Cureus
Part of SPRINGER NATURE

Open Access Original Article

Paramedian Versus Midline Spinal Anesthesia for Emergency Cesarean Delivery: A Randomized Controlled Trial of Post-Dural Puncture Headache and Low Back Pain

Review began 11/06/2026
Review ended 11/13/2026
Published 11/18/2026

© **Copyright** 2026
Rajangam et al. This is an open access article distributed under the terms of the Creative Commons Attribution License CC-BY 4.0., which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

DOI: 10.7759/cureus.119907

Hariharan Rajangam [1], M.V.S. Satya Prakash [1], Chitra Rajeswari Thangaswamy [1]

1. Anaesthesiology and Critical Care, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, IND

Corresponding author: M.V.S. Satya Prakash, munaganuri1975@yahoo.co.in

Abstract

Background

Post-dural puncture headache (PDPH) is the most common disabling complication of spinal anesthesia for cesarean delivery, and postoperative low back ache is even more frequent. Cutting-bevel spinal needles remain in routine use in many public hospitals in low- and middle-income countries. This study compared the midline and paramedian approaches with respect to both outcomes.

Methods

In this single-center randomized controlled trial (CTRI/2022/02/040343), 252 women undergoing emergency cesarean delivery under subarachnoid block with a 25-gauge Quincke needle were allocated in a 1:1 ratio to the midline or paramedian approach. The primary outcome was PDPH within seven days, defined by International Classification of Headache Disorders criteria. The incidence and intensity of low back pain were exploratory outcomes.

Results

After 12 protocol withdrawals for more than two puncture attempts, 240 women (120 per group) were analyzed. PDPH occurred in 17/120 (14.2%) women after the midline approach and 4/120 (3.3%) after the paramedian approach (risk difference 10.8%, 95% confidence interval (CI) 3.7-18.5; p=0.006). Low back ache occurred in 50/120 (41.7%) and 28/120 (23.3%) women, respectively (risk difference 18.3%, 95% CI 6.5-29.5; p=0.004). In exploratory analyses, backache was less intense after the paramedian approach (median numerical rating scale score 4 vs. 6; p<0.001), and severe back pain fell from 17/120 (14.2%) to 2/120 (1.7%; p<0.001). Hemodynamic and emetic outcomes were comparable.

Conclusions

The paramedian approach reduced PDPH approximately fourfold and, in exploratory analyses, reduced the incidence and severity of low back pain. Where cutting spinal needles remain in routine obstetric use, the paramedian approach is a simple, cost-free choice.

Categories: Obstetrics/Gynecology, Pain Management, Anesthesiology
Keywords: cesarean section, low back pain, obstetric anesthesia, paramedian approach, post-dural puncture headache, quincke needle, randomized controlled trial, spinal anesthesia

Introduction

Subarachnoid block is the anesthetic technique of choice for cesarean delivery. Its most disabling complication is post-dural puncture headache (PDPH), a positional headache caused by continued leakage of cerebrospinal fluid through the dural defect. Reported incidences vary with needle caliber and tip design, maternal characteristics, and the diagnostic criteria applied [1,2]. Parturients are the highest-risk group, and PDPH interferes with mother-infant bonding, breastfeeding, and early ambulation [3]. Postoperative low back ache is an even more frequent sequel of neuraxial block that similarly delays functional recovery.

Small-caliber pencil-point needles reduce the risk of PDPH compared with cutting-bevel needles [4], but Quincke needles remain in routine use in many high-volume public hospitals in India and other low- and middle-income settings because of cost and supply constraints. In these settings, a change in insertion technique that costs nothing has real clinical value. In the midline approach, the needle traverses the supraspinous and interspinous ligaments and crosses the dura almost perpendicularly. In the paramedian approach, it passes through the paraspinal muscles and enters the subarachnoid space obliquely. An oblique puncture has been proposed to create a valve-like dural-arachnoid flap that seals after needle withdrawal [5],

How to cite this article
Rajangam H, Satya Prakash M, Thangaswamy C (November 18, 2026) Paramedian Versus Midline Spinal Anesthesia for Emergency Cesarean Delivery: A Randomized Controlled Trial of Post-Dural Puncture Headache and Low Back Pain. Cureus 18(11): e119907. DOI 10.7759/cureus.119907

and ultrastructural work shows that the arachnoid layer governs closure of the defect [6]. Bypassing the midline ligaments may also spare them from needle trauma and so reduce back pain.

Two meta-analyses published in 2024 found that the paramedian approach reduces the incidence of PDPH [7,8]. However, in the cesarean delivery subgroup in the meta-analysis with moderate-certainty evidence from 36 randomized trials and 5,379 patients, the pooled estimate for postoperative low back ache was inconclusive and heterogeneous (odds ratio (OR) 0.35, 95% confidence interval (CI) 0.12-1.07; I^2 = 61%), and none of the included trials measured back ache intensity [8].

The primary objective of the present trial was therefore to compare the incidence of PDPH within seven postoperative days between the midline and paramedian approaches in women undergoing emergency cesarean delivery with a 25-gauge Quincke needle. The prespecified secondary objectives were to compare headache onset and severity, associated symptoms (neck stiffness, photophobia, visual disturbance, and postoperative nausea and vomiting on the first postoperative day), and intraoperative hypotension. In addition, the incidence and severity of postoperative low back pain were evaluated as exploratory outcomes added during recruitment.

Materials And Methods

Study design and setting

This single-center, parallel-group, open-label, randomized controlled superiority trial with 1:1 allocation was conducted in the Department of Anaesthesiology and Critical Care of the Jawaharlal Institute of Postgraduate Medical Education and Research, a tertiary-care teaching hospital in Puducherry, India. Enrollment began on February 25, 2022, recruitment ended in December 2022, and follow-up was completed on January 2, 2023. The trial was registered with the Clinical Trials Registry - India (registration number: CTRI/2022/02/040343) on February 16, 2022, before the first participant was enrolled, and is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [9].

Ethical approval

The protocol was approved by the Institute Ethics Committee (Interventional Studies), Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India (approval number: JIP/IEC/2020/095, dated May 31, 2021). The trial was conducted in accordance with the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and the Declaration of Helsinki [10]. Written informed consent was obtained from every participant before randomization.

