

## ORIGINAL RESEARCH

# Comparing Ultrasonography and Surface Landmark-Guided Lumbar Puncture in Patients with Obesity and Difficult Anatomy; a Randomized Controlled Trial

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**Abstract:** **Introduction:** Previous studies have shown higher lumbar puncture (LP) success rates when using ultrasound guidance. This study aimed to compare the first-attempt success rate of ultrasound-guided LP with blind technique of needle insertion using the palpable spinal surface landmark in patients with obesity or a difficult anatomy. **Methods:** This prospective randomized controlled study was performed at the emergency department of Ramathibodi Hospital, an academic tertiary university hospital, from August 2015 to July 2016. **Results:** 40 patients were enrolled (20 surface landmark-guided and 20 ultrasound-guided LPs). 52.5% of the patients were male with the mean age of 60.33 ± 4.24 years. The first-attempt success rate in the ultrasound-guided LP group was significantly higher than the landmark-guided LP group (80% vs. 35%, respectively), with risk difference (RD) of 45.00% (95% confidence interval (CI): 17.72%, 72.28%). This indicated absolute risk reduction and number needed to treat of 45.00% and 2.22, respectively. The median procedural duration required to achieve successful LP in the ultrasound-guided LP group was significantly shorter than the surface landmark-guided LP group (5 [IQR: 3–18] minutes vs. 13.5 [IQR: 5–30] minutes, respectively). Traumatic puncture as a complication occurred less frequently in the ultrasound-guided LP group than the surface landmark-guided LP group with risk ratio (RR) = 0.33 (95% CI: 0.08, 1.46) and RD = -20.00% (95% CI: -44.00%, 4.00%). This indicated absolute risk reduction and number needed to harm of 20.00% and 5.00, respectively. However, the difference was not significant. **Conclusion:** Using ultrasound to help localize the insertion point before LP increased the first-attempt success rate and improved other LP outcomes in Thai patients with obesity or a difficult anatomy. It also shortened the procedural duration and reduced the incidence of traumatic tap.

**Keywords:** Spinal Puncture; Ultrasonography, Interventional; Obesity; Emergency Service, Hospital

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## 1. Introduction

Lumbar puncture (LP) is an important procedure that is commonly performed in the emergency department to evaluate and help diagnose several emergency or life-threatening con-

ditions, such as meningitis or subarachnoid hemorrhage (1, 2). LP can be performed on patients in different positions, including the lateral recumbent, prone, and upright positions (3). Conventional LP involves palpation of certain anatomical landmarks, including the top of the iliac crest, which lies parallel to the L4 spinous process and is the most important bony landmark for LP. The L4 spinous process is located at the intersection of Tuffier's line or the line between the top of the iliac crest and the midline of the lumbar spine. Then, the lumbar spinous processes of L3, L4, and L5, and the in-

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terspaces between them, can be palpated. The spinal needle can be inserted into the subarachnoid space at the L3–L4 or L4–L5 interspace (1–3).

Several factors can impede the success of LP, including operator dependency and patient factors (4–7). Palpable surface landmarks may be absent, indistinct, or distorted because of obesity, deformity, or degenerative changes associated with aging (4, 5). A previous study indicated that one of the major factors impeding the success of LP is body mass index (BMI) (4). Specifically, in patients with a BMI of more than 35 kg/m<sup>2</sup>, the success rate of LP decreased (4). Patients with obesity have a thick layer of subcutaneous fat, which makes the bony marker unclear, and thus precisely locating the site of LP needle insertion is difficult. Abnormalities in the spinal column, such as ankylosing spondylitis or abnormalities after spinal surgery, also increase the likelihood of unsuccessful LP (5). Therefore, performing LP in patients with surface landmarks that are difficult to palpate and in patients with anatomical alterations in the lumbar spine is challenging. If an LP attempt is unsuccessful, the next step is to perform LP under fluoroscopic guidance, especially in neonates and infants (8–10).

