The Impact of Spinal Anesthesia Technique on Post-Dural Puncture Headache: A Randomized Controlled Trial Comparing Paramedian and Midline Approaches in Orthopedic Patients

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Abstract- Post-dural puncture headache (PDPH) is a common complication of spinal anesthesia. This trial compared the impact of paramedian versus midline approaches on PDPH incidence in orthopedic patients. This randomized controlled trial enrolled 160 orthopedic surgery candidates at Imam Khomeini Hospital, Jiroft (2023). Randomization was performed using computer-generated numbers and sealed opaque envelopes for allocation concealment (1:1 ratio). Patients received spinal anesthesia via paramedian (Group P, n=80) or midline (Group M, n=80) approach using a 25-G Quincke needle. The anesthesiologist performing the block could not be blinded to the technique; however, participants, outcome assessors (neurologist), and data analysts were blinded. PDPH was diagnosed according to ICHD 3 criteria (headache developing within 5 days, postural component, and associated symptoms). Incidence, duration, severity, and onset timing were recorded. Odds ratio (OR) with 95% confidence interval (CI) was calculated for the primary outcome. PDPH occurred in 31.3% of Group P vs. 62.5% of Group M. The midline group had significantly higher odds of PDPH (OR=3.67, 95% CI: 1.98-6.80, P<0.001). Mean headache duration was 2.56 days (Group P) vs. 5.34 days (Group M). Most headaches in both groups began within the first 24 hours. The paramedian technique significantly reduces the incidence, duration, and severity of PDPH compared to the midline approach. Adoption of the paramedian technique is recommended to improve patient outcomes.

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Introduction

Post-dural puncture headache (PDPH) is a prevalent and distressing complication that may arise following spinal anesthesia (1,2). According to the International Classification of Headache Disorders, 3rd edition (ICHD-3), PDPH is defined as a headache developing within 5 days after a dural puncture, worsening within 15 minutes after sitting or standing, and improving within 15 minutes after lying down, accompanied by at least one of the following: neck stiffness, tinnitus, hypacusis, photophobia, or nausea, and not better accounted for by another diagnosis (3). The American Society of Anesthesiologists (ASA) 2021 Statement on Post-Dural

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Puncture Headache Management further emphasizes that the hallmark of PDPH is a headache that exacerbates with upright positions such as sitting or standing and significantly alleviates when lying down (4). This headache is commonly described as dull and throbbing, often radiating to the frontal and occipital areas, neck, and shoulders (1,2). Recent evidence indicates that PDPH typically manifests within five days of dural puncture, with 66% of cases presenting within the first 48 hours and 90% within three days (3). Typically, the duration of PDPH is self-limiting, resolving spontaneously within a few days to two weeks. However, in rare instances, it can evolve into a chronic condition, lasting for months or even years (3,4).

Pathophysiologically, PDPH results from cerebrospinal fluid (CSF) leakage through the dural defect, which induces traction on pain-sensitive intracranial and meningeal structures. the leakage of cerebrospinal fluid (CSF) at the puncture site, leading to traction on the meninges. In contemporary clinical practice, regional anesthesia, particularly spinal anesthesia, is increasingly preferred over general anesthesia due to the potential risks associated with endotracheal intubation, such as failure and aspiration (5,6). Refining anesthesia techniques to minimize the size of the dural defect is essential to reducing the incidence of PDPH. Practitioners must also maintain a heightened awareness of the risk factors associated with PDPH, especially when performing spinal or epidural blocks (7). The administration of spinal anesthesia can be executed via two primary methodologies: the paramedian approach or the midline approach. The midline approach is often preferred, owing to familiar anatomical landmarks and straightforward access. Conversely, the paramedian approach is often reserved for specific populations, such as elderly or obese patients, or those with degenerative spine disease or distorted anatomy (8-10)

Notwithstanding available prophylactic interventions, the effectiveness of these techniques in preventing PDPH remains suboptimal. Thus, the significance of this technique in spinal anesthesia in averting this complication is underscored (11). Despite the existence of various techniques for dural puncture in spinal anesthesia, there is a notable lack of studies directly comparing their effectiveness in reducing the incidence of headaches.