Study population

Eligibility

Consecutive parturients aged 18-45 years, at 32-42 weeks of gestation, with an American Society of Anesthesiologists (ASA) physical status of II or III, and scheduled for emergency cesarean delivery under subarachnoid block were screened for eligibility. Women were excluded if they had a contraindication to neuraxial anesthesia, known bupivacaine allergy or hypersensitivity to amide local anesthetics, a history of failed spinal puncture, a significant abdominal mass or ascites, or a history of PDPH or chronic primary headache (including migraine). After early clinical observations, an additional outcome of postoperative pain was added, and women with pre-existing chronic or pregnancy-related low back pain were excluded.

Sample Size

The sample size calculation was based on anticipated PDPH incidences of 19.6% with the midline approach and 5.2% with the paramedian approach from previous obstetric literature [11]. With a two-sided alpha of 0.05 and 90% power, a minimum of 108 evaluable participants per group was required. The sample size was set at 240 (120 per group) in order to account for dropouts and protocol-excluded patients (those requiring more than two needle insertion attempts). Recruitment followed this protocol and concluded once 120 evaluable participants per group were enrolled (252 randomized in total).

Analysis Populations

The primary analysis population was the per-protocol population, comprising all randomized women in whom the block was achieved within two attempts and who completed the seven-day follow-up (n=240; 120 per group). The 12 women withdrawn per protocol after more than two attempts (six per group) had no outcome data and were therefore excluded from this population, as prespecified. To test the robustness of the results to these exclusions, intention-to-treat (ITT) sensitivity analyses included all 252 randomized women, analyzed in the groups to which they were allocated, with the outcome of the 12 withdrawn women imputed under three assumptions: (i) none of the withdrawn women developed the outcome (best case); (ii) three of the six withdrawn women in each group developed the outcome (intermediate case); and (iii) all six

withdrawn women in the paramedian group and none in the midline group developed the outcome (worst case for the paramedian approach). The worst-case assumption was also applied to low back ache.

Randomization and allocation concealment

A computer-generated block randomization sequence with varying block sizes was prepared by an investigator who was not involved in clinical care or outcome assessment. Group assignments were concealed in sequentially numbered, opaque, sealed envelopes (SNOSE), which were opened only after the participant had been transferred to the operating room. Because the two entry sites differ visibly, the operator could not be masked to group allocation, and postoperative assessments were made by the investigating anesthesiologist, as registered.

Intervention

After standard monitoring was established and 500 mL of Ringer's lactate solution was given as a co-load, subarachnoid block was performed in the left lateral decubitus position at the L3-L4 or L4-L5 interspace with a 25-gauge Quincke spinal needle (Becton, Dickinson and Company, Franklin Lakes, New Jersey, United States) by an anesthesiologist with at least two years of experience in obstetric anesthesia. In the midline group, the needle was advanced in the sagittal plane just caudal to the palpated interspinous space. In the paramedian group, it was inserted 1 cm lateral and 1 cm caudal to the inferior border of the superior spinous process and directed 15 degrees medially and cephalad. In both groups, the bevel was oriented parallel to the long axis of the spine [12]. A needle insertion attempt was defined as complete withdrawal of the needle to the skin followed by reinsertion; simple needle redirection without withdrawal to the skin was not counted as a separate attempt, and the number of dural punctures was not recorded separately. Per protocol, any participant who needed more than two needle insertion attempts was withdrawn from the study; this rule was originally designed to avoid confounding of headache outcomes from repeated dural trauma, and study outcomes were not ascertained in these women.

Intrathecal anesthesia was established with 0.5% hyperbaric bupivacaine, either 1.8 mL alone or 1.3 mL combined with fentanyl 25 micrograms, according to the attending anesthesiologist's routine practice, and the regimen used was documented for every participant. Intraoperative hypotension, defined as a decrease in mean arterial pressure of more than 20% from baseline or a systolic pressure below 90 mmHg, was treated with intravenous mephentermine in 3 mg boluses. All participants received intravenous paracetamol 1 g every eight hours after surgery.

Outcomes and follow-up

The primary outcome was the cumulative incidence of PDPH within seven postoperative days. In keeping with criterion 7.2.1 of the International Classification of Headache Disorders, third edition (ICHD-3) [2], PDPH required a headache that developed within five days of dural puncture and was not better accounted for by another ICHD-3 diagnosis. ICHD-3 does not require postural features or latency thresholds; the study's operational definition additionally required that the headache appear or worsen within 15 minutes of sitting or standing and improve within 15 minutes of lying flat, thresholds retained from the second edition of the classification (ICHD-2) [13] to increase diagnostic specificity in the postpartum period. Women with migraine or other chronic primary headaches were excluded at screening. During follow-up, participants were questioned about headache characteristics, postural variation, previous history of headache, and symptoms suggestive of alternative causes, including hypertensive disorders, neurological abnormalities, and infection; a headache attributed to an alternative cause was not classified as PDPH. Participants were assessed in person on the first postoperative day and by structured telephone interview on the third, fifth, and seventh days. Prespecified secondary outcomes were neck stiffness, nausea and vomiting, photophobia, and visual disturbance on the first postoperative day; time to onset and intensity of PDPH; and the incidence and number of episodes of intraoperative hypotension. Procedural success rates (first-attempt success and success within two attempts) were evaluated across all 252 randomized women.

Postoperative low back ache, defined as localized pain or tenderness at the lumbar puncture site distinct from incisional or uterine pain, was not a registered outcome and was added to the study proforma after early clinical observations. After this amendment, women who reported pre-existing chronic or pregnancy-related low back pain at baseline screening were excluded. Prospectively assessed participants were evaluated for postoperative low back ache on the same schedule as PDPH (in person on the first postoperative day and by structured telephone interview on the third, fifth, and seventh days), with the peak (worst) numerical rating scale (NRS) score over the seven-day period selected for the severity analysis. For participants enrolled before the proforma amendment, back ache status and peak pain scores were abstracted retrospectively from standardized inpatient clinical records and daily postoperative nursing charts, in which pain by anatomical site was recorded at every shift, and an explicit entry of "nil" (score 0) was mandatorily documented when back pain was absent, allowing an explicit record of no pain to be distinguished from a missing entry. These 34 women enrolled before the proforma amendment (20 midline, 14 paramedian) had not been screened for pre-existing back pain.

