



Performance of the ratio of posterior complex length to depth measured by ultrasound as a predictor of difficult spinal anesthesia for elective cesarean delivery: a prospective cohort study

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Abstract

Purpose Ultrasound view of the interlaminar structure is likely to be associated with difficult spinal anesthesia (DSA), and a poor ultrasound view which cannot show the anterior and posterior complex predicts a difficult spinal technique. As our target site is the posterior complex, this study aimed to assess whether the ratio of posterior complex length to depth measured by ultrasound can predict DSA in cesarean delivery.

Methods Four anesthesiologists with 1–2 years of experience located and marked the puncture interspace using a traditional surface landmark. Subsequently, the ultrasound examiner located and measured the marked interspace via an oblique parasagittal ultrasound scan. The anesthesiologists, who were blinded to the ultrasound results, performed spinal anesthesia using a 25-gauge Whitacre spinal needle. The total number of attempts, including skin punctures and needle passes, was recorded and the DSA was defined as 10 unsuccessful attempts. A multivariable logistic regression analysis was used to determine the independent predictors, and receiver operating characteristic curves were constructed to evaluate the performance of the ratio of posterior complex length to depth for predicting DSA.

Results A total of 397 cesarean delivery parturients with successfully measured posterior complex were included in the analysis. DSA occurred in 64 parturients (16.1%). Reduced length [odds ratio (OR)=0.010, 95% confidence interval (CI), 0.002–0.062, $P < 0.001$] and increased depth [OR = 6.127, 95% CI, 2.671–14.056, $P < 0.001$] of the posterior complex were independently predictive of DSA compared with body mass index, abdominal circumference, and palpable surface landmarks. The ratio of posterior complex length to depth for predicting DSA had an area under the curve of 0.86 (95% CI, 0.82–0.90). The optimal cutoff was 0.23, with a sensitivity of 86% (95% CI, 74–93%) and specificity of 72% (95% CI, 67–77%).

Conclusion The ratio of posterior complex length to depth measured by ultrasound demonstrated a considerable accuracy in predicting DSA for inexperienced anesthesiologists. A higher ratio at ultrasound is an indication to evaluate the optimal puncture body position and interspace in the clinic practice.

Clinical trial registration ChiCTR2200065171

<https://www.chictr.org.cn/showproj.html?proj=180855>

Keywords Ratio · Posterior complex · Difficult spinal anesthesia · Cesarean delivery · Ultrasound

Abbreviations

AC	Abdominal circumference
ASA	American Society of Anesthesiologists
AUC	Area under the curve
BMI	Body mass index
CI	Confidence interval
CSF	Cerebrospinal fluid
DSA	Difficult spinal anesthesia
MLRM	Multivariable logistic regression mode
OR	Odds ratio
PCD	Posterior complex depth
PCL	Posterior complex length

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ROC	Receiver operating characteristic
SD	Standard deviation
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology

Introduction

Spinal anesthesia is generally used in cesarean delivery, but somatotype changes in pregnancy, such as sizable abdominal circumference or over-obesity, may limit adequate flexion of the lumbar spine, which can make spinal anesthesia difficult to perform [1, 2]. Accurate preoperative evaluation of the lumbar spine to select optimal puncture body position and interspace is one of the methods to reduce difficult spinal anesthesia (DSA) [3–5]. Moreover, identifying potentially difficult punctures in advance can enable better management, which may potentially facilitate DSA performance. Palpation of the surface landmark is a common approach for evaluation in daily clinical practice. However, this is based on the performer's experience and may result in inaccuracies, especially for inexperienced anesthesiologists. Ultrasound can visualize the anterior (anterior dura mater and posterior longitudinal ligament) and posterior complex (ligament flavum and posterior dura mater) of the interlaminar structures and, therefore, often used to locate the insertion point or provide real-time guidance to assist in difficult punctures [6–10]. We may have overlooked another approach, which is the use of ultrasound for evaluation before spinal anesthesia.

Previous studies [11, 12] on orthopedic or urological surgery have shown that a poor ultrasound view, which cannot show the anterior and posterior complex, predicts a difficult spinal technique. This most likely is not representative of cesarean delivery spinal anesthesia, and does not reflect the difficulties of puncture caused by somatotype changes in pregnancy and obesity. In addition, whether the posterior complex is visible may not be indicative enough to comprehensively evaluate the difficulty of puncture. Some difficult puncture cases with visible posterior complex may be missed, and establishing multiple standard levels may be more reasonable. As the posterior complex is our target site, and we can measure view indicators of the posterior complex such as length and depth by ultrasound, we hypothesized that the occurrence of difficult puncture is negatively correlated with the length and positively correlated with depth, through the ratio of posterior complex length to depth can predict DSA in cesarean delivery. This may provide further reference opinions for preoperative evaluation of spine anesthesia.

