

Preventing spinal anesthesia headache in cesarean section: Randomized clinical trial

 Zeinabosadat Fattahi Saravi,  Mohammad Hossein Pourjafarian,  Mahsa Banifatemi,  Reza Jouybar,  Mohammad Hossein Eghbal,  Naeimehossadat Asmarian

Anesthesiology and Critical Care Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

SUMMARY

Objectives: Post-dural puncture headache (PDPH) is a common complication following neuraxial block in cesarean sections, typically occurring 12–72 hours postoperatively and leading to considerable challenges and financial costs. We aimed to compare dexamethasone and paracetamol for preventing spinal anesthesia headaches in cesarean sections.

Methods: A double-blind randomized clinical trial was conducted from December 2019 to April 2020. This study included 215 singleton pregnant women scheduled for elective cesarean section. To prevent PDPH, the patients were allocated to intravenous dexamethasone (n=70), paracetamol (n=75), and normal saline (n=70) groups. The primary outcomes were the incidence and severity of PDPH and VAS score evaluations. Secondary outcomes included recovery time, frequency of painkiller use, newborn Apgar scores, and patient satisfaction.

Results: Significant time ($p<0.001$) and group ($p=0.020$) effects were observed on PDPH. At 48 hours postoperatively, patients receiving dexamethasone or paracetamol reported significantly lower PDPH severity compared to the normal saline group ($p=0.009$). The incidence of PDPH was also higher in the control group at 48 hours ($p=0.033$). No significant differences were observed among the groups in recovery time, analgesic use, Apgar scores at 1 and 5 minutes, or patient satisfaction ($p>0.05$).

Conclusion: Both paracetamol and dexamethasone had a positive impact on reducing the incidence and severity of PDPH compared to the normal saline group in cesarean sections (with dexamethasone showing a stronger effect). Recovery time, painkiller use, newborn Apgar scores, and patient satisfaction did not differ significantly between the groups. Further research is needed to validate these findings and ensure reproducibility.

Keywords: Cesarean section; dexamethasone; paracetamol; post-dural puncture headache; spinal anesthesia.

Introduction

Post-dural puncture headache (PDPH), or spinal headache, a common and severe complication of neuraxial block, results from dural rupture typically arising 12–72 hours post-operation^[1] and occurs in 0.5–1.6% of cesarean sections. PDPH significantly hinders maternal self-care and newborn care, imposing substantial financial burdens on healthcare systems and escalating obstetric and gynecological emergency visits.^[2–7] PDPH occurrence and severity are influenced by various factors, including BMI (body mass index), previous migraine history, needle-related factors (such as multiple attempts, tip designs, gauge,

and orientation), young age, obstetric conditions, needle type, gender, and spinal fluid leakage.^[3,8–11]

PDPH treatment focuses on symptom relief, as its main cause remains unclear. Empirical and ineffective interventions include hydration, acetaminophen, non-steroidal anti-inflammatory drugs, opioids, DDAVP (desmopressin acetate), caffeine, gabapentin, hydrocortisone, and theophylline.^[12,13] Prevention involves addressing predisposing factors, using proper needle size and type, and exploring supportive and pharmacological methods. However, no specific protocol or guidelines have been established.^[14]

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Correspondence: Dr. Reza Jouybar. Anesthesiology and Critical Care Research Center, Shiraz University of Medical Sciences, Shiraz, Iran.
Phone: +987136474270 **e-mail:** jouybar@gmail.com



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In a Swedish study, three needle types (22G atraumatic, 25G atraumatic, and 25G cutting) were used for spinal anesthesia. The 22G atraumatic needles had a lower incidence of PDPH compared to the other groups.^[14] Evidence for the effectiveness of complete bed rest and fluid therapy in preventing PDPH is inconclusive.^[15] In a 2020 study, intrathecal morphine prophylaxis did not significantly differ from intrathecal saline in terms of PDPH incidence and severity.^[16] Another study in pregnant women compared epidural saline, IV cosyntropin, and epidural morphine after unintentional dural puncture, showing reduced PDPH incidence in all intervention groups compared to the control.^[17] Administering dexamethasone 8 mg (2 ml) on the first and fourth postoperative days significantly reduced PDPH incidence and severity compared to the control group ($p=0.01$ and $p=0.001$, respectively).^[18]

