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ORIGINAL RESEARCH ARTICLE

The Effect of Intrathecal Fentanyl on Postdural Puncture Headache in Parturients Undergoing Cesarean Section: Prospective Double-Blinded Study

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ABSTRACT

Introduction: Post-dural puncture headache (PDPH) is one of the most common side effects of spinal anesthesia, particularly in parturients undergoing cesarean section. Intrathecal fentanyl, often administered as an adjunct to local anaesthetic, has been proposed as a potential mitigating agent for PDPH. However, the evidence regarding its efficacy remains inconclusive. The purpose of this study is to evaluate the effect of intrathecal fentanyl on the incidence and severity of PDPH in parturients undergoing cesarean section.

Material and Methods: About 124 patients were randomly allocated using a simple randomization technique into 2 groups, with 62 patients in each group. Group A – 2.5 mL 0.5% Bupivacaine + 0.5 mL NS, Group B –2.5 mL 0.5% Bupivacaine + 0.5 mL fentanyl (25 mcg). Categorical variables are presented as absolute numbers and percentages. The software used for the statistical analysis was SPSS v21.0 (IBM, USA).

Results: The parturient was monitored for post-dural puncture headache PDPH during the post-operative period until discharge. Patients were questioned about the onset, duration, and severity of headache. Severity was evaluated using the visual analogue scale. There was no significant difference in the incidence of PDPH. There was a significant difference in severity between the two groups. More hypotension was seen in group A compare to group B.

Conclusion: We concluded that the women who were impacted by the addition of IT fentanyl to bupivacaine for spinal anesthesis (SA) in obstetric patients reported better postpartum recovery and a reduction in the intensity and duration of their headaches, improved hemodynamic stability, and lengthened the period of post-operative analgesia. Further well-designed RCTs with larger sample sizes are warranted to confirm these findings and elucidate optimal dosing strategies for intrathecal fentanyl in this population.

Keywords: Intrathecal fentanyl, Post dural puncture headache, Cesarean section, Parturients, Spinal anesthesia, Double-blinded study.

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INTRODUCTION

The development of appropriate patient selection and treatment is necessary to assist in avoiding common problems that arise from neuraxial anesthesia. Common complications include back discomfort, PDPH, low-frequency hearing loss, hypotension, nausea, vomiting, neurological impairment, spinal hematoma, arachnoiditis, and total spinal anesthesia (the most feared)[1] Because SA has advantages over general anesthesia (GA) or epidural anaesthesia, it is the recommended method of anaesthesia for cesarean section CS. It results in total muscle relaxation and a quick onset of anaesthesia. It is also reasonably priced and easy to use. On the other hand, it can have unforeseen repercussions.

PDPH can be caused by a variety of procedures, including dural puncture during an LP, diagnostic myelography, subarachnoid (spinal) block, or an unintentional dural puncture from an epidural anaesthetic or pain injection. Pregnancy, low body mass index, dehydration, systemic disease, and a history of headaches are risk factors for PDPH." It is less prevalent in elderly adults, presumably as a result of brain shrinkage, and more common in younger women (20–40 years old).[2] Other risk factors include the type of needle used and how it is applied, particularly if it is inserted or rotated perpendicular to the long axis of the dural fibres. Risk is decreased by re-insertion of the stylet and by using a tiny-calibre pencil-tipped needle.

We hypothesized that the addition of intrathecal fentanyl to local anesthetics may reduce the incidence, severity, and/or duration of PDPH in patients undergoing CS under SA. Therefore, it can be a cost-effective alternative to the expensive pencil-point needles in case of limited resources. The present study aimed to evaluate the effect of intrathecal fentanyl on PDPH in parturients undergoing cesarean section.

MATERIAL AND METHODS

The present study was conducted in the Department of Anaesthesia, Critical Care and Pain Medicine at SRMS Institute of Medical Sciences, Bareilly, from 1st August 2022 to 31st January 2024 on the effect of intrathecal fentanyl on postural puncture headache in parturients undergoing cesarean section after obtaining approval from the institutional ethics committee.