Methods

Study design

This study was approved by the Anhui Maternal and Child Health Care Hospital's Institutional Review Board (IRB No, YYLL2022-yb2022-1-5-11-01), and written informed consent was obtained from all subjects participating in the trial. The study also adhered to the applicable STROBE guidelines and was registered prior to patient enrollment at the Chinese Clinical Trial Registry (ChiCTR2200065171; <http://www.chictr.org.cn>; Principal investigator: JingFa Shi, MD; Date of registration: October 30, 2022).

Study population

Parturients who were scheduled for elective cesarean delivery under spinal anesthesia were consecutively recruited between December 1, 2022, and May 31, 2023. The other inclusion criteria were as follows: age of 20–40 years, normal singleton pregnancy, gestational age of ≥ 37 weeks, and American Society of Anesthesiologists physical status of grades II–III. The exclusion criteria were as follows: rejection of spinal anesthesia, contraindications for spinal anesthesia (puncture site infection, coagulation dysfunction, and allergy to local anesthesia), a history of spinal deformity or spinal surgery, and high-risk pregnancy (preeclampsia and placenta previa).

Study protocol

Venous access was established after the parturient was transferred to the operating room, and routine monitoring (noninvasive blood pressure, electrocardiogram, and pulse oximetry) was instituted. Then the parturient was placed in the left lateral decubitus position with the head and knees flexed as far as possible, and remained fixed during the study process.

A total of four anesthesiologists with 1–2 years of experience in minimally invasive spinal anesthesia puncture and one ultrasound examiner who completed training and perform more than 100 ultrasounds for localization and measurement alone were selected to participate in the experiment.

First, the anesthesiologist located the puncture interspace by traditional surface landmark and graded it using a 4-point scale (1 point, light to moderate pressure; 2 points, moderate to severe compression; 3 points, repeated heavy pressure; and 4 points, unable to judge). We excluded 4-points cases and marked interspace with a longitudinal line.

Second, the ultrasound examiner located and measured the marking interspace by the M-Turbo ultrasound machine

(UMT-400, Mindray, China) with a low-frequency curvilinear probe (2–5 MHz) with a depth of 8–10 cm and gain of 50 db. An oblique parasagittal scan localization would start from the sacrum with a long horizontal curved bright line. Moreover, we could see the first anterior/posterior complex sound window between L₅–S₁ level. Then the examiner continued to sequentially locate interspace through the sound window toward the cephalic side until the middle of the probe reached the skin-marked longitudinal line, where the center of sound window of the screen was the corresponding interspace of ultrasound localization. Cases with higher interspaces (L_{1–2} or above) would be excluded, and the anesthesiologist was informed to reselect a lower position to puncture for safety reasons. After determining the interspace, we would perform a sagittal ultrasound measurement of its posterior complex, where the ultrasound probe

along the longitudinal line was moved from the lower lateral position to the paravertebral median position, and then tilted to obtain the best view. When freezing the best screen view, the length and depth of the posterior complex were measured by the ultrasound. Each cases performed localization and measurement twice and took the average data for analysis. Also, cases in which the posterior complex could not be clearly measured were excluded (Fig. 1).

Third, the anesthesiologist was blinded to the ultrasound results, and performed spinal anesthesia using a 25-gauge Whitacre spinal needle through a minimally invasive puncture at the marked interspace. We recorded the number of skin punctures and needle passes (the intermittent or continuous passage of the spinal needle without completely removing it from the skin, which includes redirections) during the puncture, and the cerebrospinal fluid outflow would