Despite the numerous prophylactic treatments suggested based on risk factors and pathophysiology, there remains a lack of sufficient evidence supporting their benefits, highlighting the need for more reliable data to validate their effectiveness. Overall, paying careful attention to the spinal anesthesia technique is crucial. The prevention of PDPH represents a significant challenge in clinical anesthesia practice. One of the most effective strategies to mitigate the incidence of PDPH involves refining the techniques utilized during anesthesia to minimize the size of the dural puncture and consequently reduce the volume of cerebrospinal fluid leakage. In addition, increased awareness among clinicians regarding the risk factors associated with PDPH during spinal or epidural anesthesia administration is paramount. Despite these approaches, accidental dural puncture continues to occur and poses a persistent issue for patients (4,12). Therefore, this randomized controlled trial aimed to compare the effects of the paramedian and midline spinal anesthesia approaches on the incidence, onset, duration, and severity of PDPH in patients undergoing orthopedic surgery. Current research is limited and often based on small sample sizes in orthopedic settings. Addressing this gap is crucial, as anesthesia complications can lead to longer hospital stays and decreased patient comfort.

Materials and Methods

Research type

The present study utilized an interventional (experimental) research design, wherein participants were randomly allocated to two groups (P & M) to assess the differential effects of two distinct spinal anesthesia techniques.

Study population and setting

The study encompassed patients scheduled for orthopedic surgeries requiring spinal anesthesia at Imam Khomeini Hospital in Jiroft City throughout 2023. Eligible participants were defined as adults possessing an American Society of Anesthesiologists (ASA) physical status classification of I or II.

Sampling method and sample size

A census sampling method was used to enroll all eligible patients on selected surgery days. The sample size was determined from a recent 2024 meta-analysis of 13 Randomized Controlled Trials (RCTs) that found the incidence of PDPH was 10.4% in the midline group compared to 5.9% in the paramedian group (11). Based on these proportions, with a two-sided alpha level of 0.05 and a statistical power of 90% (β=0.10), and allowing for an anticipated dropout rate of 10–15%, a total sample size of 160 patients (80 per arm) was determined.and to enhance the robustness of the study and account for a potential attrition rate of 10-15%, the final sample size

was set at 160 participants, with 80 individuals allocated to each group.

Inclusion and exclusion criteria

Inclusion Criteria: The study included patients aged 18 years or older, classified as ASA I or II, and scheduled for orthopedic surgery under spinal anesthesia.

Exclusion criteria

Candidates were excluded if they had a history of seizure disorders, chronic severe headaches or migraines, known coagulopathies, signs of infection at the proposed puncture site, indications of increased intracranial pressure (ICP), space-occupying brain lesions, intraoperative bleeding exceeding 20% of total blood volume, or if they declined participation. Also, cases in which spinal anesthesia presented technical difficulties due to spinal abnormalities were grounds for exclusion.

Data collection tools and procedures

Data collection was facilitated through a researcher-developed checklist consisting of two principal sections:

Section A

Demographic Data: Captured variables such as patient age, gender, weight, height, and residential location.

Section B

Clinical Characteristics: Comprised seven items assessing variables including the number of dural punctures, heart rate, blood pressure (preoperatively and intraoperatively), and detailed headache characteristics (onset, severity, nature, duration, and associated symptoms). A specific scoring system was implemented to quantify responses within this section.

Intervention and randomization

Eligible participants were randomly divided into two equal groups

Group M (Midline): This group received a spinal block via the midline approach.

Group P (Paramedian): Participants in this group received a spinal block via the paramedian approach.

The random allocation sequence was generated using computer-generated random numbers. Allocation concealment was ensured by preparing sequentially numbered, sealed, opaque envelopes containing the group assignment (P or M). An independent researcher who was not involved in patient enrollment or the procedure prepared the envelopes. The enrolling anesthesiologist opened the envelope only after obtaining informed consent and immediately before the spinal block. Even-numbered codes were designated to Group A and odd-numbered codes to Group B, which were subsequently identified as Groups M and P, respectively. To ensure comparability between groups, matching was performed based on critical variables such as age and gender. The anesthesiologist performing the spinal block could not be blinded to the technique due to the visible differences in needle insertion point and angle. However, participants, outcome assessors (a neurologist who was unaware of group allocation), and data analysts were blinded to group assignment. A trained specialist conducted the spinal block for both groups using a 25-G Quincke spinal needle and administered a standardized mixture of 3 ml of bupivacaine. Thus, while the treating anesthesiologist was aware of the technique, all other parties remained blinded. Our study complies with CONSORT guidelines.