Criteria For Inclusion

- Admitted to SRMS between the ages of 18 and 40 for an elective CS.
- ASA Class II
- The surgery takes no more than two hours.

Criteria For Exclusion

- Patient declines to participate.
- Coagulation disorder.
- Age range: under 18 to beyond 40.
- ASA classifications III and IV
- Surgery took longer than two hours.
- Anomalies related to the heart, concomitant conditions such as HTN, DM, CAD, and morbid obesity
- Pre-existing brain impairment,
- skin infection at the point of entrance,
- Hypersensitivity to the medication under trial.
- Cases where GA conversion was required intraoperatively

Data Analysis

The study involved the systematic collection and documentation of a widen range of parameters, including demographic data, clinical history, investigations, intra- and post-operative vitals, and vas score.

The collected data was entered into Microsoft Excel to create an organized and structured database for additional study. To guarantee that every data point was correct prior to entry, stringent quality controls were used. Every data point is presented as a quantitative variable, denoted by either mean ± SD or median (interquartile range). The parameters between the two groups have been compared using the "T" test and the Kruskal-Wallis Chi-square test. For attribute independence, the chi-square test was also applied.

For categorical variables, percentages and frequencies were used as expressions. A statistically significant P value was defined as less than 0.05.

Proforma data was collected, placed into a Microsoft Excel 2019 workbook, and exported for statistical analysis into IBM's SPSS v21.0 (USA). With its extensive suite of analytical tools, SPSS offered a strong basis for in-depth statistical analysis.

RESULTS

Table 1 shows the comparison of the heart rate of two groups intraoperatively. The study's baseline parameters were similar for each group, and we found that group A's baseline HR did not differ substantially from group B's baseline HR (>0.05). In the first several minutes, there was a noticeable difference in both groups' HR. Comparably to group B, there was more tachycardia in group A.

Table 2 signifies that SBP comparison between the two groups intraoperative; The baseline parameters in this study were similar for both groups, and we found that "there was no significant difference in baseline SBP between group A and group B (>0.05). SBP decreased in the first few minutes" and this difference was substantial for both groups.

Table 3 reveals the comparison of DBP of two groups intra-operative; As the study's baseline characteristics were similar for each group, we saw that group A's baseline DBP did not differ substantially from group B's baseline, DBP at 60 minutes or 12 hours (>0.05). DBP decreased in the first few minutes, and it differed considerably between the two groups.

Table 4 shows the incidence of PDPH of both groups; Between the groups in this study, there was a 0.093 difference in the incidence of PDPH, with 30.64% in group A and 17.74% in group B.

Table 5 shows the onset of PDPH of both groups; The results of this study showed that the groups' beginning of PDPH was positively correlated (p =0.965). Table 6 shows the severity of PDPH between the two groups. In this investigation, 11.29% of patients in group B had mild PDPH, 4.84% had moderate PDPH, and 1.61% had severe PDPH. In group A, 3.23% of patients had mild PDPH, 8.06% had moderate PDPH, and 19.35% had severe PDPH.

Accompanying symptoms between both groups; The study found in group A, neck stiffness was the most common side effect, followed by photophobia, vomiting, nausea, and vertigo; in group B, vomiting, nausea, and photophobia were the most common side effects, followed by neck stiffness (Table 7).

DISCUSSION

"SA is the recommended anesthetic technique for CS due to its advantages over epidural or GA." It causes complete muscle relaxation and a rapid onset of anesthesia. It is also reasonably priced and simple to administer. On the other hand, it can have unforeseen repercussions. Parturients frequently encounter PDPH following childbirth.[3]"While PDPH is not a life-threatening condition, it can significantly limit daily activities." Moreover, in extreme situations, it can cause disastrous aftereffects such as convulsions and subdural hematomas. When