In this double-blind, randomized controlled trial, we compared the analgesic effects of intravenous paracetamol and dexamethasone with a control group on PDPH incidence and severity. Our hypothesis is that paracetamol can effectively reduce PDPH occurrence and severity, as well as medication requirements for its management. Notably, intravenous administration of paracetamol during labor is safe and devoid of side effects.^[19]

Materials and Methods

A double-blind randomized clinical trial was conducted in accordance with the Declaration of Helsinki at Hafez Hospital affiliated with Shiraz University of Medical Sciences, from December 2019 to April 2020. This study included 219 singleton pregnant women with term pregnancies and ASA physical status classifications I and II, scheduled for elective cesarean section. The allocation ratio was one for three studied groups. The study received approval from the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.MED.REC.1396.130), with the IRCT code (IRCT20141009019470N80) (<https://www.irct.ir/trial/>), and informed consent was obtained from all participants.

Exclusion criteria included contraindications to spinal anesthesia, patient refusal, local infection at the lumbar region, use of antiplatelet and anticoagulant medications, known anesthesia sensitivity, comor-

bidities (diabetes, renal dysfunction [creatinine level >2], coagulation disorders, liver disease, heart disease, seizures, neurological disease), extreme blood pressure levels, intrauterine fetal growth retardation (IUGR), weight >100 kg, height <150 cm or >180 cm, pre-eclampsia, fetal anomalies, low hemoglobin levels (level <8 g/liter), history of post-cesarean migraine headaches, and more than three previous cesarean sections.

Patients received preoperative explanations about PDPH and its associated symptoms. They were informed that PDPH is a headache in the frontal or occipital area with a throbbing nature. It is usually accompanied by photophobia, blurred vision, double vision, decreased hearing with tinnitus, dizziness, nausea, and vomiting.^[12] To distinguish between PDPH and migraine headaches, patients were advised to observe how their headache responds to changes in position—PDPH is generally aggravated by an upright position and relieved by a decumbent posture.

After surgery, a nurse anesthetist who was not involved in the procedure documented the nature and severity of the patients' headaches using a VAS score.

Sample Size and Randomization

The sample size was determined based on a previous study conducted by Hamzai et al.^[20] Considering a 25% dropout rate and comparing the incidence of headache after spinal anesthesia between the sample and control groups during the first week, with proportions of $p_1=11.3\%$ and $p_2=32.5\%$ respectively, a sample size of 75 patients in each group was calculated to achieve 80% power with a 0.05 alpha error. To ensure randomization, eligible patients were divided into three groups (treatment and control) using the block randomization method. The randomization process was performed using 25 blocks, each consisting of 9 patients (www.sealedenvelope.com). A staff member with access to the randomization list prepared sealed envelopes containing the names of each group of patients. To maintain blinding throughout the study, other colleagues involved, such as anesthesiologists, surgeons, and data collection members, were unaware of the patient study groups and the block sizes.

Sampling

Participants' medical history was obtained, and clinical and airway examinations were conducted. They were positioned supine with a slight left tilt on the operating room bed. Oxygen was administered through a mask at 5 liters per minute. Patient monitoring included non-invasive blood pressure measurement, pulse oximetry, and electrocardiography. Intravenous access was established using an angiocath number 18, and hydration began with normal saline at 8 ml/kg.

Blinding Method

A nurse anesthetist, not involved in the study, prepared a blinded microset containing dexamethasone, paracetamol, or normal saline for injection during patient hydration. The administering researcher remained unaware of the medication's identity throughout the process.

Medications and Dosage

- Dexamethasone Group: Administered 8 mg of dexamethasone in 100 ml of normal saline over 15 minutes.
- Paracetamol Group: Administered 1000 mg of paracetamol in 100 ml of normal saline over 15 minutes.
- Control Group: Administered 100 ml of normal saline over 15 minutes.

Spinal anesthesia was administered in the sitting position using a 25-gauge needle at the L3-4 and L4-5 intervertebral spaces. An anesthesia assistant delivered 9 mg of Marcaine (bupivacaine) and 10 mg of pethidine in a total volume of 3 ml. After the procedure, patients were repositioned semi-laterally with left uterine displacement to prevent supine hypotension. Continuous monitoring of blood pressure, heart rate, arterial oxygen saturation, nausea, and vomiting was performed every two minutes for the initial 20 minutes and then every five minutes until discharge from the recovery room.