Diagnostic criteria for PDPH

Post-dural puncture headache was diagnosed according to the International Classification of Headache Disorders, 3rd edition (ICHD-3) criteria, which require: (a) headache developing within 5 days after a dural puncture, (b) worsening within 15 minutes after sitting or standing and improving within 15 minutes after lying down, and (c) at least one associated symptom (neck stiffness, tinnitus, hypacusis, photophobia, or nausea). The American Society of Anesthesiologists (ASA) 2021 definition (headache exacerbated by upright posture and relieved by recumbency) was also considered. These criteria were applied by a neurologist blinded to group assignment.

Data analysis

Data analysis was executed using SPSS software version 25. Descriptive statistics were utilized to summarize the dataset; continuous variables were expressed as means (±standard deviation), while categorical variables were conveyed as frequencies and percentages. Inferential analyses included independent T-tests or Mann-Whitney U tests for continuous variables, and Chi-square or Fisher's exact tests for categorical variables, facilitating comparisons of outcomes between the two groups. For the primary outcome (incidence of PDPH), we calculated the odds ratio (OR) with its 95% confidence interval (CI). A P of less than 0.05 was considered indicative of statistical significance.

Ethics approval and consent to participate

All participants were informed that studies involving human participants complied with the ethical standards of the Institutional Research Committee and the 1964

Declaration of Helsinki and its latest amendment. The University's Thesis Committee and the Vice Chancellery for Research and Technology Ethics Committee approved the study protocol. An official letter of introduction was secured from the Faculty of Medicine and presented to the hospital administration. Patient data confidentiality was rigorously maintained, and for post-discharge follow-up, verbal consent was implied through participants' responses to the telephone questionnaire. Also, informed consent was taken from people. Ongoing PDPH monitoring was conducted during hospitalization and thereafter. Ethical approval for this research has been secured from the ethics committee of Jiroft University of Medical Sciences, designated by the code IR.JMU.REC.1401.066.

Results

The current study is an interventional one examining 160 candidates for orthopedic surgery at Imam Khomeini Hospital in Jiroft in 2023 who underwent spinal anesthesia. Table 1 presents the demographic characteristics of the study participants. Notably, the highest frequency is observed in the age group of 10 to 19 years (23.75%), and 82.5% of the subjects were male (Table 1).

Comparison of headache duration and incidence in groups P and M showed that headache incidence was lower in group P and this difference was significant (P<0.001) (Table 2). The odds of developing PDPH in the midline group were 3.67 times that of the paramedian group (OR=3.67, 95% CI: 1.98-6.80, P<0.001).

During the hospitalization period, headache severity was evaluated in two groups. In Group P, 22 patients reported the onset of their headaches during this time. Among these, 13 patients (16.25% of the total group) classified their headaches as mild, while nine (11.25%) rated theirs as moderate. In Group M, 44 patients experienced headaches during hospitalization. Of these, 28 patients (35% of the total group) described their headaches as mild, 12 patients (15%) as moderate, and four patients (5%) as severe (Table 5).

The analysis of headache onset timing revealed a significant distinction between the two groups. In the Paramedian group (P), 13 patients (16.25%) reported the onset of headaches within the first 24 hours, while nine patients (11.25%) experienced onset within the first 48 hours, and three patients (3.75%) reported headaches after discharge. This resulted in 22 patients experiencing headache onset during their hospitalization. Conversely, the Midline group (M) exhibited a much higher and earlier incidence, with 32 patients (40%) reporting onset within the first 24 hours, nine patients (11.25%) within the first 48 hours, three patients (3.75%) after 48 hours but before discharge, and six patients (7.5%) after discharge. This brought the total to 44 patients whose headaches began during their hospital stay. This trend suggests that the Paramedian technique is linked to a delayed onset and a lower overall incidence of PDPH during the critical post-operative period (Table 6).

Table 1. Demographic information of patients undergoing orthopedic surgery at imam khomeini hospital, jiroft, 2023

Variable	Frequency	Percentage
Age (Years)		
10-19	38	23.75
20-29	36	22.5
30-39	32	20
40-49	23	14.37
50-59	16	10
60-69	11	6.875
>70	4	2.5
Gender		
Female	28	17.5
Male	132	82.5

Table 2. Headache duration and incidence by anesthetic technique

Headache duration (Days)	Group *P* (n=80)	Group M (n=80)
0	55(68.8%)	30(37.5%)
Headache Lasting 1-2 Days	17(21.3%)	21(26.3%)
Headache Lasting ≥3 Days	8(10.0%)	29(36.3%)
***P* (Incidence of any headache)**	<0.001	

* *P* from Chi-Square test comparing 'No Headache' vs. 'Any Headache'.