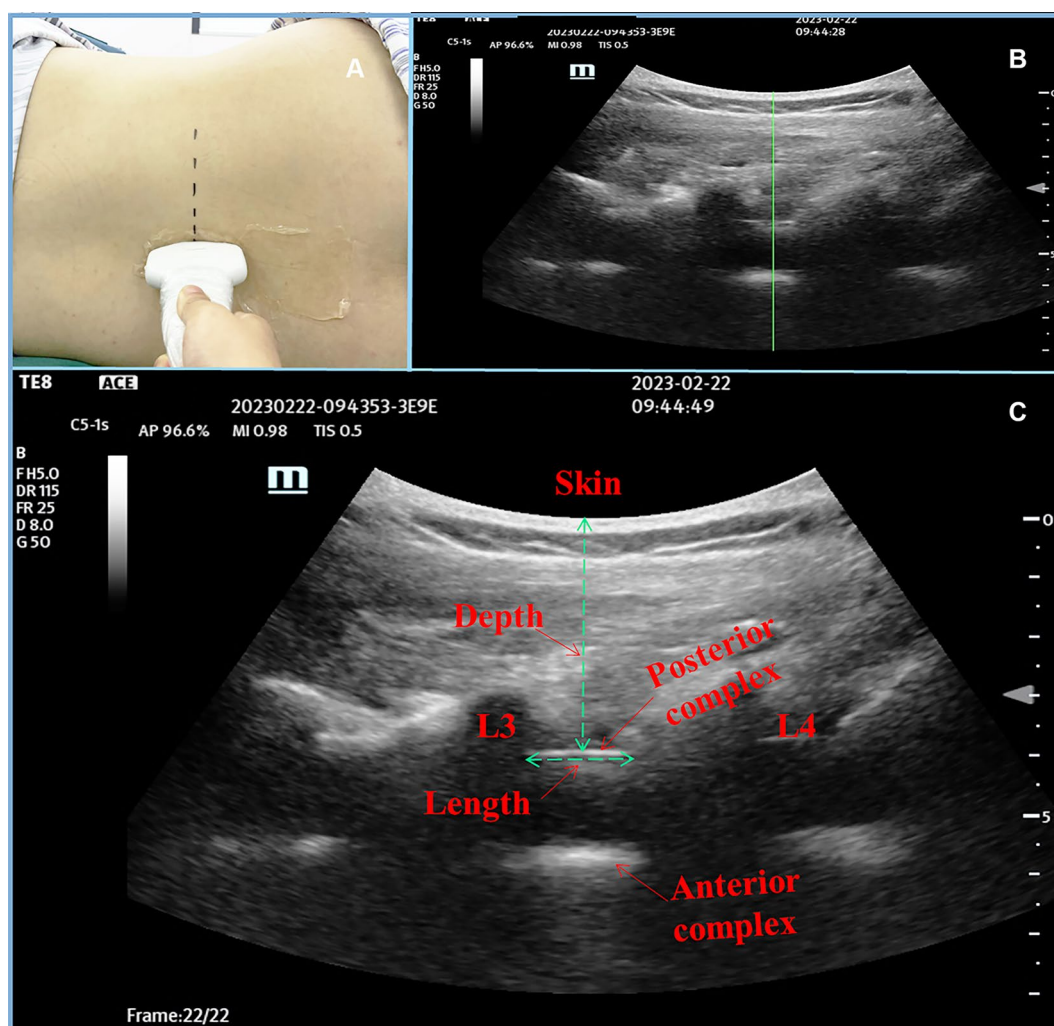


Fig. 1 Schematic diagram illustrating ultrasound localization and measurement. The curved probe was located from the sacrum until the probe's midline reached the skin-marking longitudinal line (A). The screen's center anterior/posterior complex sound window was

the ultrasound localization corresponding interspace (B). The probe was adjusted by parasagittal oblique scan to obtain the clear posterior complex of localization interspace in the screen, and then the length and depth of the posterior complex were measured (C). (Fig. 1)

be considered as successful puncture. After the anesthesiologist completed 10 unsuccessful attempts (total of skin punctures and needle passes), the blind approach was terminated and the ultrasound examiner would use paramedian oblique sagittal scanning to facilitate the puncture under real-time ultrasound guidance [13, 14]. Similarly, if the real-time ultrasound-guided punctures got 10 unsuccessful attempts, our emergency team would intervene with the next step of treatment. The team's solutions included selecting experienced anesthesiologists, reevaluating the optimal puncture interspace and body position, using the needle-through-needle puncture approach, and considering alternative options, such as epidural or general anesthesia. Furthermore, our emergency team also addressed cases of palpation grade 4 and DSA of unmeasured posterior complex.

Study endpoints

The primary endpoint determined the predictive value of the ratio of posterior complex length to depth for DSA, which was defined as 10 unsuccessful blind puncture attempts [6, 12]. The secondary endpoint was determined as the predictive value of characteristics of parturient obtained from electronic medical records for DSA.

Sample size calculation

A pilot study was conducted in the same institution. Based on a DSA incidence of 17.6% and to reduce the impact of logistic regression model overfitting and ensure that the ratio of the number of parturients experiencing DSA to the number of potential predictors was not less than 10, a sample size of over 350 subjects was required.