Ultrasound is a non-invasive and radiation-free imaging approach. Ultrasound imaging for assisting LP has been used for many years (11). Pre-procedural ultrasound imaging is used to locate the intervertebral space, obtain additional anatomical information, and permit more accurate estimation of needle depth and direction (12, 13). Reducing the number of LP attempts using ultrasound guidance is also desirable because multiple attempts at needle insertion are associated with complications, such as hematoma, spinal nerve damage, and infection (13). Previous studies have shown higher LP success rates when using ultrasound guidance and when the technique is performed by emergency medicine physicians or anesthesiologists, especially in patients with obesity and patients with a difficult anatomy (9, 13–21). However, even though the utility of ultrasound guidance for LP has shown concrete results in some studies, other studies have demonstrated opposite outcomes, such as no difference in the success rate or the number of total attempts (22–27), which do not support routine use of ultrasound guidance for LP. The overall procedural duration of LP is of concern to many physicians in clinical practice. Some studies have shown benefits with ultrasound guidance in terms of the procedural duration (15, 28, 29); however, other studies have shown no difference in the total procedural duration (16, 17, 22, 26). Moreover, other studies have reported that the use of ultrasound increases the overall procedural duration because of the increased scanning duration (14, 21).

The aim of the present study was to compare the first-attempt success rate of ultrasound-guided LP with the standard blind technique of needle insertion using palpable

spinal surface landmarks in patients with obesity or a difficult anatomy. We also compared the overall success rate, procedural duration, and complications between the two methods.

## 2. Methods

### 2.1. Study design and setting

This prospective randomized controlled study was performed at the emergency department of Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, which is an academic tertiary university hospital that is staffed with medical students, nurses, residents, and attending physicians. The study was performed in accordance with the CONSORT guidelines.

The primary objective of the study was to compare the first-attempt success rate between the two groups. The secondary objectives of the study were to analyze the overall success rate (defined as success within three attempts), compare the procedural duration (the time from needle insertion to obtaining cerebrospinal fluid), and compare immediate complications (including traumatic tap, local infection, hematoma, spinal cord or nerve root injury, and brain herniation) between the two groups.

The study protocol was approved by the ethics committee of Ramathibodi Hospital (ID 04-58-03), and written informed consent was obtained from all patients. This trial was retrospectively registered in the Thai Clinical Trial Registry at Clinicaltrials.gov, identification number TCTR20200716007 (2020-07-16).

### 2.2. Study population

Adult patients aged >18 years who underwent LP for any clinical indication at the emergency department and who had difficult LP criteria (BMI of >25 kg/m<sup>2</sup>, which is defined as obesity in the Thai population (30); previous lumbar spine surgery; or scoliosis) were included. The exclusion criteria included pregnancy, unstable vital signs, signs of an increase in intracranial pressure, skin infection in the area of LP, or bleeding tendency (e.g., coagulopathy).

### 2.3. Study protocol and interventions

The participating physicians included two 3rd year emergency residents and two emergency medicine attending staff members. All of the LP procedures were performed by these participating physicians, all of whom were certified to perform this procedure and had completed the ultrasound-guided LP training course. One of the authors (C.B.), who is an interventional radiologist and expert in ultrasound-guided procedures, delivered the ultrasound-guided LP training course to the participating physicians. The four physicians passed the training course, which in-

volved a standardized 120-minute teaching module to perform ultrasound-guided LP. This teaching module consisted of a 20-minute lecture describing the use of the ultrasound machine, a 10-minute video about ultrasound-guided LP, an 80-minute ultrasound guidance simulation session to localize the LP insertion point, and 10 minutes of questions at the end. After finishing the module, all four physicians were required to attend a hands-on workshop and take a picture of the LP needle insertion point in 10 patients, with subsequent approval from the radiologist. When the four physicians had finished the training module and had correctly collected 10 pictures of the LP needle insertion point, they were considered to have passed and were eligible for involvement in the study.

Randomization was performed using computer-generated random numbers. Block randomization was done with the block size of 4.