Table 3. Baseline body mass index (BMI) of study participants by group

BMI Category, n (%)	Group P (n=80)	Group M (n=80)	*P*
Underweight/Normal (<25.0 kg/m²)	59(73.8%)	53(66.3%)	0.094*
Overweight (25.0-29.9 kg/m²)	16(20.0%)	19(23.8%)	
Obese (≥30.0 kg/m²)	5(6.3%)	8(10.0%)	

* *P* derived from the Chi-Square test comparing the distribution of BMI categories between the groups.

Table 4. Nature and incidence of headache following spinal anesthesia by technique

Variable	Nature of Headache	Group P (n=80)	Group M (n=80)	*P*
Headache Incidence	No Headache	55(68.8%)	30(37.5%)	<0.001*
	Any Headache	25(31.3%)	50(62.5%)	
Nature of Headache (Among patients with headache)	Pulsating/Throbbing	5(20.0%)	7(14.0%)	0.221**
	Tension-type	13(52.0%)	28(56.0%)	
	Migrainous	7(28.0%)	15(30.0%)	
	Total with Headache	25(100%)	50(100%)	

* The *P* from the Chi-Square test compares the incidence of "No Headache" vs. "Any Headache" between groups.
** *P* from Chi-Square test comparing the distribution of headache nature among the 75 patients who experienced a headache.

Table 5. Headache Severity During Hospitalization by Anesthetic Technique

Headache Severity	Group P (n=80)	Group M (n=80)	*P*
No Headache	55(68.8%)	30(37.5%)	0.011
Mild	13(16.3%)	28(35.0%)	
Moderate	9(11.3%)	12(15.0%)	
Severe	0(0.0%)	4(5.0%)	

Data are presented as n (%). The *P* is derived from the Chi-Square test for independence, which compares the distribution of severity categories between groups.

Table 6. Comparison of headache incidence and timing by anesthetic technique

Variable	Category	Group P (n=80)	Group M (n=80)	*P*
Headache Incidence	No Headache	55(68.75%)	30(37.5%)	<0.001*
	Any Headache	25(31.25%)	50(62.5%)	
Timing of Onset (Among patients with headache)	Within the first 24 hours	13(52.0%)	32(64.0%)	0.027**
	Within the first 48 hours	9(36.0%)	9(18.0%)	
	After 48 hours (during hosp.)	0(0.0%)	3(6.0%)	
	After Discharge	3(12.0%)	6(12.0%)	
	Total with Headache	25(100%)	50(100%)	

* *P* from Chi-Square test comparing "No Headache" vs. "Any Headache".
** *P* from Chi-Square test comparing the distribution of timing categories (excluding the "No Headache" group).

Discussion

The findings of this study indicate that the paramedian approach to spinal anesthesia demonstrates a statistically significant advantage over the midline approach in terms of reducing the incidence, duration, and severity of PDPH among orthopedic patients. Specifically, 68.75% of patients in the paramedian group reported no headaches compared to only 37.5% in the midline group.

Furthermore, the mean duration of headaches was markedly shorter in the paramedian group (2.56 days) versus the midline group (5.34 days). These results align with previous studies that have suggested a correlation between the technique used for spinal anesthesia and the occurrence of PDPH (11,13).

In the study by Seyfi Kartal *et al*., 103 patients over 70 years of age who underwent urological and orthopedic surgery were examined, and the success rate in the paramedian approach was 90.5% and in the median approach was 79.1%. The duration of the operation in the paramedian approach was shorter than in the median approach, which compared to the present study, which was mostly under 50 years of age, the difference between the two groups in the Seyfi Kartal study was less, and it is likely that the effect of the two methods is not significant in patients over 70 years of age, but in patients under 50 years of age, according to the present results, the use of the paramedian approach is more effective and appropriate (14).

Implications for clinical practice

The clinical implications of these findings are significant. PDPH not only affects patient comfort but can also prolong hospital stays and complicate recovery. By adopting the paramedian technique more widely, anesthesiologists may be able to reduce the incidence of this complication, thereby improving postoperative outcomes and patient satisfaction. Furthermore, understanding the anatomical and technical considerations that make the paramedian approach effective can guide training and education for practitioners, enhancing the overall quality of care provided during orthopedic procedures. In the study by Alatni et al. regarding the posture of the patient and its consequences on the incidence of the headache, lateral decubitus is better than a sitting position, and a prone position is better than a supine position. Smaller non-cutting needles play a role in avoiding PDPH (15).