Statistical analysis

Data management and analysis were performed using SPSS Version 20 (IBM Corp, Armonk, NY, USA). The distribution of continuous variables was tested for normality using the Shapiro–Wilk ($n \leq 50$) or Kolmogorov–Smirnov ($n > 50$) test. The normal distributions are expressed as mean \pm standard deviation and non-normal distributions are expressed as median [IQR], categorical data are presented as n (%), and ratios are expressed as the values with 95% confidence intervals (CIs). Univariate comparisons were performed using Student's t tests (normally distributed continuous variables) or Mann–Whitney U test (non-normal continuous and ranked data variables). Variables that were significant in the univariate logistic regression analysis were included in the multivariable logistic regression analysis. While the remaining variables (screened according to $P < 0.05$) were deemed independent predictors. Receiver operating characteristic (ROC) curve analysis and area under the curve

(AUC) were used to examine the discrimination capacity of variables to predict DSA, and calculate the multivariable logistic regression model of AUC. The Youden index [15] (sensitivity + specificity – 1) was used to determine the optimal cutoff point for predictors and calculate the odds ratio, sensitivity, specificity, positive predictive value, and negative predictive value of those predictors.

Results

A total of 501 parturients scheduled for cesarean delivery were screened during the study recruitment, of whom 104 were excluded and 397 were included in the final analysis. Of the 397 parturients, 64 (16.1%) experienced DSA. After real-time ultrasound-guided for DSA, success with ≤ 10 attempts was achieved in 20 parturients (Fig. 2).

Regarding parturient characteristics, there were statistically significant correlations of body mass index (BMI), abdominal circumference, and palpation grade with DSA; however, there were no significant correlations for parturients' mean age, gestational age, and fundal height (Table 1). Ultrasound measurement of the length and depth of posterior complex and its ratio was significantly correlated with DSA (Table 1).

Through the univariate and multivariate logistic regression analyses for significant variables, we identified two independent predictors of DSA: posterior complex length and depth (Table 2).

ROC curves displaying the ability of different indexes to predict DSA are shown in Fig. 3. The ratio of posterior complex length to depth for predicting DSA showed a significant AUC of 0.86 (95% CI, 0.82–0.90) (Fig. 3).

The optimal criteria as determined by the Youden index of predictors of DSA, as well as their odds ratios, sensitivities, specificities, positive predictive values, negative predictive values, and 95% CIs are shown in Table 3. Posterior complex length of < 0.95 cm (sensitivity, 77% [95% CI, 64–86%]; specificity, 71% [95% CI, 65–75%]) and depth of > 4.42 cm (sensitivity, 72% [95% CI, 59–82%]; specificity, 78% [95% CI, 73–83%]) were independently predictive of DSA. The ratio of posterior complex length to depth of < 0.23 for predicting DSA had a sensitivity of 86% (95% CI, 74–93%) and specificity of 72% (95% CI, 67–77%) (Table 3).

Discussion

Similar to previous studies, our study confirms the efficacy of BMI, abdominal circumference, and palpation quality for predicting DSA [16–19]. However, our study also found that posterior complex length and depth measured by ultrasound are useful and independent predictors of DSA, and that their