Allocation concealment was achieved using the sequentially numbered opaque sealed envelopes (SNOSE) technique. The patients were enrolled by an emergency physician who served as the primary physician. The participating physicians were assigned the patients for intervention. The patients were randomly divided into two groups: the surface landmark-guided LP group and the ultrasound-guided LP group. The group allocation was concealed using sealed opaque envelopes, which were opened by the participating physicians who would perform the LP procedure before performing the intervention. Due to the nature of the study, blinding of the physicians who performed the procedure was not possible. All patients were unaware of which method of LP would be performed on them. The person who analyzed the outcomes was also blinded to which approach was used. The ultrasound machine used in this study was the GE Logiq e Portable Ultrasound Machine with the linear probe (12LRS). Standard monitoring and intravenous access were established in all patients.

The patients were recruited after the study was approved by the ethics committee. The period of recruitment was 1 year. The baseline characteristics of the patients were recorded, including age, sex, weight, height, BMI, underlying diseases, previous spinal surgery, history of brain computed tomography, and indication for LP.

All of the patients were positioned in the left lateral decubitus position, and the back was placed next to the edge of the bed. Then, the patient's chin was set near to the chest, and the knees were bent toward the chest.

In both groups, the physicians palpated the iliac crest, lumbar spinous processes, and interspinous spaces for landmark identification. Additional ultrasonography of the lumbar area was performed in the group that underwent ultrasound-guided LP to examine the spinal anatomy.

## 2.4. Ultrasonography

The ultrasound transducer was first placed in the transverse position to identify the spinous processes in the center of the image. The spinous processes were seen as distinct hyperechoic peaks with posterior acoustic shadows (Figure 1) (11, 19). The ultrasound transducer was slowly moved superiorly until the next upper spinous process was identified. Subsequently, the transducer was rotated 90° clockwise to align the ultrasound orientation longitudinally over the midline. From this view, the two previously identified spinous processes were indicated as two crescent-shaped, concave, hyperechoic structures with posterior acoustic shadows. The space between these two spinous processes represented the intervertebral space and was marked on the middle of the probe (Figure 1). The ultrasound images were collected and recorded in each patient's record, and the images recorded were checked and confirmed as correct by the radiologist. Follow-up assessments were performed after the procedure following the routine hospital protocol. We observed the patients until 24 hours after LP.

## 2.5. Outcomes

The primary outcome was the first-attempt success rate of LP procedure. Any additional needle attempt was defined as complete withdrawal of the introducer needle from the skin and subsequent reinsertion. LP success was observed and recorded by the LP operator and investigator. The secondary outcomes were the overall success rates, the procedural durations, and immediate complications. Patients who underwent more than three LP attempts were excluded from the analyses of procedural duration and complications.

## 2.6. Definitions

A successful attempt was defined as obtaining sufficient cerebrospinal fluid for analysis. Traumatic tap was defined as a decrease in the erythrocyte count between the first and last tubes of at least 25%, together with an absolute erythrocyte count of <400 erythrocytes/ $\mu$ L in tube 3 or tube 4 (31).

## 2.7. Statistical analysis

The sample size was calculated using SPSS software (version 18) based on the results of a previous study on patients with difficult LP criteria (14), which demonstrated first-attempt success rates of 100% and 42.5% in the ultrasound-guided LP group and the surface landmark-guided LP group, respectively. Accepting an alpha error of 5% and a beta error of 20% (80% power), a total of 34 patients were required, which were then divided into two groups (at least 17 patients per group were required).

For describing data, normally distributed continuous data were presented as mean  $\pm$  standard deviation; otherwise,

the data were presented as median with interquartile range. Categorical data were presented as frequency and percentage. Intention to treat was applied for final analysis. Comparisons between groups were made using the Student's *t*-test if two independent continuous datasets were normally distributed; otherwise, the groups were analyzed using the Mann–Whitney *U* test. Differences in categorical variables were evaluated using the chi-square test or Fisher's exact test, as appropriate. In addition, risk difference (RD) and risk ratio (RR) and their 95% confidence interval (CI) were also estimated. A *P* value of <0.05 was considered statistically significant.

### 3. Results

#### 3.1. Baseline characteristics of studied cases

A total of 40 patients were enrolled in the study. All of the patients underwent computed tomography, and no patients were lost to follow-up (Figure 2). Twenty patients underwent surface landmark-guided LP, while the other 20 patients underwent ultrasound-guided LP. Most of the patients were male (52.5%), and the mean age of the patients was 60.33 ± 4.24 (range: 18 – 89) years. The mean BMI, mean weight, mean age, percentage of patients with underlying disease, and the indications for LP were not significantly different between the two groups (Table 1).