In their study, Patel *et al*., determined the overall incidence of PDPH after neuraxial procedures to be 6-36%. Mild PDPH focused on conservative treatments such as bed rest and oral caffeine, and the headache improved after one week (16). Factors such as the size and shape of the needle, the technique employed, and the bevel orientation and angle of needle insertion also influence the risk of developing this complication. Furthermore, the number of attempts made during dural puncture is another significant risk factor (16-18). To minimize the occurrence of PDPH and other complications, it is crucial to simplify the neuroaxial block technique using methods like ultrasonography. This approach is particularly beneficial in cases where anatomical landmarks are scarce, as it reduces the number of needle insertions and the duration of the spinal block procedure (19-21). A study involving 112 patients undergoing orthopedic surgery revealed a success rate of 58.9% for the first needle pass using the paramedian technique, in contrast to just 21.4% for the midline approach. Additionally, the paramedian method yielded a shorter average procedure time of 113 seconds, compared to 196 seconds for the midline technique (21).

Risk factors for PDPH

Rodriguez-Camacho *et al*., conducted a prospective descriptive study of 57 patients who underwent lumbar puncture, and found that the incidence of PDPH was 38.6%, with factors associated with onset including younger age and prior history of headaches. The study findings reinforce the need for anesthesiologists to remain vigilant regarding risk factors associated with PDPH. As documented in the literature, factors such as age, sex, and prior history of headaches can play a role in the likelihood of developing PDPH (22). The predominance of males in this study (82.5%) and the high incidence of PDPH in younger patients warrant further investigation into the biological and sociocultural factors that may contribute to these trends.

In the study by Jasem Al-Hashel *et al*., a total of 285 patients were enrolled; 225 were female (78.9%), mean age 11.7±32.9 years. Eighty-four patients (29.5%) reported PDPH, with a mean duration of 2.4±2.1 days. The most common headache type was vague pain in 49 patients (58.3%). Headache severity was mild to moderate in 64 patients (76.2%). Most headaches resolved with conservative medical management. There was an association between PDPH and younger age, female gender, lower BMI, previous headache, and number of LP anesthesia procedures. Of the patients, 32% in group P and 38% in group M reported headache, which was not significantly different. Therefore, the difference in results between the two studies is likely due to the lower mean age and higher percentage of men in the present study (23).

However, contrary to the results of our study, in the study of Islam, M. T. in Bangladesh (24), women aged 40 to 60 years showed a higher prevalence of headache after dural puncture. Also, higher number of puncture attempts, older age groups, female gender, large-bore needles, and dehydration were all significantly associated with PDPH. The larger sample size and different geographical area could be the reason for the difference

in the results of the two studies. But, in the study by Nasir *et al*., and Firdous *et al*., only 6% of the 100 patients studied reported postoperative headaches (25,26). However, according to research conducted by Kumari *et al.*, in 2021, there is no significant difference in the incidence of PDPH between the midline and paramedian techniques (27). The number of patients in the present study was greater than the number of samples in the study of Kumari et al., showing stronger results. The reason for the difference could be the greater number of patients in the present study than in the study of Kumari *et al.,*

However, the precise mechanisms remain unclear and may involve individual variations in CSF dynamics or pain perception. Future research could explore these aspects to better identify at-risk populations and develop targeted prevention strategies.

The paramedian technique is superior to the midline approach, significantly reducing the incidence, intensity, and duration of PDPH. Existing prophylactic treatments remain inadequate, highlighting the importance of the spinal anesthesia technique itself. Therefore, adopting the paramedian approach is recommended. This method lessens headache severity and duration, minimizing adverse effects on patients' functional capacity and quality of life. Ultimately, it contributes to enhanced patient satisfaction and reduces hospital resource burden.

Limitations

While the study provides valuable insights, it is essential to acknowledge its limitations. The sample size, although sufficient for preliminary findings, may not account for all demographic variations present in broader populations. Additionally, the single-center design may limit the generalizability of the findings. Future studies should aim for multicenter trials that include diverse patient populations to validate these results. Moreover, longer-term follow-up on patients experiencing PDPH would yield insights into the chronicity and management of this complication. Investigating adjunct therapies or prophylactic measures, such as hydration or the use of specific needle types, could also enhance the understanding of PDPH prevention.

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