Of the 240 participants analyzed, back ache data were obtained retrospectively for 34 (midline 20 (16.7%)

and paramedian 14 (11.7%)) and prospectively for 206 (midline 100 (83.3%) and paramedian 106 (88.3%)) ($\chi^2(1)=0.86$, p=0.355, $\phi=0.07$). Because data capture changed from record review to prospective enquiry, the low back ache analyses are reported as exploratory. The presence or absence of low back ache was known for all 240 analyzed participants. Pain scores were compared in the 77 women with a recorded score; one woman in the paramedian group reported back ache, but her score was not recorded. In the primary 120-per-group binary severity-threshold analyses (moderate-to-severe back ache (NRS 4-10) and severe back ache (NRS 7-10)), this participant with a missing NRS score was conservatively classified as not meeting the moderate or severe threshold, and sensitivity analyses were performed by imputing her missing score as severe (NRS 7-10). The intensity of both PDPH and low back ache was scored on an 11-point NRS (0, no pain; 10, worst pain imaginable) [14] and graded as mild (1-3), moderate (4-6), or severe (7-10) [15].

Statistical analysis

The protocol specified a single confirmatory analysis: comparison of the seven-day incidence of PDPH between groups with the chi-square test with Yates' continuity correction at a two-sided 5% significance level. All secondary and exploratory analyses, including low back ache incidence and intensity, multivariable regression, and first-attempt subgroup analyses, were performed without adjustment for multiplicity, and their p-values are descriptive. Continuous variables were tested for normality with the Shapiro-Wilk test and compared with the unpaired Student's t-test or the Mann-Whitney U test. Categorical variables were compared with the chi-square test with Yates' correction or, when any expected cell count was below five, Fisher's exact test. For every comparison, the test statistic is reported with its degrees of freedom: chi-square (χ^2) with one degree of freedom for 2×2 tables, t with 238 degrees of freedom for unpaired t-tests, and the Mann-Whitney U statistic with its standardized Z value. Effect sizes are reported as the phi coefficient (ϕ, calculated from the uncorrected χ^2 statistic) for 2×2 comparisons, Cohen's d for t-tests, and r (Z divided by the square root of the total sample size) for Mann-Whitney tests. Fisher's exact test has no test statistic, so the exact p-value is reported with ϕ. For binary outcomes, the absolute risk difference (RD) with Newcombe hybrid score 95% CI [16], the relative risk (RR), and the number needed to treat (NNT) are also reported. Low back ache severity was examined with threshold-specific ORs after testing the proportional-odds assumption, and predictors of low back ache were assessed with multivariable logistic regression adjusted for maternal age, body mass index (BMI), and number of puncture attempts. Analyses were performed with Python version 3.11 (Python Software Foundation, Wilmington, Delaware, United States) using the SciPy (version 1.15) and statsmodels (version 0.14) libraries.

Results

Participant flow and baseline characteristics

Of 380 parturients assessed for eligibility, 16 did not meet the inclusion criteria and 112 declined to participate. A total of 252 women were randomized, 126 to each group. Across all 252 randomized participants, subarachnoid block was achieved on the first needle insertion attempt in 105/126 (83.3%) women in the midline group and 102/126 (81.0%) in the paramedian group (RD 2.4%, 95% CI -7.1 to 11.9; $\chi^2(1)=0.11$, p=0.742, $\phi=0.03$), on the second attempt in 15/126 (11.9%) and 18/126 (14.3%) women, respectively, and within two attempts in 120/126 (95.2%) women in both groups (RD 0.0%, 95% CI -5.8 to 5.8; $\chi^2(1)=0.00$, p=1.000, $\phi=0.00$). Six women in each group (4.8%) needed more than two needle insertion attempts and were withdrawn per protocol before postoperative outcome assessment, and no outcome data were collected for them. No participant withdrew consent or was lost to follow-up, leaving 120 women per group in the per-protocol population for the primary analysis (Figure *1*).

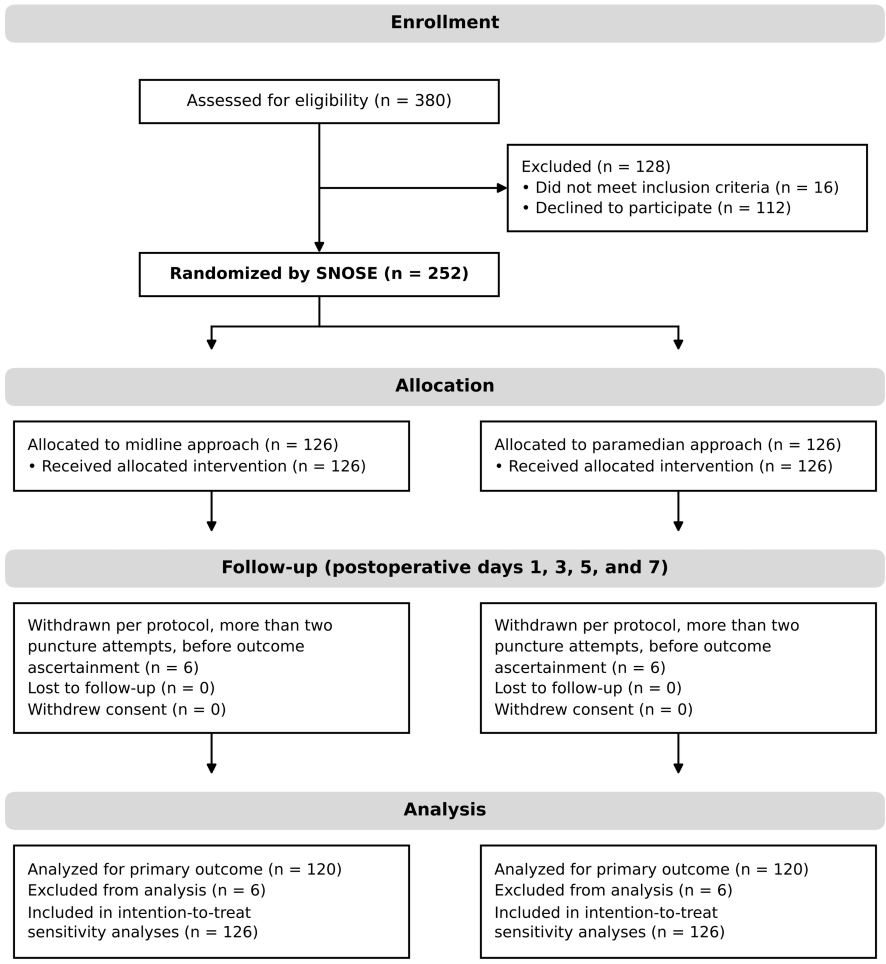


FIGURE 1: CONSORT flow diagram of participant enrollment, allocation, follow-up, and analysis

CONSORT: Consolidated Standards of Reporting Trials; SNOSE: sequentially numbered, opaque, sealed envelopes

Baseline maternal and procedural characteristics in the per-protocol population (n=120 per group), as well as procedural success across all randomized participants (n=126 per group), were similar in the two groups, as was the intrathecal regimen: bupivacaine with fentanyl was given to 49 (40.8%) women in the midline group and 50 (41.7%) in the paramedian group ($\chi^2(1)=0.00$, p=1.000, $\phi=0.01$) (Table *1*).