#### 3.2. Comparing the outcomes between groups

Table 2 shows the primary and secondary outcomes of the study. The first-attempt success rate in the ultrasound-guided LP group was significantly higher than the landmark-guided LP group (80% vs. 35%, respectively), with RD of 45.00% (95% CI: 17.72%, 72.28%). This indicated absolute risk reduction and number needed to treat of 45.00% and 2.22, respectively. In addition, RR was 2.29 (95% CI: 1.21, 4.32). Every patient achieved successful LP within three attempts; therefore, the overall successful rate was 100% in both groups.

The median procedural duration required to achieve successful LP in the ultrasound-guided LP group was significantly shorter than in the surface landmark-guided LP group (5 [IQR: 3–18] minutes vs. 13.5 [IQR: 5–30] minutes, respectively). Traumatic puncture as a complication occurred less frequently in the ultrasound-guided LP group than the surface landmark-guided LP group with RR = 0.33 (95% CI: 0.08, 1.46) and RD = -20.00% (95% CI: -44.00%, 4.00%). This indicated absolute risk reduction and number needed to harm of 20.00% and 5.00, respectively. However, the difference was not significant. The other complications were monitored and observed until 24 hours after LP following the routine hospital protocol. No other complications were reported in any of the patients.

### 4. Discussion

This randomized controlled study included 40 patients with obesity or a difficult anatomy. We demonstrated that ultrasound-guided LP significantly increased the first-attempt success rate and reduced the procedural LP duration in Thai patients with obesity or a difficult anatomy when compared with conventional surface landmark-guided LP.

Our study supports the findings of other studies showing that ultrasound improves the success of LP in patients with a difficult anatomy (11, 17, 20, 27) and in patients classified as overweight or obese, especially in the emergency setting (16, 27, 28). We used a lower BMI than some studies that used a BMI of >28–35 kg/m<sup>2</sup> (14, 16, 28). One study used a BMI of >25 kg/m<sup>2</sup>, which is similar to our study; however, the patients were of a different ethnicity. The BMI in that study was considered to be overweight; however, in Thai people, a BMI of >25 kg/m<sup>2</sup> is considered as obesity. One study performed in emergency department shows that ultrasound-guided LP improves success rates and decreases LP time in obese patients with difficulty in the LP. This study was performed in Chinese adult obese patients; however, BMI >28 kg/m<sup>2</sup> was used as the obesity diagnostic criteria.

Our study also supported previous observations showing that less experienced operators, such as residents, could perform LP with ultrasound assistance (27, 29).

We also found that the procedural duration was shorter in the ultrasound-guided LP group; however, we did not evaluate the time taken for landmark identification, and thus the total length of the procedure in the ultrasound-guided LP group may not necessarily have been shorter than in the surface landmark-guided LP group. This was the case in previous studies showing that although the performance time was shorter, the landmark identification time was longer, so the total procedural duration was longer (14, 21, 32).

However, a shorter procedural duration might provide some advantages or improve patient satisfaction by decreasing the duration of uncomfortable positioning for the patient during LP. The shorter procedural duration might also infer that ultrasound guidance could identify the needle site more precisely than the conventional surface landmark-guided LP method.

In terms of complications, although no statistically significant differences were observed between the two groups, the ultrasound-guided LP group demonstrated a lower incidence of traumatic tap than the surface landmark-guided LP group. Similar to previous studies, the number of cases of traumatic LP was significantly lower in the ultrasound-guided LP group (2, 4, 5, 11).

On the basis of our findings, we believe that the use of ultrasound to guide LP in adult patients should be considered to increase the procedural success rate and reduce the number

of needle insertion attempts, especially in patients with obesity or those with anatomical landmarks that are difficult to palpate.