Table 1: Comparison of heart rate of two groups intra-operative

Heart rate	Group		p-value
	A	B	
Baseline	92.72 ± 19.39	95.06 ± 18.09	0.485
5 Minutes	110.17 ± 18.31	98.08 ± 18.17	<0.0001
10 Minutes	120.30 ± 19.71	100.90 ± 19.46	<0.0001
15 Minutes	126.64 ± 17.98	88.58 ± 18.08	<0.0001
20 Minutes	118.82 ± 14.48	78.46 ± 14.82	<0.0001
30 Minutes	108.48 ± 12.09	82.46 ± 12.16	<0.0001
60 Minutes	95.54 ± 10.57	80.95 ± 10.73	<0.0001
90 Minutes	92.19 ± 9.90	80.58 ± 10.06	<0.0001
120 Minutes	90.80 ± 8.70	75.82 ± 8.86	<0.0001
4 Hours	98.14 ± 9.42	75.19 ± 10.27	<0.0001
8 Hours	93.61 ± 8.41	74.85 ± 8.94	<0.0001
12 Hours	100.90 ± 7.89	80.72 ± 8.05	<0.0001
18 Hours	90.56 ± 6.97	71.17 ± 6.71	<0.0001
24 Hours	88.43 ± 7.79	74.75 ± 7.77	<0.0001

Test used T- test

Table 2: SBP comparison between the two groups intraoperative.

SBP	Group		p-value
	A	B	
Baseline	121.61 ± 18.18	125.30 ± 18.05	0.259
5 Minutes	70.70 ± 14.14	98.67 ± 13.73	<0.0001
10 Minutes	80.16 ± 14.06	110.98 ± 13.43	<0.0001
15 Minutes	106.83 ± 12.32	116.45 ± 12.47	<0.0001
20 Minutes	120.69 ± 8.13	118.13 ± 8.16	<0.0001
30 Minutes	111.1 ± 10.03	127.76 ± 10.10	<0.0001
60 Minutes	110.35 ± 8.44	128.65 ± 8.73	<0.0001
90 Minutes	98.17 ± 9.79	127.14 ± 10.57	<0.0001
120 Minutes	121.32 ± 8.15	128.74 ± 8.48	<0.0001
4 Hours	100.70 ± 8.04	127.41 ± 8.19	<0.0001
8 Hours	123.40 ± 7.76	128.04 ± 7.45	0.0009
12 Hours	100.08 ± 7.82	129.40 ± 7.53	<0.0001
18 Hours	110.37 ± 7.71	126.88 ± 7.59	<0.0001
24 Hours	120.61 ± 7.39	130.29 ± 7.52	<0.0001

Test used T- test"

Table 3: Comparison of DBP of two groups intra operative.

DBP	Group		p-value
	A	B	
Baseline	74.95 ± 10.76	76.48 ± 10.40	0.422
5 Minutes	40.62 ± 11.76	68.22 ± 11.28	<0.0001
10 Minutes	48.41 ± 11.92	67.58 ± 11.91	<0.0001
15 Minutes	66.62 ± 9.84	76.75 ± 9.86	<0.0001
20 Minutes	78.61 ± 8.64	74.56 ± 8.72	<0.0001
30 Minutes	70.25 ± 9.35	76.88 ± 8.75	<0.0001
60 Minutes	69.38 ± 7.59	68.87 ± 8.67	0.728
90 Minutes	64.20 ± 9.50	80.67 ± 10.59	<0.0001
120 Minutes	62.27 ± 10.16	72.90 ± 10.55	<0.0001
4 Hours	72.37 ± 10.53	67.56 ± 10.65	0.007
8 Hours	82.59 ± 10.21	77.78 ± 10.33	<0.0001
12 Hours	74.91 ± 10.15	72.43 ± 10.78	0.189
18 Hours	66.50 ± 10.28	70.37 ± 10.73	<0.0001
24 Hours	78.40 ± 9.94	74.23 ± 9.61	0.019

"Test used T- test"

Table 4: Incidence of PDPH of both groups

Incidence of PDPH	Group			p-value
	A	B	Total	
Yes	19 (30.6%)	11 (17.7%)	30	0.093
No	43 (69.3%)	51 (82.2%)	94	
Total	62	62	124	

"Test used Chi square test"

Table 5: Onset of PDPH of both groups

PDPH	Group			p-value
	A (n = 19)	B (n = 11)	Total	
At day 1	10 (52.6%)	6 (54.5%)	16	0.919
At day 2	6 (31.5%)	3 (27.2%)	9	
At day 3	3 (15.7%)	2 (18.18%)	5	
Total	19	11	30	