Characteristic	Midline (n=120)	Paramedian (n=120)	Test statistic	p-value	Effect size
Age (years), median (IQR)	28.5 (23.0-33.0)	30.0 (25.8-33.3)	U=6384.5, Z=-1.52	0.129	r=0.10
Height (cm), mean ± SD	152.4 ± 5.9	153.3 ± 6.7	t(238)=-1.07	0.286	d=-0.14
Weight (kg), mean ± SD	63.9 ± 7.6	62.8 ± 7.9	t(238)=1.12	0.264	d=0.14
BMI (kg/m²), mean ± SD	27.6 ± 3.7	26.9 ± 4.1	t(238)=1.49	0.137	d=0.19
ASA physical status II, n (%)	110 (91.7)	109 (90.8)	$\chi^2(1)=0.00$	1.000	φ=0.01
ASA physical status III, n (%)	10 (8.3)	11 (9.2)	$\chi^2(1)=0.00$	1.000	φ=0.01
First-attempt success (all randomized, n=126 per group), n (%)	105 (83.3)	102 (81.0)	$\chi^2(1)=0.11$	0.742	φ=0.03
Success within two attempts (all randomized, n=126 per group), n (%)	120 (95.2)	120 (95.2)	$\chi^2(1)=0.00$	1.000	φ=0.00
More than two attempts, withdrawn per protocol (all randomized, n=126 per group), n (%)	6 (4.8)	6 (4.8)	$\chi^2(1)=0.00$	1.000	φ=0.00
Second-attempt block among per-protocol participants (n=120 per group), n (%)	15 (12.5)	18 (15.0)	$\chi^2(1)=0.14$	0.708	φ=0.04
Bupivacaine alone, n (%)	71 (59.2)	70 (58.3)	$\chi^2(1)=0.00$	1.000	φ=0.01
Bupivacaine with fentanyl 25 micrograms, n (%)	49 (40.8)	50 (41.7)	$\chi^2(1)=0.00$	1.000	φ=0.01

TABLE 1: Baseline and procedural characteristics of the participants

Baseline maternal characteristics and intrathecal regimens are reported for the per-protocol population (n=120 per group), whereas procedural success rates are reported across all randomized participants (n=126 per group) as well as within the per-protocol cohort. p-values are provided for completeness; no baseline comparison was used to select covariates or adjust any analysis. Age was compared with the Mann-Whitney U test (not normally distributed on the Shapiro-Wilk test); height, weight, and BMI with the unpaired Student's t-test; and categorical variables with the chi-square test with Yates' continuity correction.

ASA: American Society of Anesthesiologists; BMI: body mass index; d: Cohen's d; IQR: interquartile range; r: Z divided by the square root of the total sample size; SD: standard deviation; U: Mann-Whitney U statistic; φ: phi coefficient; $\chi^2(1)$: chi-square statistic with one degree of freedom; t(238): t statistic with 238 degrees of freedom.

Primary outcome

In the per-protocol population (n=120 per group), PDPH occurred in 17/120 (14.2%) women after the midline approach and 4/120 (3.3%) after the paramedian approach (RD 10.8%, 95% CI 3.7-18.5; $\chi^2(1)=7.51$, p=0.006, ϕ=0.19), giving an RR of 0.24 (95% CI 0.08-0.68) and an NNT of nine (95% CI 5-27) (Table *2*).

Outcome	Midline (n=120)	Paramedian (n=120)	Risk difference, % (95% CI)	Test statistic	p-value	Effect size
Post-dural puncture headache (primary outcome), n (%)	17 (14.2)	4 (3.3)	10.8 (3.7 to 18.5)	$\chi^2(1)=7.51$	0.006	φ=0.19
Intraoperative hypotension, n (%)	85 (70.8)	82 (68.3)	2.5 (-9.1 to 14.0)	$\chi^2(1)=0.08$	0.779	φ=0.03
Hypotensive episodes, median (IQR)	1 (0-2)	1 (0-2)	Not applicable	U=7458.0, Z=0.50	0.619	r=0.03
Intraoperative nausea, n (%)	25 (20.8)	22 (18.3)	2.5 (-7.6 to 12.5)	$\chi^2(1)=0.11$	0.745	φ=0.03
Intraoperative vomiting, n (%)	10 (8.3)	9 (7.5)	0.8 (-6.4 to 8.1)	$\chi^2(1)=0.00$	1.000	φ=0.02
Nausea on postoperative day one, n (%)	35 (29.2)	33 (27.5)	1.7 (-9.7 to 12.9)	$\chi^2(1)=0.02$	0.886	φ=0.02
Vomiting on postoperative day one, n (%)	18 (15.0)	16 (13.3)	1.7 (-7.3 to 10.6)	$\chi^2(1)=0.03$	0.853	φ=0.02
Blurred vision on postoperative day one, n (%)	0 (0)	0 (0)	Not applicable	Not applicable	Not applicable	Not applicable
Serious adverse events, n (%)	0 (0)	0 (0)	Not applicable	Not applicable	Not applicable	Not applicable

TABLE 2: Primary and secondary outcomes

Post-dural puncture headache was the single confirmatory comparison specified in the protocol; all other p-values are exploratory and unadjusted for multiplicity. Binary outcomes were compared with the chi-square test with Yates' continuity correction and hypotensive episodes with the Mann-Whitney U test. Risk differences are midline minus paramedian, in percentage points, with Newcombe hybrid score 95% CIs.

CI: confidence interval; IQR: interquartile range; r: Z divided by the square root of the total sample size; U: Mann-Whitney U statistic; φ: phi coefficient; $\chi^2(1)$: chi-square statistic with one degree of freedom.