## 5. Limitation

The main limitation of this study was that LP procedure and the ultrasound are operator-dependent procedures that require experience and skill to perform effectively. Although a standard educational workshop was held to train the participating physicians, the four physicians may have had different levels of skill in performing ultrasound-guided LP. This limitation could potentially impact the generalizability and precision of the study's results, given the variations in levels of experience and procedural skills among the participants. However, when physicians have received prior training on ultrasound-guided LP, the utilization of ultrasound-guided LP may present an alternative approach to enhance the initial success rate of LP in cases involving obesity and difficult anatomy. Another limitation was the lack of blinding regarding the technique used, which could introduce information bias for the participating physicians who performed the procedure. However, the analyst who analyzed the outcomes remained blind to the intervention arms.

## 6. Conclusion

Our study provides support for the benefits of ultrasound-guided LP in specific patient populations, particularly those with challenging anatomical landmarks that are difficult to identify through manual palpation. In this study, ultrasound-guided LP was associated with an increased rate of success on the first attempt, decreased procedural duration, and a lower incidence of traumatic tap. Furthermore, the use of ultrasound guidance has the potential to enhance physician confidence, improve patient safety, and optimize the diagnostic yield, making it a valuable option for challenging LP cases.

## 7. Declarations

### 7.1. Acknowledgments

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This study was presented as poster presentation in 37th ISICEM: International Symposium on Intensive Care & Emergency Medicine, Brussels, Belgium.

### 7.2. Competing interests

The authors declare that they have no competing interests.

### 7.3. Consent for publication

Not applicable.

### 7.4. Funding and support

No funding was received for this study.

### 7.5. Authors' contribution

PS, PT, and CB designed the study and developed the protocol. PT, SS, and CB were responsible for data collection. PS, PT, PA, and ST were responsible for data analysis. PS, PT, and ST wrote the manuscript. PS, and ST provided final approval of this version to be published. PS and ST agree to be accountable for all aspects of the work. All authors read and approved the final manuscript.

### 7.6. Data Availability

The data are not available for public access because of patient privacy concerns, but they are available from the corresponding author upon reasonable request.

### 7.7. Ethics approval and informed consent

This study was approved by the ethics committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University (ID 04-58-03, MURA2015/217). All methods were carried out in accordance with relevant guidelines and regulations, such as The Declaration of Helsinki, The Belmont Report, CIOMS Guidelines, and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP). Informed consent was obtained from all participants/patients.

### 7.8. Using artificial intelligence chatbots

The authors declare that they did not use artificial intelligence chatbots.