"Test used Chi square test"

CSF pressure is consistently low, traction and subdural blood vessel rupture can result, potentially leading to a subdural hematoma.[5] Therefore, it is imperative to give priority to preventing it through the optimization of controllable parameters such as the anesthetic procedure, the number of tries at dural puncture, needle size, and needle tip design.[4]

Pencil-point needles have a narrower gauge than cutting-point needles, and clinical studies show that using them reduces the risk of PDPH.[5] However, because pencil-point needles are expensive and hard to come by, especially in low-income countries, their regular usage in parturients presents challenges. Patients treated with neuraxial narcotics have been found to have a decreased incidence of ADP under epidural anesthesia.[5,6] Furthermore, Martlew found that spinal opioids could be able to stop PDPH in a nine-year prospective audit.[7]

"PDPH is one of the most painful side effects of neuraxial anesthesia. Extensive use of neuraxial anesthesia is linked to an increased risk of PDPH. Additionally, pregnant women, young women, and females sex are considered to be unchangeable risk factors for PDPH.[8] The cause of PDPH is intentional dural puncture or ADP under neuraxial anesthesia. Neuraxial narcotics have been shown to lower the incidence of ADP during epidural anesthesia and PDPH following SA.[9] The current study was intended to assess the impact of IT fentanyl on PDPH in parturients undergoing CS labor.

Table 6: Severity of PDPH between both groups

Severity of PDPH	Group			p-value
	A	B	Total	
No	43 (69.3%)	51 (82.2%)	94	0.002
Mild	2 (3.23%)	7 (11.29%)	9	
Moderate	5 (8.06%)	3 (4.84%)	8	
Severe	12 (19.35%)	1 (1.61%)	13	
Total	62	62	124	

"Test used Chi square test"

Table 7: Accompanying symptoms between both groups

Side effects	Group			P Value
	A	B	Total	
No	51 (82.26%)	57 (91.93%)	108	0.472
Photophobia	3 (4.84%)	2 (3.22%)	5	
Nausea and vomiting	1 (1.61%)	2 (3.22%)	3	
Neck Stiffness	6 (9.68%)	1 (1.61%)	7	
Vertigo	1 (1.61%)	0 (0%)	1	
Total	62	62	124	

"Test used Chi square test"

With a *p-value* > 0.05(0.950)"the age distribution in our study is statistically insignificant and comparable in both groups. Additionally, there was no discernible difference in the groups' mean ages (26.58 ± 3.43 *vs.* 27.08 ± 3.15; p = 0.400)." The weight distribution in both groups remained similar in our study, and there was no discernible difference in weight between the groups (60.39 ± 9.84 *vs.* 60.57 ± 10.50; p = 0.924). By Ali *et al.*. "the age, weight, height, body mass index (BMI), ASA grade, and SA method (midline vs. paramedian) were similar for both groups. The number of tries required for successful LP did not significantly differ between the two groups."[11] By Lalwani *et al.*, two groups' demographic characteristics—mean age, height, weight, and BMI—were similar.[10]

The study found a "significant difference in the mean duration of anesthesia between the groups (2.25 ± 0.12 hours *vs.* 4.29 ± 0.13 hours; p =<0.0001). Compared to group A, group B experienced effective analgesia for a longer period of time" The length of surgery for groups A and B did not significantly differ from one another in our study (1.64 ± 0.33 *vs.* 1.66 ± 0.34 hours; p = 0.803). By Ali *et al.*, "when comparing the BF group to the B0 group, surgical anesthesia significantly improved (p < 0.01). In comparison to group B0, the BF group experienced effective analgesia for a longer period of time (p < 0.001)"[11]

The baseline characteristics in our study were similar for both groups, and we found that "there was no significant difference in baseline HR between group A and group B (>0.05)" In the first several minutes, there was a noticeable difference in both groups' HR. Comparably to group B, there was more tachycardia in group A. The baseline parameters in our study were similar for both groups, and we found that there was no significant difference in baseline SBP between group A and group B (>0.05)" SBP decreased in the first few minutes, with a significant difference between the two groups. The baseline parameters in our study were similar for both groups, and we found that there was no significant difference in baseline DBP between groups A and B at 60 minutes or 12 hours (>0.05). DBP decreased in the first few minutes, with a significant difference between the two groups. The MAP time intervals in this study were comparable between the groups, and we found that there was no significant difference (>0.05) between group A and group B for the baseline, 60 minutes, 12 hours, 18 hours, and 24 hours MAP."