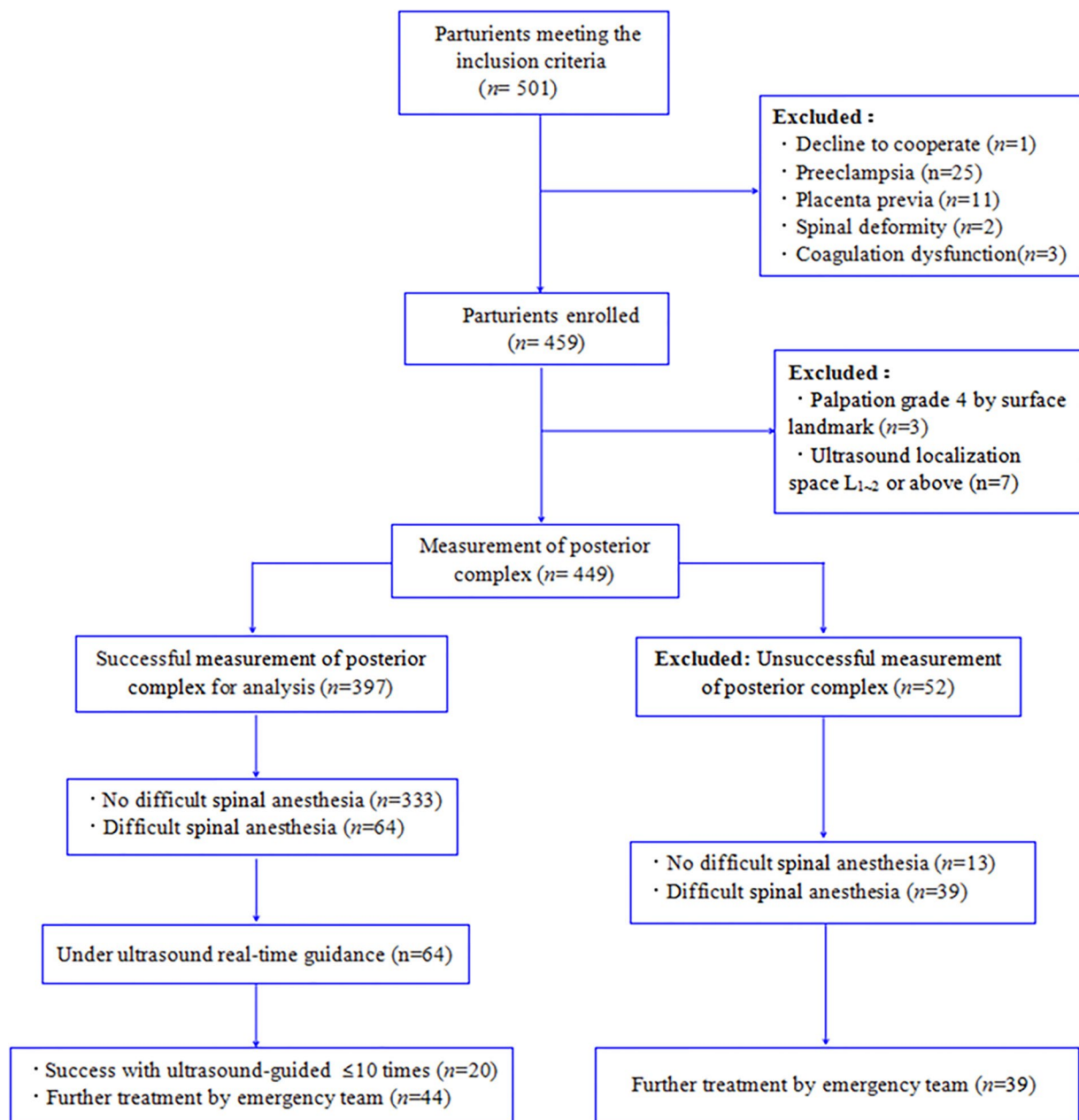


Fig. 2 Study flow chart and parturient outcomes. A total of 501 parturients were recruited, 104 cases were excluded, and 397 cases were ultimately included for analyses. 64 cases of parturients experienced difficult puncture, with a difficult rate of 16.1%. (Fig. 2)

predictive value is superior to that of BMI, abdominal circumference, and palpation evaluation. Our study further demonstrated that the ratio of posterior complex length to depth had a high value for predicting DSA.

Spinal anesthesia is performed as the puncture needle reaches the posterior complex and then the subarachnoid space from the skin. On ultrasound imaging, if the path of intervertebral puncture is obstructed by bone, it is difficult for ultrasound to penetrate and obtain clear images of the posterior complex, or the structure of the intervertebral

complex might be relatively short. Hence, some studies [11, 12] predicted the difficulty of spinal puncture based on whether ultrasound can clearly obtain images of the posterior complex. It is also easy to understand that a longer length of the structure is associated with easier puncture.

In previous studies, posterior complex depth measured by ultrasound was commonly used to assess the distance from the skin to the epidural space, and it was highly correlated with the actual puncture depth [20–23]. Similar to the findings in our study, Kim et al. [24] found that the distance from

Table 1 Univariate comparisons of preoperative characteristics and ultrasound measurement indicators between parturients with and without difficult spinal anesthesia

Variables	Difficult spinal anesthesia		
	Yes (<i>n</i> = 64)	No (<i>n</i> = 333)	<i>P</i> value
Age(y)	31.5 (29.0–34.0)	31.0 (28.5–34.0)	0.628
Gestational age (d)	274.0 (272.0–277.8)	274.0 (272.0–278.0)	0.624
BMI (kg/m ²)	30.5 (27.8–33.1)	27.2 (25.2–29.7)	<0.001 ^a
Abdominal circumference (cm)	106.0 (100.0–112.0)	100.0 (96.0–105.0)	<0.001 ^a
Fundal height(cm)	34.0 (33.0–36.0)	34.0 (33.0–36.0)	0.472
Palpation grade			<0.001 ^a
1 point	14 (21.9)	212 (63.7)	
2 points	38 (59.4)	106 (31.8)	
3 points	12 (18.8)	15 (4.5)	
Posterior complex length (cm)	0.84 (0.74–0.94)	1.08 (0.91–1.34)	<0.001 ^a
Posterior complex depth(cm)	4.67 ± 0.56	4.07 ± 0.45	<0.001 ^a
Ratio of posterior complex length(cm) to depth (cm)	0.18 (0.15–0.21)	0.27 (0.22–0.34)	<0.001 ^a