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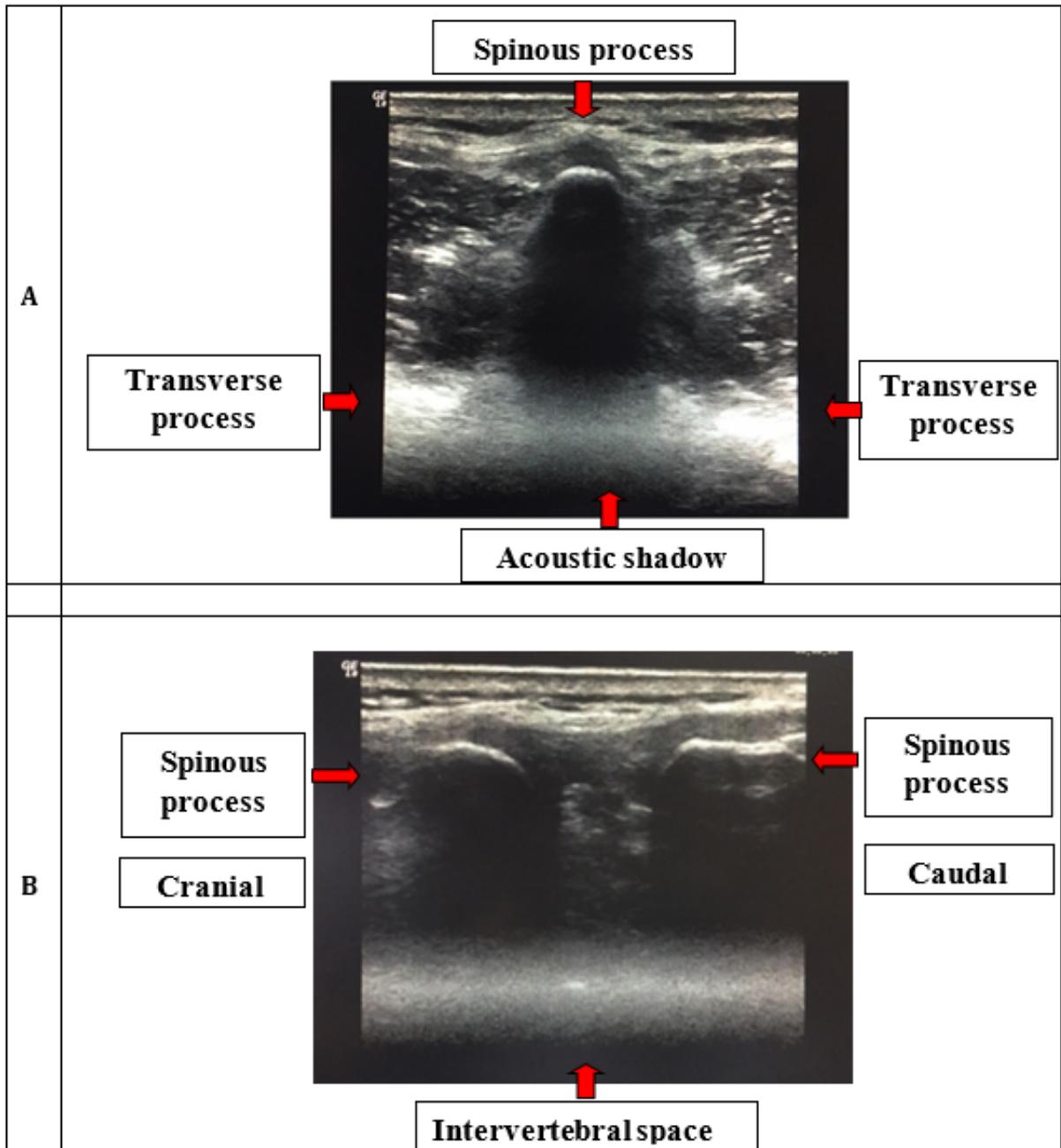
**Table 1:** Comparing the baseline characteristics of studied cases between groups

Characteristics	Lumbar puncture guided with		P value
	Ultrasound (n = 20)	Surface landmark (n = 20)	
<b>Gender</b>			
Male	9 (45.0)	12 (60.0)	0.342
Female	11 (55.0)	8 (40.0)	
<b>Age (years)</b>			
Mean $\pm$ SD	66.1 $\pm$ 18.76	54.55 $\pm$ 18.59	0.058
<b>Anthropometry</b>			
Weight (kg)	67.45 $\pm$ 9.62	69.55 $\pm$ 6.28	0.419
Height (cm)	157.45 $\pm$ 7.3	158.95 $\pm$ 6.61	0.500
Body mass index (kg/m <sup>2</sup> )	27.14 $\pm$ 1.95	27.48 $\pm$ 1.11	0.497
<b>Underlying disease (%)</b>			
Yes	14 (70.0)	17 (85.0)	0.451
No	6 (30.0)	3 (15.0)	
<b>Indications (%)</b>			
Central nervous system infection	18 (90.0)	15 (75.0)	0.408
Headache	0 (0.0)	1 (5.0)	1.00
Others	2 (10.0)	4 (20.0)	0.661

Data are presented as mean  $\pm$  standard deviation (SD) or frequency (%).

**Table 2:** Comparing the outcomes between ultrasound-guided lumbar puncture and surface landmark-guided lumbar puncture

Parameters	Lumbar puncture guided with		P value
	Ultrasound (n = 20)	Surface landmark (n = 20)	
<b>The first-attempt success rate</b>			
Number (%)	16 (80.0)	7 (35.0)	0.009
<b>The procedural duration (minutes)</b>			
Median (range)	5 (3–18)	13.5 (5–30)	0.002
<b>Traumatic tap</b>			
Number (%)	2 (10.0)	6 (30.0)	0.235



**Figure 1:** Cross-sectional view of the ultrasound showing a hyperechoic peak with a posterior acoustic shadow from the spinous process in the midline and transverse processes on both sides (A); Longitudinal view of the ultrasound showing two spinous processes in the craniocaudal orientation and the intervertebral space at the center (B).