In ITT sensitivity analyses of all 252 randomized women, the benefit of the paramedian approach persisted under the best-case assumption (17/126 vs. 4/126; RD 10.3%, 95% CI 3.5-17.6; $\chi^2(1)=7.48$, p=0.006) and the intermediate assumption (20/126 vs. 7/126; RD 10.3%, 95% CI 2.7-18.2; $\chi^2(1)=5.97$, p=0.015). Only under the worst-case assumption was the difference attenuated (17/126 vs. 10/126; RD 5.6%, 95% CI -2.2 to 13.5; $\chi^2(1)=1.49$, p=0.222) (Table 3).

Outcome and assumption for the 12 withdrawn women	Midline (n=126), n (%)	Paramedian (n=126), n (%)	Risk difference, % (95% CI)	Test statistic	p-value	Effect size
Post-dural puncture headache, best case: none developed the outcome	17 (13.5)	4 (3.2)	10.3 (3.5 to 17.6)	$\chi^2(1)=7.48$	0.006	φ=0.19
Post-dural puncture headache, intermediate case: three of six in each group developed the outcome	20 (15.9)	7 (5.6)	10.3 (2.7 to 18.2)	$\chi^2(1)=5.97$	0.015	φ=0.17
Post-dural puncture headache, worst case: all six in the paramedian group and none in the midline group developed the outcome	17 (13.5)	10 (7.9)	5.6 (-2.2 to 13.5)	$\chi^2(1)=1.49$	0.222	φ=0.09
Low back ache, worst case: all six in the paramedian group and none in the midline group developed the outcome	50 (39.7)	34 (27.0)	12.7 (1.1 to 23.9)	$\chi^2(1)=4.02$	0.045	φ=0.13

TABLE 3: Intention-to-treat sensitivity analyses including all 252 randomized women

Six women in each group were withdrawn per protocol after more than two puncture attempts and had no outcome data; their outcomes were imputed under the stated assumptions and all 252 randomized women were analyzed in their allocated groups. Comparisons used the chi-square test with Yates' continuity correction. Risk differences are midline minus paramedian, in percentage points, with Newcombe hybrid score 95% CIs.

CI: confidence interval; φ: phi coefficient; $\chi^2(1)$: chi-square statistic with one degree of freedom.

Every headache met both postural criteria and began within 67 hours of dural puncture, and no new case occurred after the third postoperative day (Figure 2).

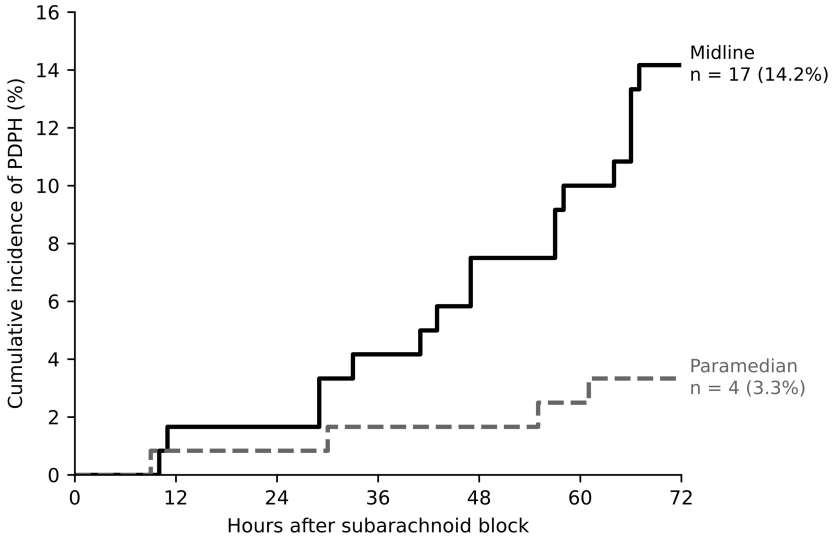


FIGURE 2: Cumulative incidence of post-dural puncture headache during the first 72 hours after subarachnoid block

Values are expressed as a percentage of the 120 women analyzed in each group (solid line, midline approach; dashed line, paramedian approach). The numbers at the right show the cumulative number of cases. No new case occurred between 72 hours and the seventh postoperative day.

PDPH: post-dural puncture headache

Among affected women, the time to onset, supine and upright NRS scores, severity, neck stiffness, and photophobia were similar in the two groups (Table 4). No participant needed an epidural blood patch, and all headaches resolved with conservative management (hydration, oral caffeine, and regular analgesics) by the seventh day.

Characteristic	Midline (n=17)	Paramedian (n=4)	Test statistic	p-value	Effect size
Time to onset (hours), median (IQR)	47.0 (33.0-64.0)	42.5 (24.8-56.5)	U=43.0, Z=0.81	0.446	r=0.18
NRS score supine, median (IQR)	1.0 (0.0-3.0)	2.0 (1.5-2.5)	U=31.5, Z=-0.23	0.854	r=0.05
NRS score upright, median (IQR)	5.0 (5.0-8.0)	6.0 (5.8-6.5)	U=28.0, Z=-0.55	0.612	r=0.12
Moderate headache (NRS 4-6), n (%)	10 (58.8)	3 (75.0)	Fisher’s exact test	1.000	φ=0.13
Severe headache (NRS 7-10), n (%)	7 (41.2)	1 (25.0)	Fisher’s exact test	1.000	φ=0.13
Neck stiffness, n (%)	7 (41.2)	2 (50.0)	Fisher’s exact test	1.000	φ=0.07
Photophobia, n (%)	4 (23.5)	1 (25.0)	Fisher’s exact test	1.000	φ=0.01

TABLE 4: Characteristics of post-dural puncture headache among the 21 affected women

No headache was graded as mild (NRS 1-3), so the moderate and severe rows are a single comparison of severity. Continuous variables were compared with the Mann-Whitney U test and proportions with Fisher’s exact test, which has no test statistic.

IQR: interquartile range; NRS: numerical rating scale (0-10); r: Z divided by the square root of the total sample size; U: Mann-Whitney U statistic; φ: phi coefficient

Low back ache

Low back ache was reported by 50/120 (41.7%) women after the midline approach and 28/120 (23.3%) after the paramedian approach (RD 18.3%, 95% CI 6.5-29.5; $\chi^2(1)=8.38$, p=0.004, $\phi=0.20$), giving an RR of 0.56 (95% CI 0.38-0.82) and an NNT of six (95% CI 3-16) (Table *5*). The reduction remained significant under the worst-case ITT assumption (50/126 vs. 34/126; $\chi^2(1)=4.02$, p=0.045, $\phi=0.13$) (Table *3*).

