat" image (*Figure 3*). The patient's back was then marked where the US delineated the midline position of an interspace, and the needle was inserted without extensive palpation as is usually the case with the landmark technique.
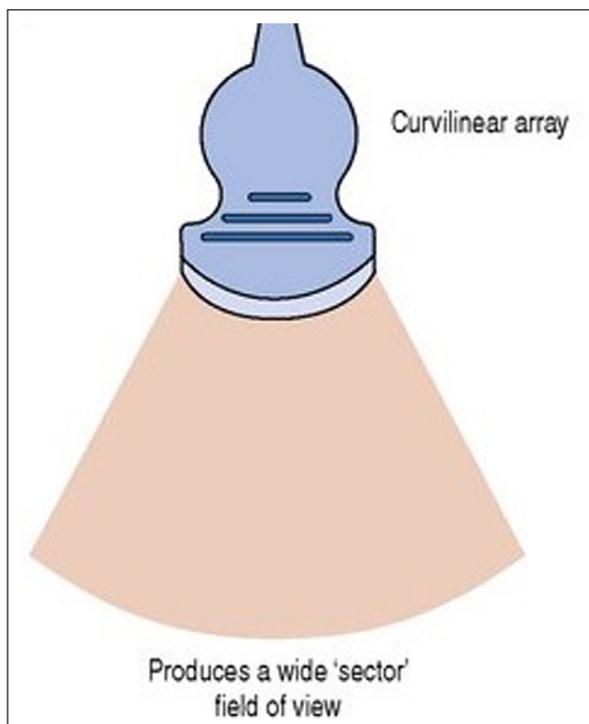

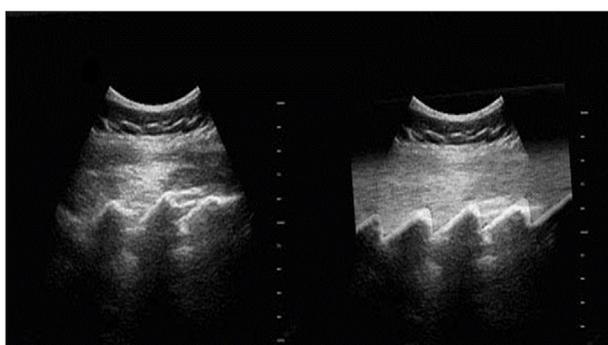**Figure 1** Curvilinear transducer.
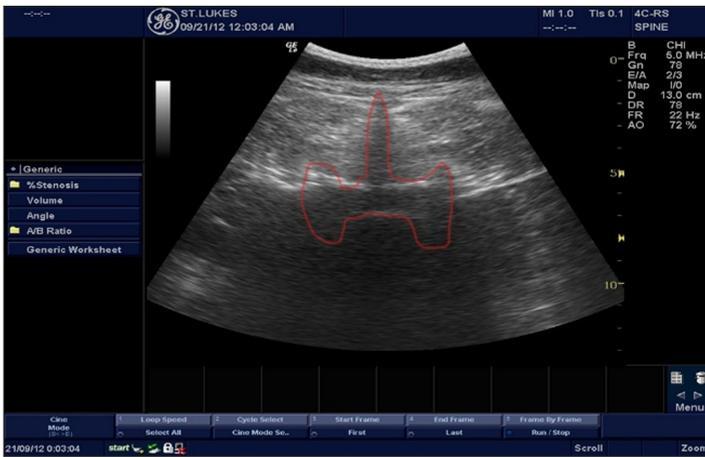

Figure 2 Chain Saw image.

Figure 3 Flying bat image.

The following information was recorded: number of interspaces attempted, number of adjustments or redirections of the needle in the same interspace and the presence/absence of CSF flow upon dural puncture. This information was observed and recorded by the study coordinators. After 2 hours, adequacy of the block was assessed using temperature and sensation to needle prick, and the need to replace the epidural for inadequate analgesia.

The level of significant difference we were hoping to show was a p value <0.05. We calculated the sample size to ensure a study power of 90%, predicting a 10% improvement in ultrasound vs landmark technique, which required including 22 participants in each group. We added an extra 2 participants in each group to account for the possibility of exclusions. The tests used for statistical analysis included 2-sample t-test, Wilcoxon rank sum test and Fisher's exact test.