Measurement Tools and Indicators

Primary Outcome

Post-dural puncture headache (PDPH) severity was assessed using the Visual Analog Score (VAS) on a scale of 0–10. Evaluations were conducted 6, 12,

48, and 72 hours after anesthesia induction. A non-study nurse performed these assessments. PDPH pain intensity was measured using the VAS, ranging from 0 to 10 cm. A score of 0 indicated no pain, 1–3 represented mild headache, 4–7 indicated moderate headache, and a score >7 indicated severe headache.

Secondary Outcome

The secondary outcomes included the amount of pain relief patients required, newborn Apgar scores at 1 and 5 minutes, and patient satisfaction. Nurses not involved in the study were responsible for measuring these outcomes.

If a patient experienced bradycardia, itching, shivering, nausea, vomiting, or postoperative pain, specific steps were followed. Bradycardia (heart rate <44 beats per minute) was treated with atropine, starting with 0.6 mg and repeated every 3–5 minutes if needed, up to a maximum of 2 mg. If systolic blood pressure decreased by >20% from baseline or dropped <90 mmHg, 5 mg of intravenous ephedrine was administered. Persistent nausea and vomiting were treated with intravenous ondansetron at 0.15 mg/kg, while severe itching was managed with 25 mg of intravenous promethazine. Shivering was treated with 10 mg of intravenous pethidine. For postoperative surgical pain, patients initially received diclofenac suppositories, and if pain persisted, they were given 25 mg of intravenous pethidine. Patients experiencing PDPH with a score >3 were treated with rehydration, acetaminophen, NSAIDs, opioids, caffeine, sumatriptan, and epidural patches.

Statistical Analysis

Continuous variables were presented as mean ± standard deviation, while categorical variables were reported as numbers and percentages. Nonparametric variables were analyzed using the Kruskal-Wallis test with Dunn's post hoc test for group comparisons. For categorical data, the chi-squared test was applied to detect significant differences between groups. Repeated measures analysis was used to evaluate VAS scores over time within groups. Statistical analyses were performed using SPSS software (version 22, SPSS Inc., Chicago, IL) and GraphPad Prism 9. Results were considered statistically significant if $p < 0.05$. If needed, Bonferroni correction was applied to ensure accuracy of conclusions.

Results

From December 2019 to April 2020, a total of 240 patients were assessed. Nine did not meet the inclusion criteria, and six declined participation. As a result, 225 patients were randomized into three groups: dexamethasone ($n=75$), paracetamol ($n=75$), and normal saline ($n=75$). During follow-up, ten patients were excluded (five from the dexamethasone group and five from the normal saline group) due to loss to follow-up. Ultimately, 215 patients successfully completed the study (Fig. 1).

No significant differences were observed in demographic and baseline data, including age, BMI, MAP, heart rate, and recovery time, among the three groups (Table 1).

Pain levels (VAS scores) in patients experiencing PDPH after receiving dexamethasone, paracetamol, or normal saline are shown in Table 2. At 6 hours, participants in the normal saline group reported higher pain levels compared to those in the dexamethasone and paracetamol groups ($p=0.002$). This difference was likely related to general postoperative pain rather than PDPH, which usually develops 12–72 hours after lumbar puncture. Further analysis confirmed significant differences between the normal saline and paracetamol groups ($p=0.002$), as well as between the normal saline and dexamethasone groups ($p=0.038$). By 48 hours, patients in the normal saline group reported significantly higher pain scores compared to those in the dexamethasone and paracetamol groups ($p=0.009$). However, no significant differences were observed at 12 or 72 hours post-surgery.

Figure 2 illustrates changes in pain scores over time across the three groups. A significant time effect was observed ($p<0.001$), indicating that pain scores changed notably over time. However, the interaction between time and groups was not significant ($p=0.299$). Although the trend of VAS scores was similar across groups, the group effect was significant ($p=0.020$). Post hoc analysis revealed significant differences between the normal saline and dexamethasone groups ($p=0.006$).