Outcome	Midline (n=120)	Paramedian (n=120)	Effect estimate (95% CI)	Test statistic	p-value	Effect size
Back ache data collected retrospectively from records, n (%)	20 (16.7)	14 (11.7)	Not applicable	$\chi^2(1)=0.86$	0.355	φ=0.07
Low back ache, n (%)	50 (41.7)	28 (23.3)	RD 18.3 (6.5 to 29.5)	$\chi^2(1)=8.38$	0.004	φ=0.20
Moderate or severe back ache (NRS 4-10), n (%)	48 (40.0)	19 (15.8)	RD 24.2 (12.9 to 34.6)	$\chi^2(1)=16.23$	<0.001	φ=0.27
Severe back ache (NRS 7-10), n (%)	17 (14.2)	2 (1.7)	RD 12.5 (5.9 to 20.0)	$\chi^2(1)=11.20$	<0.001	φ=0.23
NRS score among affected women, median (IQR)	6 (5-7)	4 (3-5.5)	MD 1.0 (1.0 to 2.0)	U=1020.0, Z=3.75	<0.001	r=0.43
Low back ache, multivariable adjusted analysis	Not applicable	Not applicable	Adjusted OR 0.37 (0.21 to 0.66)	Wald z=-3.35	<0.001	Not applicable

TABLE 5: Low back ache (exploratory outcomes)

Denominators are 120 participants per group except for continuous NRS scores, which include the 77 affected women with a recorded score (midline 50, paramedian 27); the presence or absence of back ache was known for all 240 women. In the primary rows for moderate or severe back ache (NRS 4-10) and severe back ache (NRS 7-10), the single paramedian participant with back ache of unrecorded NRS intensity was classified as not meeting the threshold; if her pain were classified as severe, the comparison would be 48/120 (40.0%) vs. 20/120 (16.7%) (RD 23.3%, 95% CI 12.0 to 33.9; $\chi^2(1)=14.96$, p<0.001, φ=0.26) for moderate or severe back ache and 17/120 (14.2%) vs. 3/120 (2.5%) (RD 11.7%, 95% CI 4.8 to 19.2; $\chi^2(1)=9.22$, p=0.0024, φ=0.21) for severe back ache. Binary outcomes were compared with the chi-square test with Yates' continuity correction and NRS scores with the Mann-Whitney U test; MD is the Hodges-Lehmann median difference. The adjusted OR is for the paramedian versus the midline approach from a multivariable logistic regression model adjusted for maternal age, body mass index, and number of puncture attempts, tested with the Wald test (z statistic).

CI: confidence interval; IQR: interquartile range; MD: median difference; NRS: numerical rating scale (0-10); OR: odds ratio; r: Z divided by the square root of the total sample size; RD: risk difference in percentage points (midline minus paramedian); U: Mann-Whitney U statistic; φ: phi coefficient; $\chi^2(1)$: chi-square statistic with one degree of freedom

Among the 77 affected women with a recorded pain score, peak pain was less intense after the paramedian approach (median NRS 4, interquartile range (IQR) 3-5.5 vs. 6, IQR 5-7; Hodges-Lehmann median difference 1.0, 95% CI 1.0-2.0; Mann-Whitney U=1020, Z=3.75, p<0.001, r=0.43) (Figure *3A*), a result unchanged by imputing the single missing score at either extreme. In the severity-threshold analyses across all 120 participants per group, the one paramedian participant with unrecorded NRS intensity was conservatively not counted as moderate or severe in the primary estimates (48/120 (40.0%) vs. 19/120 (15.8%), p<0.001 for moderate or severe back pain; 17/120 (14.2%) vs. 2/120 (1.7%), p<0.001 for severe back pain). In sensitivity analyses classifying her missing pain score as severe (NRS 7-10), the reductions remained statistically significant for both moderate or severe back ache (48/120 (40.0%) vs. 20/120 (16.7%); RD 23.3%, 95% CI 12.0-33.9; Yates-corrected $\chi^2(1)=14.96$, p<0.001, $\phi=0.26$) and severe back ache (17/120 (14.2%) vs. 3/120 (2.5%); RD 11.7%, 95% CI 4.8-19.2; Yates-corrected $\chi^2(1)=9.22$, p=0.0024, $\phi=0.21$). The distribution of back pain severity among all 240 analyzed women is shown in Figure *3B*.

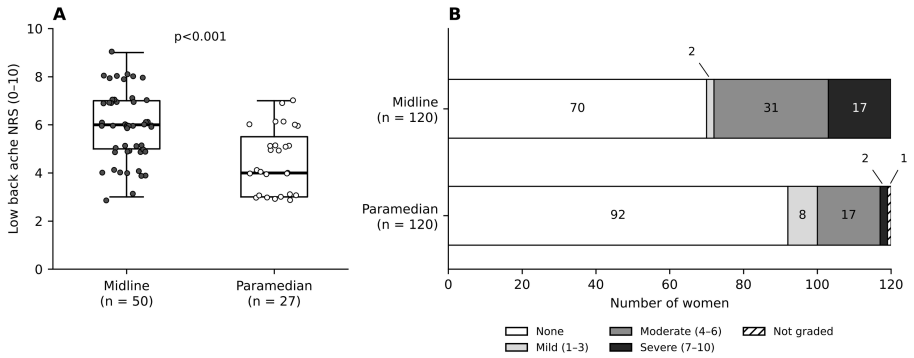


FIGURE 3: Postoperative low back ache in the two groups

(A) Individual NRS pain scores among the 77 affected women with a recorded score; points are jittered for visibility, boxes show the median and interquartile range, and whiskers show the full range (Mann-Whitney U test, U=1020, Z=3.75, p<0.001, r=0.43). (B) Distribution of back ache severity among the 120 women analyzed in each group, graded from the NRS as mild (1-3), moderate (4-6), or severe (7-10); numbers show participant counts. One woman in the paramedian group who reported back ache without a recorded score is shown as the hatched segment.