RESULTS

As shown in *Figure 4* CONSORT diagram, forty-eight patients were assessed for eligibility for the study, then randomized to either the US (24) or landmark group (24). One patient in each group was excluded because they delivered before the 2 hour-mark (but they were still randomized) and one patient in the landmark group did not receive the allocated intervention because
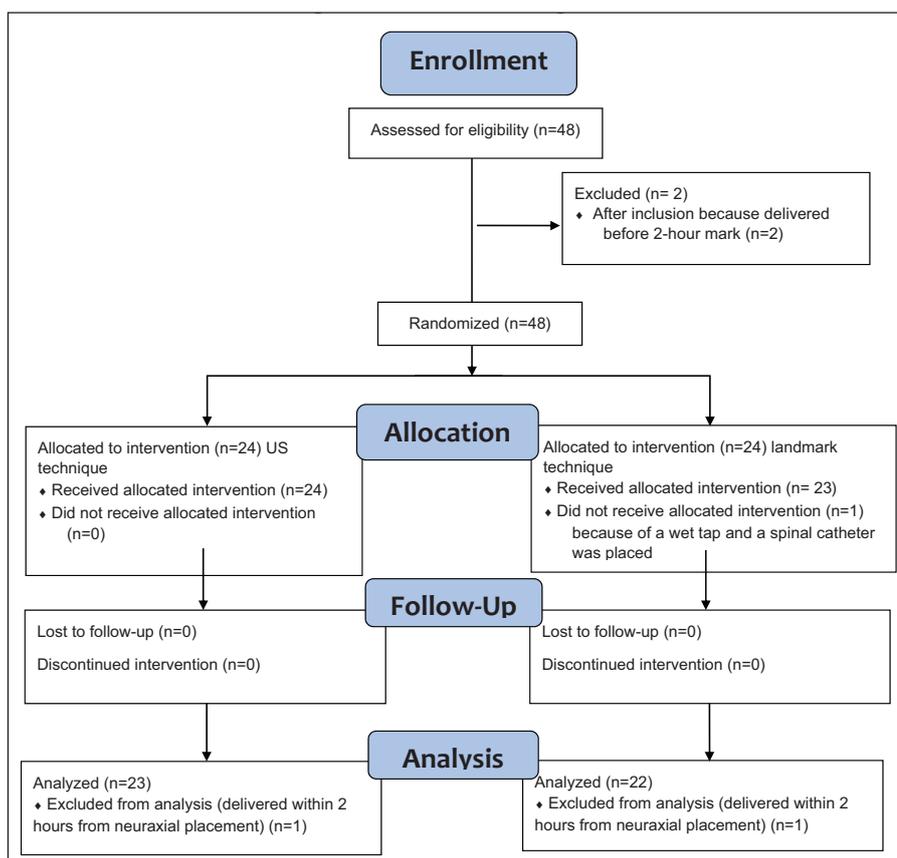

Figure 4 CONSORT Flow Diagram.

of an inadvertent wet tap leading to the placement of a spinal catheter (also excluded after randomization). The final analysis had 23 patients in the US group and 22 in the landmark group. The detailed findings for each patient in each group are summarized in **Tables 2** and **3** (these tables also include the 3 patients who were secondarily excluded and not part of the finale data analysis). The 2 patients who delivered before 2 hours were removed altogether for all parameters from the finale analysis. There was no statistical difference between the groups in patients' age (average of 31.7 in the US group versus 31.8 in the landmark group) or BMI (average of 28.9 with SD: 4.7 in the US group and 29.5 with SD 5.8 in the landmark group, p = 0.68). No statistical difference was found between groups for positive CSF flow at the first interspace attempt at CSE (OR = 0.44, 95% CI: 0.01, 9.10; p = 0.60). All secondary outcomes were statistically insignificant as well: number of spaces attempted (p = 0.87), number of needle adjustments (p = 0.11), presence of symmetrical anesthesia at 2 hours (p = 1.00) and need for epidural replacement (p = 1.00) (**Table 4**).

AGE	BMI	CSF	SYMMETRICAL BLOCK	NUMBER OF INTERSPACES ATTEMPTED	NUMBER OF ANGLE ADJUSTEMENTS	REPLACEMENT
29	33.7	Y	Y	1	0	N
32	29.7	Y	Y	2	2	N
39	28.3	Y	Y	1	0	N
35	28.4	Y	Y	1	0	N
31	30.8	Y	Y	1	0	N
35	24.8	Y	Y	1	1	N
21	25.6	Y	Y	1	0	N
35	30.7	Y	Y	1	0	N
32	40.4	Y	N	3	3	N
29	24.9	Y	Y	1	0	N
35	36.8	Y	Y	1	0	N
31	26.9	Y	Y	1	0	N
34	27	Y	Y	1	0	N
33	31	Y	Y	1	0	n
31	32.3	Y	Y	1	0	n
31	23.5	Y	Y	1	0	n
28	21.3	Y	Y	1	0	n
36	27.4	Y	Y	1	0	N
36	29	Y	Y	1	2	Y
35	25.4	Y	Y	1	0	N
31	34.2	N	Y	1	2	N
29	33.7	Y	Y	1	0	N
32	29.7	Y	Y	2	2	N
39	28.3	Y	Y	1	0	N

Table 2 Group 1: US.