By Ali *et al.*, three hemodynamic parameters—HR, SBP, and DBP—had baseline values that were comparable among the groups. After five minutes of anesthetic induction, HR values in all groups rose noticeably above baseline levels Both groups' SBP and DBP significantly decreased from their baseline readings two minutes after induction. There were never any noticeable differences in SpO2 across groups or within a single group during the treatment. No parturient in either group experienced respiratory depression[11]

Ebrie *et al.*, Both the diastolic and systolic blood pressure in the standard dose bupivacaine groups, with and without the addition of fentanyl, decreased significantly (p < 0.05) in the first half hour after SA compared to the low dose bupivacaine with fentanyl group. The first ten to fifteen minutes were when the SBP dropped the most in all three groups. There is no statistically significant difference in systolic blood pressure between the CBF and CB groups at any time interval, as shown by the *p-value* > 0.05.[12]

The incidence of PDPH in our study was 17.74% in group B compared to 30.64% in group A. Between the groups, there was no discernible difference in the incidence of PDPH (0.093). The start of PDPH in each group showed a positive connection (p = 0.965) in our study. The results of this study showed that the groups' beginning of PDPH was positively correlated (p = 0.965). According to our research, 11.29% of patients in group B had mild PDPH, 4.84% had moderate PDPH, and 1.61% had severe PDPH. In group A, 3.23% of patients had mild PDPH, 8.06% had moderate PDPH, and 19.35% had severe PDPH. The study found that in group A, neck stiffness was the most common side effect, followed by photophobia, vomiting, nausea, and vertigo; in group B, vomiting, nausea, and photophobia were the most common side effects, followed by neck stiffness. Lalwani

et al., when compared to the control group, the fentanyl group had less severe headaches and a lower VAS for PDPH pain intensity.[86] Elevated VAS scores indicate a noteworthy distinction in the severity of PDPH between the opioid and control cohorts.[13,4]

By Lalwani *et al*., there was no statistically significant difference in the incidence of backache, nausea, vomiting, vertigo, or pruritis between the groups, and neither group exhibited any additional symptoms. Combining fentanyl with an LA prevents nausea and vomiting while also eliminating visceral pain.[14] When fentanyl is used instead of morphine, there is a lower incidence of nausea and vomiting. However, when combined with epidural analgesia, neuraxial opioids do not appear to have a protective effect against post-ADP PDPH, according to other studies.[15]

Brinser *et al*.[16] looked over old medical records. Furthermore, "there was a significant difference in the mode of birth between the two groups (i.e., 50% of vaginal deliveries occurred in the group that received morphine, compared to 2% in the group that did not get morphine), despite the sample size being restricted. Pressing during the second stage after a dural puncture was an additional risk factor for PDPH in comparison to those with CS.[17]

CONCLUSION

We concluded that greater postpartum recovery and a decrease in the severity and duration of headaches were reported by the women who were affected by "the addition of IT fentanyl to bupivacaine for SA in obstetric patients."

"Fentanyl and bupivacaine together reduce nausea, increase hemodynamic stability, and prolong the duration of post-operative analgesia while eliminating visceral pain; bradycardia, nausea, vomiting, shivering, or mother or baby breathing remain unaffected. Because fentanyl not only provides positive effects but also delays the negative effects and lowers bupivacaine dosages, the combined effect of fentanyl and bupivacaine is therefore superior to bupivacaine alone."

At our facility, group A had a 30.6% incidence of PDPH in the obstetric population, while group B had a 17.7% incidence. It's significantly less than what obstetric centers report. For this population, drug-based treatment provides an efficient means of controlling PDPH.

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