NRS: numerical rating scale

Because the ordinal model did not meet the proportional-odds assumption, threshold-specific ORs for the paramedian approach were estimated: 0.43 (95% CI 0.24-0.74) for any back ache, 0.28 (95% CI 0.15-0.52) for moderate or severe back ache (0.30, 95% CI 0.16-0.55 if the missing score was classified as severe), and 0.10 (95% CI 0.02-0.46) for severe back ache (0.16, 95% CI 0.04-0.55 if the missing score was classified as severe). In the multivariable logistic model adjusted for maternal age, BMI, and number of puncture attempts, paramedian allocation was independently associated with less low back ache (adjusted OR 0.37, 95% CI 0.21-0.66; Wald z=-3.35, p<0.001). The number of attempts was not associated with back ache (OR 1.01 per attempt, 95% CI 0.44-2.33), whereas maternal age showed a modest association (OR 1.07 per year, 95% CI 1.01-1.12). Among the 207 women blocked at the first attempt, back ache occurred in 44/105 (41.9%) midline and 24/102 (23.5%) paramedian participants. Low back ache was not associated with PDPH (OR 0.46, 95% CI 0.15-1.42; $\chi^2(1)=1.29$, p=0.257, $\phi=0.09$).

Secondary outcomes

Intraoperative hypotension, the number of hypotensive episodes, and nausea and vomiting during surgery and on the first postoperative day did not differ between groups (Table *2*). No participant reported blurred vision, and there were no serious adverse events, neurological complications, or conversions to general anesthesia.

Discussion

In this randomized controlled trial of women undergoing emergency cesarean delivery with a 25-gauge Quincke needle, the paramedian approach reduced the seven-day incidence of PDPH more than fourfold compared with the midline approach in the per-protocol population of women whose block was achieved within two attempts (3.3% vs. 14.2%). In ITT sensitivity analyses across all 252 randomized women, this reduction remained statistically significant under best-case and intermediate assumptions, whereas in the scenario least favorable to the paramedian approach the risk difference was 5.6 percentage points (95% CI -2.2 to 13.5; p=0.222). In exploratory analyses, the paramedian approach also nearly halved the incidence of postoperative low back ache (23.3% vs. 41.7%) and reduced its intensity, with severe back ache falling from 14.2% to 1.7% (or 2.5% if the single missing pain score was classified as severe). When PDPH did occur, its onset, severity, and associated symptoms were similar in the two groups, and all cases resolved with conservative management.

Our per-protocol finding is consistent with the two 2024 meta-analyses showing a reduction in PDPH with the paramedian approach [7,8], and our midline incidence of 14.2% is in line with obstetric studies using 25-gauge Quincke needles [17-19]. An obstetric trial that found no difference between the two approaches neither limited the number of puncture attempts nor applied strict postural latency criteria, and reported headache rates above 30% in both groups [20]. For low back ache after cesarean delivery, where pooled evidence was inconclusive [8], our exploratory findings agree with a recent double-blind randomized trial [21] and add data on pain intensity. In these exploratory analyses, the association appeared stronger at higher severity thresholds (OR 0.43 for any back ache and 0.10, or 0.16 under worst-case imputation, for severe back ache), although the confidence intervals overlap widely. This pattern is consistent with the

anatomy. An oblique dural-arachnoid puncture leaves overlapping openings that seal once the threshold for symptomatic leakage is avoided [5,6], whereas back ache reflects graded trauma to the densely innervated supraspinous and interspinous ligaments, which the paramedian route bypasses. A similar difference among women blocked at the first attempt (41.9% vs. 23.5%) is consistent with, but does not establish, a mechanism related to sparing the midline ligaments rather than to fewer needle passes.

Strengths and limits of this study

The strengths of this trial include prospective registration, concealed allocation, a standardized operational definition of PDPH, complete seven-day follow-up of the per-protocol cohort, and ITT sensitivity analyses of the primary outcome. However, several limitations must be acknowledged.

First, six randomized women in each group (12 in total) were withdrawn per protocol after requiring more than two needle insertion attempts, and outcome follow-up was discontinued in these participants. Although this rule was intended to avoid confounding from multiple traumatic passes, needle insertion attempts reflected skin reinsertions, the number of dural punctures was not recorded, and excluding participants after randomization on the basis of a procedural outcome that may be influenced by the assigned approach can introduce selection bias. Because outcomes were missing for these 12 women, certainty across all randomized women is bounded by the sensitivity analysis, in which the worst-case risk difference was 5.6 percentage points (95% CI -2.2 to 13.5). Moreover, while first-attempt success (105/126 vs. 102/126) and success within two attempts (120/126 in both groups) were comparable across all randomized participants, restricting the per-protocol comparison to successful blocks within two attempts cannot establish that either technique requires fewer attempts overall. Second, our operational definition of PDPH incorporated 15-minute onset and relief postural thresholds (derived from ICHD-2 [13]) that are no longer required by ICHD-3 [2]; while this increased specificity alongside screening for alternative postpartum headache causes, it could yield lower absolute headache rates than broader ICHD-3 criteria.

Third, because the entry site is evident to the operator and outcomes were recorded by the clinical team, the open-label design carries a risk of assessment bias for subjective pain outcomes. Fourth, low back ache was added as an exploratory outcome during the trial, with early data for 34 women (14.2%) abstracted retrospectively from standardized inpatient nursing records by an unmasked investigator rather than by prospective interview and without baseline screening for pre-existing back pain, and one paramedian participant lacked a numerical severity score; thus, the back ache findings are exploratory and hypothesis-generating. Fifth, intrathecal fentanyl followed routine clinical practice rather than a fixed protocol, although its use was similar in the two groups and postoperative analgesia with scheduled intravenous paracetamol was uniform. Finally, these single-center data come from emergency cesarean deliveries performed with 25-gauge cutting needles, should not be extended to pencil-point needles, and were not powered to establish comparative safety for rare complications.

The findings are, however, relevant to high-volume public hospitals in low- and middle-income countries, where Quincke needles remain standard because of procurement constraints. In these settings, the paramedian approach is a cost-free change in technique that needs no additional equipment and achieves comparable first- and second-attempt block success and hemodynamic stability. Multicenter trials with masked outcome assessors and complete follow-up of all randomized participants are needed to confirm the effect on low back ache as a primary outcome.