Table 3 compares the incidence and severity of PDPH across the three groups from 6 to 72 hours

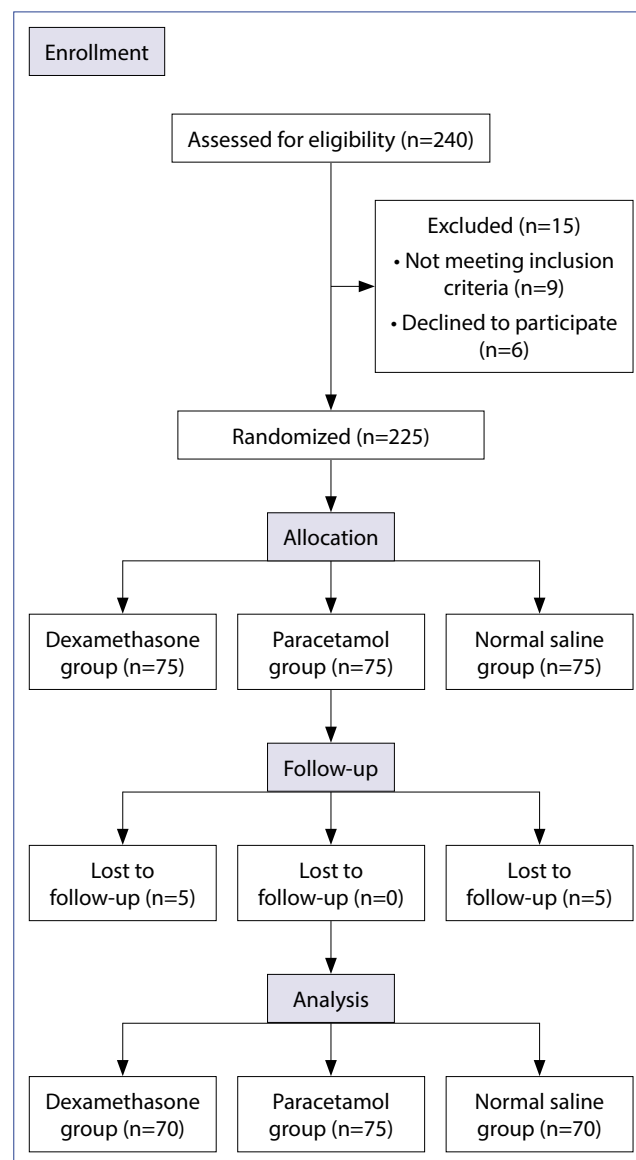


Figure 1. CONSORT flow diagram of the patient enrolment process.

after cesarean section. Significant differences were found at 6 hours ($p=0.003$) and 48 hours ($p=0.03$). At 6 hours, 69.3% of patients in the paracetamol group and 67.1% in the dexamethasone group reported moderate headaches, while 54.3% of patients in the normal saline group experienced severe headaches. This early difference was likely due to immediate post-procedural discomfort rather than PDPH. By 48 hours, 50% of patients in the dexamethasone group and 49.3% in the paracetamol group reported mild headaches, compared to 65.7% in the control group who experienced moderate headaches.

Table 4 presents recovery time (in hours), frequency of painkiller use, and Apgar scores at 1 and 5 minutes. Recovery time was similar across groups ($p=0.87$).

Table 1. Demographic and Baseline data of studied groups

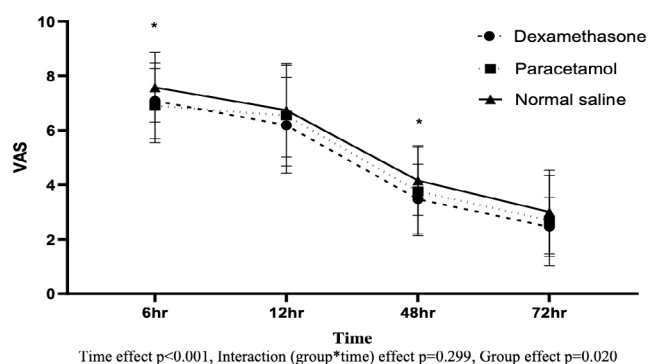
	Dexamethasone (n=70) Mean (SD)	Paracetamol (n=75) Mean (SD)	Normal saline (n=70) Mean (SD)	p
Age (year)	31.31±5.89	32.01±5.54	30.53±5.22	0.27
BMI (kg/m ²)	31.35±3.82	31.49±4.01	30.73±3.56	0.45
MAP	89.42±7.88	87.81±7.91	87.66±8.08	0.34
Heart rate	87.10±13.36	86.20±10.58	86.94±13.14	0.89

SD: Standard deviation; BMI: Body mass index.