^a*P* < 0.05, statistically significant. Data are expressed as median [IQR], mean ± SD or *n* (%). *BMI*, body mass index; *SD*, standard deviation

Table 2 Univariate and multivariable logistic regression analysis of significant variables for independent predictors of difficult spinal anesthesia

Variables	Univariate logistic regression		Multivariable logistic regression	
	Odds ratio (95%CI)	<i>P</i> value	Odds ratio (95%CI)	<i>P</i> value
BMI	1.278 (1.177–1.388)	<0.001 ^a	1.016 (0.877–1.176)	0.833
Abdominal circumference	1.120 (1.074–1.169)	<0.001 ^a	1.027 (0.956–1.102)	0.470
Palpation grade (1/2/3)	3.824 (2.478–5.900)	<0.001 ^a	1.517 (0.900–2.557)	0.118
Posterior complex length	0.006 (0.001–0.030)	<0.001 ^a	0.010 (0.002–0.062)	<0.001 ^a
Posterior complex depth	11.02 (5.805–20.92)	<0.001 ^a	6.127(2.671–14.056)	<0.001 ^a

^a*P* < 0.05, statistically significant *CI*, confidence interval

the skin to the subarachnoid or epidural space had a greater impact on the ability to perform a puncture than BMI and the quality of anatomical landmarks. An increase in puncture depth may impact traditional anatomical landmarks and puncture location recognition, thereby increasing puncture difficulty [25, 26].

Qu et al. [27] used ultrasound to measure the maximum cephalad angle between the connecting lines from the insertion point to the far and near ends of the posterior complex as the suggested cephalad angle. The outcomes showed high accuracy between the suggested and actual puncture angles. Based on this finding, we connected the line from the insertion point to the two ends of the posterior complex to obtain the reference puncture angle in our study and kept the puncture depth measurement line on the center line of the angle. The images indicated that if we want to achieve a successful puncture from the puncture point to the posterior complex, we need to follow a puncture path within that reference angle. This means that a larger reference angle of the puncture is associated with a greater chance of success. Depth is one of the influencing factors of the degree of the reference angle, and as depth increases, the angle will

decrease. This may be another reason for DSA due to depth. We also found that posterior complex length influences the degree of the reference angle, and as the length decreases, the angle will decrease. As the ratio of posterior complex length to puncture depth simultaneously expresses these two independent predictors, a higher predictive value is generated as compared with other predictors. We can even calculate the reference insertion degree of the angle corresponding different ratio by trigonometric function (Fig. 4).

Our results demonstrate a relatively high incidence (22.9%, 103/449) of difficult punctures for all parturients undergoing ultrasound measurement of the posterior complex. This may be due to several factors. First, the physicians who blindly performed the puncture were anesthesiologists with only 1 or 2 years of experience. Second, we chose a 25-gauge Whitacre spinal needle to perform direct punctures. This is a minimally invasive method; however, adjusting the needle direction is challenging. Third, DSA is defined as 10 unsuccessful attempts, which include all skin punctures and needle passes. Furthermore, for obese parturients ($30 \text{ kg/m}^2 \leq \text{BMI} \leq 46 \text{ kg/m}^2$), our difficulty rate was 39.1% (52/133), which is similar to the rate reported by Li

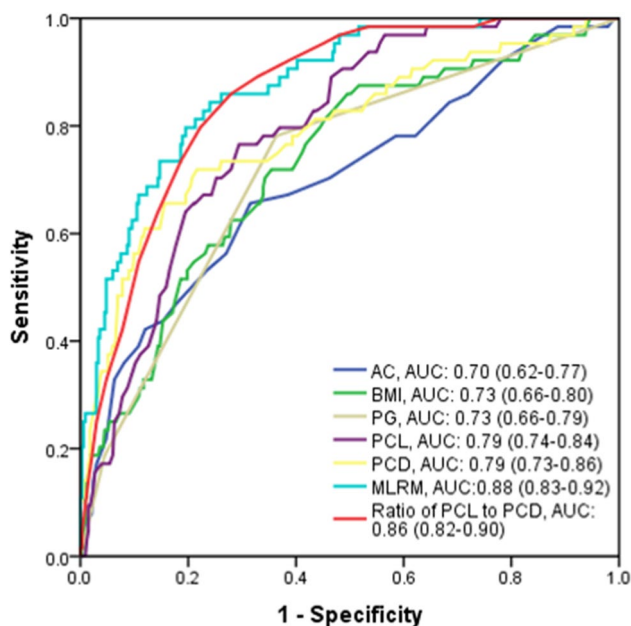


Fig. 3 ROC of spinal anesthesia assessment tests and their areas under curve (AUCs; value and its 95% confidence interval) for predicting difficult spinal anesthesia. ROC is a plot of true positive rate (sensitivity) and false positive rate (specificity) at index values from 0 to 100. Abbreviations: *AC*, abdominal circumference; *AUC*, area under the curve; *BMI*, body mass index; *CI*, confidence interval; *MLRM*, multivariable logistic regression model; *PCD*, posterior complex depth; *PCL*, posterior complex length; *PG*, palpation grade; *ROC*, receiver operating characteristic (Fig. 3)