Conclusions

In women undergoing emergency cesarean delivery with a 25-gauge Quincke needle whose block was achieved within two attempts, the paramedian approach reduced post-dural puncture headache approximately fourfold compared with the midline approach in the per-protocol analysis, although sensitivity analysis for the 12 post-randomization exclusions yielded a risk difference of 5.6 percentage points in the scenario least favorable to the paramedian approach. In exploratory analyses, it also reduced both the incidence and the severity of postoperative low back ache, with similar success rates within one or two attempts and comparable hemodynamic and emetic outcomes. Because it needs no additional equipment and adds no cost, the paramedian approach is a practical choice wherever cutting spinal needles remain in routine obstetric use. Multicenter trials with masked outcome assessment and full intention-to-treat follow-up should confirm its effect on postoperative back pain.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Hariharan Rajangam, M.V.S. Satya Prakash, Chitra Rajeswari Thangaswamy

Acquisition, analysis, or interpretation of data: Hariharan Rajangam, M.V.S. Satya Prakash, Chitra

Rajeswari Thangaswamy

Drafting of the manuscript: Hariharan Rajangam, M.V.S. Satya Prakash, Chitra Rajeswari Thangaswamy

Critical review of the manuscript for important intellectual content: M.V.S. Satya Prakash, Chitra Rajeswari Thangaswamy

Supervision: M.V.S. Satya Prakash, Chitra Rajeswari Thangaswamy

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Institute Ethics Committee (Interventional Studies), Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India issued approval JIP/IEC/2020/095. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **AI use statement:** The authors used Grammarly Pro (Superhuman, San Francisco, California, United States) and Claude (Anthropic, PBC, San Francisco, California, United States) as follows: language polishing, structure or formatting, literature comparison, methodological or statistical suggestions in Introduction, Discussion, References. The authors manually reviewed and edited all AI-assisted text and code, cross-checking every table value and figure against the primary study dataset. Every reference and DOI was verified directly against PubMed and original publisher records to confirm bibliographic accuracy and clinical validity. The authors confirm that they have reviewed and verified all AI-assisted content and take full responsibility for the work. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

References

1. Uppal V, Russell R, Sondekoppam R, et al.: Consensus practice guidelines on postdural puncture headache from a multisociety, international working group: a summary report. JAMA Netw Open. 2023, 6:e2325387. 10.1001/jamanetworkopen.2023.25387
2. Headache Classification Committee of the International Headache Society (IHS): The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018, 38:1-211. 10.1177/0333102417738202
3. Choi PT, Galinski SE, Takeuchi L, Lucas S, Tamayo C, Jadad AR: PDPH is a common complication of neuraxial blockade in parturients: a meta-analysis of obstetrical studies. Can J Anaesth. 2003, 50:460-9. 10.1007/BF03021057
4. Arevalo-Rodriguez I, Muñoz L, Godoy-Casasbuenas N, Ciapponi A, Arevalo JJ, Boogaard S, Roqué I Figuls M: Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) . Cochrane Database Syst Rev. 2017, 4:CD010807. 10.1002/14651858.CD010807.pub2
5. Hatfalvi BI: Postulated mechanisms for postdural puncture headache and review of laboratory models. Clinical experience. Reg Anesth. 1995, 20:329-36. 10.1136/rapm-00115550-199520040-00009
6. Reina MA, Puigdellívol-Sánchez A, Gatt SP, De Andrés J, Prats-Galino A, van Zundert A: Electron microscopy of dural and arachnoid disruptions after subarachnoid block. Reg Anesth Pain Med. 2017, 42:709-18. 10.1097/AAP.0000000000000667
7. Ng KT, Lim WE, Teoh WY, Shariffuddin II, Ti LK, Abidin MF: Paramedian versus midline approach of spinal anesthesia: a systematic review and meta-analysis with trial sequential analysis. J Anesth. 2024, 38:65-76. 10.1007/s00540-023-03281-6
8. Kim SY, Na HS, Park JI, Lee KO, Shin HJ: Comparison of the effect of landmark-based midline and paramedian approaches on spinal anesthesia-related complications in adult patients: a meta-analysis of randomized controlled trials. Medicina (Kaunas). 2024, 60:178. 10.3390/medicina60010178
9. Schulz KF, Altman DG, Moher D: CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010, 340:c332. 10.1136/bmj.c332
10. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013, 310:2191-4. 10.1001/jama.2013.281053
11. Behery MA, Elshahat M: Post dural lumbar puncture headache (PDPH) after spinal anesthesia for cesarean section, comparative study between para median and median approaches. Indian J Med Res Pharm Sci. 2016, 3:66-73. 10.5281/zenodo.177355
12. Salik F, Kiliç ET, Akelma H, Güzel A: The effects of the Quincke spinal needle bevel insertion on postdural puncture headache and hemodynamics in obstetric patients. Anesth Essays Res. 2018, 12:705-10. 10.4103/aer.AER_101_18
13. The International Classification of Headache Disorders: 2nd edition . Cephalalgia. 2004, 24:9-160. 10.1111/j.1468-2982.2003.00824.x
14. Hawker GA, Mian S, Kendzerska T, French M: Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res (Hoboken). 2011, 63 Suppl 11:S240-52. 10.1002/acr.20543
15. Lybecker H, Djernes M, Schmidt JF: Postdural puncture headache (PDPH): onset, duration, severity, and associated symptoms. An analysis of 75 consecutive patients with PDPH. Acta Anaesthesiol Scand. 1995,

39:605-12. 10.1111/j.1399-6576.1995.tb04135.x
16. Newcombe RG: Interval estimation for the difference between independent proportions: comparison of eleven methods. Stat Med. 1998, 17:873-90. 10.1002/(SICI)1097-0258(19980430)17:8%3C873::AID-SIM779%3E3.0.CO;2-I
17. Ramegowda DS, Gurulingaswamy S, Santhosh MC, Iyyappan A: Postdural puncture headache: a comparison between median and paramedian approach under spinal anesthesia in cesarean section. Indian J Anesth Analg. 2019, 6:2241-8.
18. Wanjari D, Bhalerao N, Paul A, Bele A: Post-dural puncture headache: a comparative study using 25 G Quincke's needle in midline and paramedian approaches in patients undergoing elective cesarean section. Cureus. 2024, 16:e66656. 10.7759/cureus.66656
19. Vallejo MC, Mandell GL, Sabo DP, Ramanathan S: Postdural puncture headache: a randomized comparison of five spinal needles in obstetric patients. Anesth Analg. 2000, 91:916-20. 10.1097/00000539-200010000-00027
20. Uluer MS, Sargin M, Akin F, Uluer E, Sahin O: A randomized study to evaluate post-dural puncture headache after cesarean section: comparison with median and paramedian approaches. Niger J Clin Pract. 2019, 22:1564-9. 10.4103/njcp.njcp_100_19
21. Dutta S, Senapati LK, Pattnaik A, Mohapatra PS: Incidence of post-dural puncture headache and low backache following median versus paramedian spinal anesthesia: a randomized double-blind trial. Cureus. 2025, 17:e98172. 10.7759/cureus.98172