Table 2. Comparing VAS score regarding PDPH in studied groups

	Dexamethasone (n=70) Mean (SD)	Paracetamol (n=75) Mean (SD)	Normal saline (n=70) Mean (SD)	p
VAS 6hr	7.09±0.16 ^N	6.91±0.15 ^N	7.58±0.15 ^{DP}	0.002*
VAS 12hr	6.19±0.20	6.55±0.21	6.74±0.21	0.154
VAS 48hr	3.47±0.15 ^N	3.76±0.18 ^N	4.16±0.15 ^{DP}	0.009*
Vas 72hr	2.46±0.13	2.69±0.19	3.00±0.18	0.110

VAS: Visual Analog Score; PDPH: Post-dural puncture headache; SD: Standard deviation. Based on the Bonferroni correction in comparing with a significant level of 0.012. VAS 6hr is significant: Dexamethasone and Normal Saline (p=0.038), Paracetamol and Normal Saline (p=0.002). VAS 48hr is significant: Dexamethasone and Normal Saline (p=0.012), Paracetamol and Normal Saline (p=0.048).

**Figure 2.** Change in pain over time in the three groups according to the Visual Analogue Scale (VAS).

*: Indicates a significant p-value.

Discussion

After spinal anesthesia, some individuals may experience a headache known as PDPH. This can be particularly challenging for women undergoing cesarean section. Although the reported incidence ranges from 0.5% to 1.6%, PDPH can significantly hinder maternal recovery, affect mother–infant bonding, and burden healthcare systems. The causes of PDPH are diverse, involving both patient- and procedure-related factors.

The pathophysiology of PDPH is multifactorial, with several patient-related and procedural factors implicated in its development and severity. These include BMI, migraine history, number of dural puncture attempts, needle gauge and tip design, patient age, obstetric comorbidities, and cerebrospinal fluid (CSF) leakage.^[3,8–11] Despite decades of research, the precise mechanism remains incompletely understood, and most clinical strategies remain symptomatic rather than preventive. While interventions such as bed rest, aggressive hydration, and needle modifications have been proposed to reduce PDPH risk, their effectiveness remains controversial.^[21–25]

No significant differences were observed among the groups in terms of recovery time, painkiller use, or Apgar scores (p>0.05).

Table 5 shows patient satisfaction levels. No statistically significant differences were found among the groups (p=0.08). Notably, 50% of patients in the dexamethasone group, 56% in the paracetamol group, and 34% in the normal saline group reported being completely satisfied.

Importantly, none of the groups experienced significant harm or adverse side effects from the medications.

Table 3. Comparing the incidence of PDPH and the severity in the studied groups

	Dexamethasone (n=70)	Paracetamol (n=75)	Normal saline (n=70)	p
	Frequency (percentage)	Frequency (percentage)	Frequency (percentage)	
6hr				0.003*
No headache	0 (0)	0 (0)	1 (1.4)	
Mild	0 (0)	0 (0)	1 (1.4)	
Moderate	47 (67.1)	52 (69.3)	30 (42.9)	
Severe	23 (32.9)	23 (30.7)	38 (54.3)	
12hr				0.428
No headache	0 (0)	0 (0)	1 (1.4)	
Mild	2 (2.9)	4 (5.3)	1 (1.4)	
Moderate	53 (75.7)	49 (65.3)	46 (65.7)	
Severe	15 (21.4)	22 (29.3)	22 (31.4)	
48hr				0.033*
No headache	2 (2.9)	1 (1.3)	1 (1.4)	
Mild	35 (50)	37 (49.3)	21 (30)	
Moderate	33 (47.1)	35 (46.7)	48 (68.6)	
Severe	0 (0)	2 (2.7)	0 (0)	
72hr				0.687
No headache	3 (4.3)	4 (5.3)	3 (4.3)	
Mild	56 (80)	53 (70.7)	49 (70)	
Moderate	11 (15.7)	17 (22.7)	18 (25.7)	
Severe	0 (0)	1 (1.3)	0 (0)	

*: Indicates a significant p-value.

Table 4. Comparing clinical variables during the study between three groups

	Dexamethasone (n=70)	Paracetamol (n=75)	Normal saline (n=70)	p
Recovery time (hr.)	1.22±0.32	1.25±0.36	1.22±0.36	0.87
Painkiller use	49 (33.1)	50 (33.8)	49 (33.1)	0.41
Apgar 1	9±0.00	8.95±0.36	8.96±0.20	0.38
Apgar 5	9.95±.20	9.96±0.20	9.94±0.23	0.87

Values indicate Mean±SD or number (percentage). SD: Standard deviation.