DISCUSSION

The use of neuraxial US to facilitate placement of epidural catheters has proliferated in recent years, particularly for the purpose of improving the success of labor analgesia. The rationale behind using this modality, compared to traditional palpation technique, is the expectation that it would improve both the success and safety of these catheters, as it has for other procedures such as peripheral nerve blocks and facilitating central vascular access [12, 13].

The results of our study were unexpected and did not confirm our hypothesis that the use of US, even by experienced providers, would show superiority compared to the landmark technique.

AGE	BMI	CSF	SYMMETRICAL BLOCK	NUMBER OF INTERSPACES ATTEMPTED	NUMBER OF ANGLE ADJUSTEMENTS	REPLACEMENT
32	29	Y	Y	2	1	N
37	23.6	Y	Y	2	3	N
32	28.3	Y	Y	1	0	N
32	40.6	Y	Y	1	0	N
35	29	Y	Y	1	2	N
23	25	Y	Y	1	0	N
31	36.8	Y	Y	1	2	N
24	35.6	Y	Y	1	3	N
37	23	Y	Y	1	0	N
31	24.2	Y	N	1	1	Y
36	29.2	Y	Y	1	0	Y
41	26.6	Y	Y	1	2	N
31	24.8	Y	Y	1	4	N
19	26.6	Y	Y	1	0	N
25	36.5	Y	Y	1	0	N
32	29.5	Y	Y	1	0	N
29	27.5	Y	Y	1	0	N
24	25.8	Y	Y	1	0	N
28	25.3	Y	Y	1	2	N
30	22.4	Y	Y	2	2	N
39	31.5	Y	Y	1	0	N
41	38.1	N	Y	1	3	N
38	42.5	Y	Y	1	1	N
37	26.8	Y	Y	1	0	N

Table 3 Group 2: Palpation.

	US GROUP	LANDMARK GROUP	STATISTICAL DIFFERENCE
	N = 23	N = 22	
Positive CSF at first attempt, N (%)	20 (86.9%)	22 (100%)	P = 0.60[1] OR = 0.44 [95% CI: 0.01, 9.10]
Number of space attempted, Median [Min, Max]	1 [1, 3]	1 [1, 2]	P = 0.97[2]
Number of needle's adjustment (angle change), Median [Min, Max]	1 [0, 3]	0 [0, 4]	P = 0.11[2]
Presence of asymmetrical analgesia at 2 hours	1 (4.3%)	1 (4.5%)	P = 1[1]
Need for epidural replacement	1 (heme) (4.3%)	2 (1 heme and 1 pain) (9.1%)	P = 0.5
BMI (kg/m^2), Mean (SD)	28.9 (4.7)	29.5 (5.8)	P = 0.68 [3]

Table 4 Data results and comparison in both groups. 1: Fisher's exact test; 2: Wilcoxon rank sum test; 3: 2-sample t-test.

Our results showed no significant difference between the 2 groups regarding any of the 3 objectives of this study. The use of US was correlated with less redirections of the Tuohy and attempts at obtaining CSF, but this was not statistically significant.

Broadbent et al. in a study from 2000, showed that the ability of anesthesiologists to identify a lumbar interspace using landmark technique was accurate only in 29% of the patients included in the study, with a range of error from one space below to four spaces above to where the experienced provider believed it to be [14]. The results of this study highlight the limitations of the landmark technique for neuraxial placement.

In the literature, the evidence for advantages of using US for the placement of labor epidurals or neuraxial procedures in general, is sometimes conflicting but overall shows superiority of the US technique vs landmark. In 2002, Grau et al. showed superiority of labor epidural placement under US guidance in term of the number of attempts, the quality of analgesia and improved pain scores [15]. Although using US for procedural guidance significantly decreased the number of attempts, it seemed to have no effect on postprocedural pain or the time to obtain CSF. Another study by Evans et al. showed that the use of US guidance to assist in lumbar punctures did not improve the procedural success rate over traditional landmark techniques in an academic setting with novice providers [16]. The reason for the heterogeneity of results could be due to the facts that in many studies the full spectrum of trainees, from junior residents to fellows, is assessed, and because the US scanning is variably done either by the trainees themselves or by the principal investigator depending on the study. In 2 meta-analyses and systematic reviews of the literature, one published by Shaikh in 2013 [17], and one by Perlas [18] in 2016, results are overwhelmingly in favor of the US increasing both accuracy and safety of epidural placements. Shaikh et al. [17] included 14 studies with 1334 patients and concluded that "ultrasound imaging can reduce the risk of failed or traumatic lumbar punctures and epidural catheterizations, as well as the number of needle insertions and redirections". Perlas et al. [18] looked at 31 clinical trials and one meta-analysis and concluded that "there is significant evidence supporting the role of neuraxial ultrasound in improving the precision and efficacy of neuraxial anesthetic techniques".