et al.: 42.5% (17/40) [6]. The difficulty of spinal anesthesia depends on the experience of the practitioner, and inexperienced anesthesiologists are more likely to encounter difficulties in clinical practice. Their higher difficulty rates also indicate that providing accurate preoperative assessments is more urgent.

Similar to previous studies [11, 12] on orthopedic or urological surgery, our study also confirms that the parturients with unsuccessful measurement of the posterior complex have a high difficulty rate (75%, 39/52), and a poor ultrasound view where the posterior complex could not be measured showed a high predictive value for DSA

with a sensitivity of 75% and specificity of 84%. This finding highlights its potential as an evaluation indicator. However, our study further revealed that the parturients with length to depth < 0.23 were associated with a significantly higher incidence of difficult punctures compared with the length to depth ≥ 0.23 parturients (37.2%, 55/148 vs. 3.6%, 9/249). This indicates that the three levels of posterior complex view better delineate the difficulty experienced during puncture than the two posterior complex view grading. If ultrasound is used to observe the view of the posterior complex to evaluate the interspace, it is recommended that inexperienced anesthesiologists further measure its length and depth and select the optimal interspace or body position to improve the success rate of puncture and reduce puncture damage. Moreover, the evaluation method of this ratio also provides a reference angle for puncture and identifies potential difficult punctures, thereby enabling better management. Furthermore, the ability of ultrasound to observe the posterior complex is a prerequisite for ultrasound-guided and localization-assisted puncture. After performing real-time ultrasound guidance treatment for DSA, this study also demonstrated that the length and depth of posterior complex and its ratio were significantly correlated with the success of ultrasound guidance. This finding indicates that even for ultrasound-assisted puncture, preoperative ultrasound evaluation is still necessary (eTable 1 in Supplement).

This study has some limitations. First, we have only provided criteria to assess puncture difficulty for anesthesiologists with fewer years of experience. Second, the quality of the sonographic images was user-dependent, which was very likely to influence the visualized length of the posterior complex. Further confirmation of the critical value of the prediction is needed. However, the other value of this study is to recommend selecting high ratio interspaces for puncture as much as possible to reduce the incidence of DSA. Third, the study only assessed the ratio of posterior complex length to depth in the parasagittal oblique view. As it is difficult to accurately measure the posterior complex length in the transverse midline view, the predictive value of the ratio in this view was not assessed, which may be related to puncture difficulty.

Table 3 Odds ratio, sensitivity, specificity, PPV, and NPV were computed at the optimal cutoff point

Variables	Odds ratio (95%CI)	Sensitivity, %	Specificity, %	PPV, %	NPV, %
BMI > 28.4 (kg/m ²)	4.7 (2.6–8.4)	72 (59–82)	65 (59–70)	28 (21–36)	92 (88–95)
Abdominal circumference > 104(cm)	4.1 (2.4–7.3)	66 (53–77)	68 (63–73)	29 (22–37)	91 (87–94)
Posterior complex length < 0.95(cm)	7.8 (4.2–14.6)	77 (64–86)	71 (65–75)	33 (26–42)	94 (90–96)
Posterior complex depth > 4.42(cm)	9.3 (5.1–17.0)	72 (59–82)	78 (73–83)	39 (30–48)	94 (90–96)
Ratio of posterior complex length(cm) to depth (cm) < 0.23	15.8 (7.5–33.2)	86 (74–93)	72 (67–77)	37 (29–46)	96 (93–98)

CI, confidence interval; *PPV*, positive predictive value; *NPV*, negative predictive value