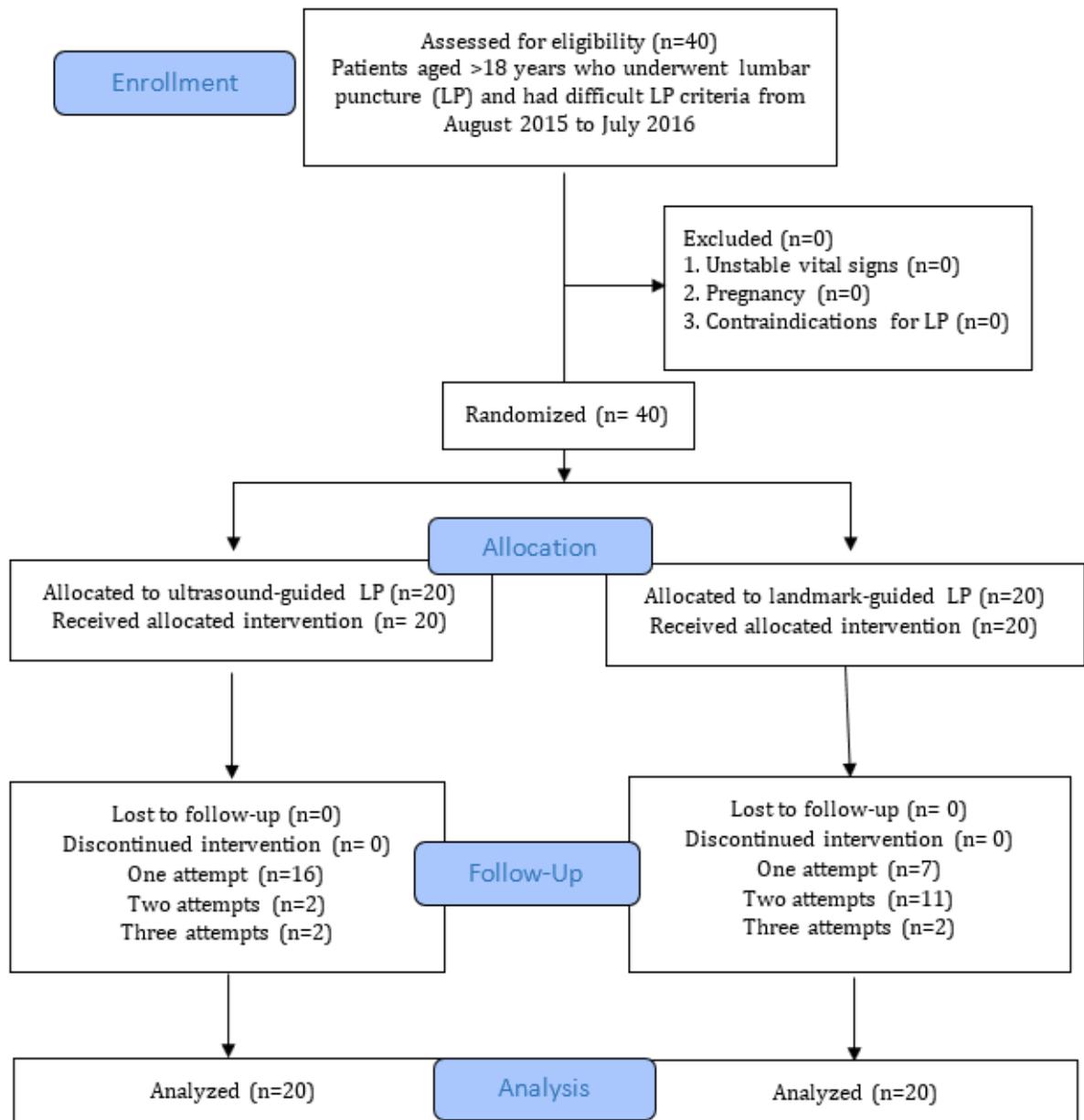


Figure 2: Study Flow Diagram.