Arzola et al., compared pre-procedure US to landmark technique epidural placement done by residents and fellows and found similar results to our study: no difference in time to complete the procedure, number of interspaces attempted, or number of needle angulations [19]. Their study was done among residents and fellows with various levels of training. The US scanning of the back as well as the landmark identification was done by the resident or fellow who was placing the epidural. They also included only parturients with "easy" palpable lumbar spines, which of course could be an advantage given to the landmark technique.

When considering studies that include only junior residents for example, pre-procedure neuraxial US does seem to improve ease of placement [20]. Vallejo et al. in a study from 2010 done with first year anesthesia residents with limited prior exposure to epidural placement via landmark technique, showed a decreased in the rate of epidural catheter replacement for failed labor analgesia, and a reduction in the number of epidural attempts when using US versus the landmark technique [20]. However, in this study, the scanning of the back in the US group was performed by the primary investigator who had performed US-guided epidural catheter placements for 6 months prior to the initiation of the study. The reasoning behind that, was that US visualization is very much dependent on the skill of the user. The landmark assessment was not clearly specified as done by the primary investigator or the resident placing the epidural, which could potentially introduce a bias in the results showing superiority of the US placement, since the primary investigator's US skills were tested and not the residents, which could also explain the contradictory results with our study.

Tawfik et al. found similar results to ours, finding that pre-procedural neuraxial US did not confer any benefit over landmark technique for placement of epidural catheters by one single experienced anesthesiologist for elective cesarean sections in terms of first pass success rate, number of skin punctures, and patients' satisfaction [21]. This study designed as a double blinded study assessed pre-procedure US versus landmark technique in only one experienced anesthesiologist with 10 years of clinical practice and 4 years of experience with US-assisted neuraxial technique. They also, as we did, excluded parturients with marked spinal deformity, previous spinal surgery, and BMI > 35 or impalpable anatomical landmarks. Of note our population of patients is generally of normal body habitus with Body Mass Index (BMI) less than 40, making the palpation technique achievable and we did not exclude patients based on their BMI.

However, one very recent study published in 2021 in Eur J Anesthesiology [22] is challenging our hypothesis. This double blinded randomized controlled study showed that pre-procedural US imaging done by experienced anesthesiologists (more than 10 years of experience in neuraxial technique and 1 year of experience in US assisted neuraxial anesthesia) increased the first pass success rate of spinal needle placement through the epidural needle for OB patients undergoing cesarean section under CSE. The main difference between our cohort and theirs is that our OB anesthesiologists might be less experienced with the use of US than the providers included in this study.

The limitations of our study include the facts that the study was not blinded, and the physicians included in this study are very experienced OB trained anesthesiologists. Despite a standardized training in the US technique, there could be a bias in the fact that the practitioners have more experience in the landmark technique, impacting the results. Our patient population has an average BMI with typically easy to identify anatomical landmarks. Furthermore, given that our faculty supervise and teach residents, they typically only need to take over the placements that are challenging. As a result, our estimated improvement of 10% with US, may have been overestimated compared to our general population of patients. Another bias we need to mention is the fact that we did exclude 2 patients who delivered before 2 hours from the finale analysis, even though we could have analyzed some of the results for them. However, it is unlikely this would have changed the final conclusion.

We recognize that in patient populations with a BMI > 40, musculoskeletal pathology such as scoliosis, or a history of back surgery, the palpation technique may be difficult. In these cases, US use may be of significant benefit regardless of the provider's experience level as these patients may present difficulty of placement and thus may be at increased risk for complications [23, 24, and 25]. Additionally, US exam has been shown to decrease number of attempts in patients without palpable landmarks suggesting it is of benefit in high BMI populations [26]. In 2009 for example, Balki et al. showed that the pre-assessment of the lumbar epidural space depth with US is well correlated with the actual depth in obese parturient [27]. Similarly, Nomura et al. showed that the use of ultrasound for lumbar puncture significantly reduced the number of failures in all patients and improved the ease of the procedure in obese patients [28].

In patients with normal BMI, our findings suggested that in the hands of an experienced obstetric anesthesiologist, attending physician or fellow, US examination of the spine does not improve the successful placement of CSE in terms of number of interspaces attempted, number of angle adjustments required, or need for catheter replacement.

CONCLUSION

In this study, when performed by an experienced anesthesiologist, pre-procedure neuraxial US did not improve ease of CSE placement in laboring parturients compared to traditional landmark based technique.

COMPETING INTERESTS

The authors have no competing interests to declare.

CLINICAL TRIAL

Study registered on the *ClinicalTrial.gov* website under the NCT number 02207972.

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