In this study, the primary outcome revealed significant differences in headache intensity between groups at 6 and 48 hours postoperatively. The higher pain scores observed in the normal saline group at 6 hours may reflect surgical discomfort rather than true PDPH, which typically appears 12–72 hours after dural puncture. By 48 hours—generally the peak period for PDPH—patients in the dexamethasone and paracetamol groups demonstrated significantly lower pain scores compared to placebo. These results high-

light the potential of these agents in reducing PDPH during the critical 24–72-hour postoperative window.

Dexamethasone proved to be the most effective, particularly in reducing moderate to severe PDPH, consistent with previous studies pointing to its anti-inflammatory and membrane-stabilizing properties.^[18,26,27] Paracetamol also significantly reduced PDPH severity, though its effect was slightly less pronounced than dexamethasone, consistent with its

Table 5. Patient satisfaction

	Dexamethasone (n=70) n (%)	Paracetamol (n=75) n (%)	Normal saline (n=70) n (%)	p
Completely satisfied	35 (50)	42 (56)	24 (34.2)	0.08
Satisfied	7 (10)	10 (13.4)	7 (10)	
Neutral	9 (12.9)	9 (12)	15 (21.4)	
Unsatisfied	6 (8.6)	3 (4)	12 (17.2)	
Completely unsatisfied	13 (18.5)	11 (14.6)	12 (17.2)	

known analgesic mechanism through central COX inhibition and serotonergic modulation.^[19] In contrast, patients in the placebo group experienced the most pronounced and persistent symptoms.

The literature on pharmacologic PDPH prophylaxis remains mixed. While some studies support the benefit of corticosteroids and acetaminophen in reducing PDPH incidence,^[27,28] others, such as Yang et al.,^[29] have reported contradictory findings, even suggesting a potential increase in PDPH with dexamethasone. In line with our results, Yousefshahi et al.^[26] conducted a study on 372 women and found that the overall incidence rate of PDPH was 10.8%, with 28 cases from the dexamethasone group compared with 11 subjects from the placebo group ($p=0.006$). Similarly, Khraise et al.^[22] reported a lower incidence of PDPH in the dexamethasone group compared to the control group. On the other hand, Yang and colleagues found that dexamethasone as a preventive measure did not reduce PDPH. In fact, it might have led to more cases of PDPH occurring within the first 24 hours after spinal anesthesia.^[29] These discrepancies may be due to differences in study design, patient populations, timing and method of drug administration, and outcome measurement criteria.

No adverse effects were observed with either dexamethasone or paracetamol in our study, underscoring their safety for women undergoing cesarean section. Other factors such as recovery time, need for additional analgesia, newborn Apgar scores, and patient satisfaction did not significantly differ among the groups. However, patients in the treatment groups tended to be more satisfied, particularly those in the paracetamol group, which had the highest number of “completely satisfied” individuals. Postoperative pain management may have contributed to this

sense of satisfaction. Analgesics can influence the incidence of PDPH as well as patients’ perceptions of headache type. Since analgesic use was distributed evenly across all three groups (approximately 33%), the comparison of PDPH rates remains valid.

It is noteworthy that few studies have directly compared dexamethasone and paracetamol in preventing PDPH. Our findings indicate that both medications are beneficial, with dexamethasone appearing more effective. However, the lack of significant differences in other outcomes highlights the complexity of PDPH prevention and the need for multimodal strategies.

Overall, our study contributes to the growing evidence that prophylactic administration of dexamethasone or paracetamol may reduce the severity of PDPH. Nonetheless, these results require confirmation in larger, multicenter studies with longer follow-up and more diverse patient populations.

Conclusion

In this study, both intravenous dexamethasone and paracetamol significantly reduced the incidence and severity of headaches following spinal anesthesia during cesarean sections. Dexamethasone was particularly effective in lessening moderate to severe headaches within the first 24–48 hours after surgery, while paracetamol also provided protection with minimal risk. Although no significant differences were observed in recovery time, analgesic use, newborn health, or patient satisfaction, the reduction in headache severity suggests that these medications may be beneficial in preventing PDPH. Given the multifactorial causes of PDPH and the variability of results across studies, larger multicenter trials are needed to confirm these findings, refine treatment strategies, and establish specific guidelines for PDPH prevention in obstetric anesthesia.

Ethics Committee Approval: The Shiraz University of Medical Sciences Ethics Committee granted approval for this study (date: 08.04.2018, number: IR.SUMS.MED.REC.1396.130).

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Conflict of Interest: None declared.

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