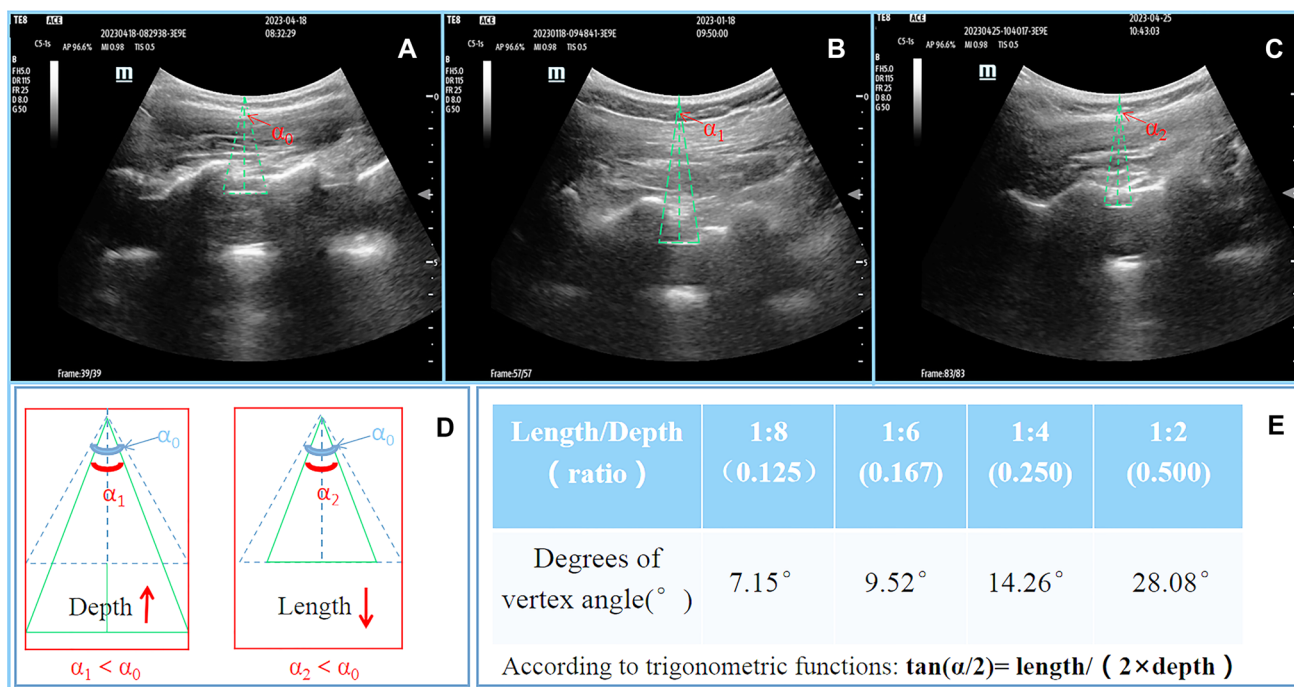


Fig. 4 The reference insertion degree of the angle corresponding to the different ratios of posterior complex length to depth by the trigonometric functions. The reference angle (α_0) is formed by the puncture needle insertion skin point and the posterior complex (A). The angle (α_1) is formed by the puncture needle insertion skin point and the posterior complex when the depth increases (B). The angle (α_2) is formed by the puncture needle insertion skin point and the posterior

complex when the length decreases (C). Compared to the reference angle, the degree of angle decreases as the depth increases and the length decreases ($\alpha_1 < \alpha_0$, $\alpha_2 < \alpha_0$) (D). We can calculate the reference insertion degree of the angle corresponding to the different ratios of posterior complex length to depth by the trigonometric functions (E) (Fig. 4)

Fourth, for subsequent analysis of whether the state of the sagittal posterior complex also affects the results of real-time guidance, we used real-time sagittal ultrasound guidance as a remedial measure for difficult blind punctures. Although, the pre-procedural ultrasound method is considered a better adjunctive option and even the standard of care in our clinical practice [28, 29]. Moreover, we noted that the anterior and posterior complexes of a few parturients with DSA were not in a vertical line. We speculate that the lumbar spine structure in these parturients is similar to the “stacked tiles” of the thoracic spine, which increases puncture difficulty.

In conclusion, our study shows that the ratio of posterior complex length to depth can be used to predict the DSA. This indicator can facilitate the selection of the optimal interspace and provide a puncture reference angle, which may potentially facilitate the performance of DSA for inexperienced anesthesiologists.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00540-024-03394-6>.

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Author contributions Jingfa Shi: This author contributed to design of study, data interpretation, and writing first draft of manuscript. Meng Ning: This author helped in coordination and data interpretation. Lei Xie: This author helped in coordination, patient recruitment, and data collection. Rong Zhang: This author helped in patient recruitment, data collection, and interpretation. Rongrong Liu: This author contributed to patient recruitment and data collection and interpretation. Xiuli Yang: This author contributed to study design, coordination, and critical revision of the manuscript. Lijian Chen: This author contributed to study design, coordination, and critical revision of the manuscript. All authors approved the final revision of the manuscript.

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Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request. No AI-assisted technologies were used in the writing process.

Declarations

Conflict of interest None.

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