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Efficacy of Sphenopalatine Block in Patients with Post-Dural Puncture Headache after Cesarean Section

Iram Shahzadi[1]*, Mohammad Saleem[2], Misal Khan[3], Seemab Zafar[1]

[1]Azad Jammu and Kashmir Medical College, Muzaffarabad, Pakistan
[2]Abbottabad International Medical College, Abbottabad, Pakistan
[3]Saidu Group of Teaching Hospital, Swat, Pakistan

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Abstract

Our study emphasised the efficacy of sphenopalatine ganglion block (SPGB) in patients with post-dural puncture headache (PDPH) after cesarean section. In this clinical experiment, the effectiveness of the SPGB in treating PDPH in pregnant women was examined. 40 individuals with PDPH were randomly divided into two equal groups for a prospective randomised clinical trial. The group receiving paracetamol (PG) for one day, the patients take 1 gram of paracetamol intravenously three times daily. Rescue analgesia in intravenous ketorolac is administered if sufficient pain relief cannot be found. Block group (SPGBG): Each nostril of the patients received a 3 ml dose of a lignocaine and dexamethasone mixture during bilateral SPGB. Recordings were made of the heart rate, arterial pressure, and mean pain score. Additionally noted were the initiation and end of the analgesic effect, any adverse effects, the amount of ketorolac used, patient satisfaction, and whether the patient stayed in the hospital for an EBP (epidural blood patch) or was discharged after 24 hours. The block group's pain perception (measured by a numeric rating scale [NRS]) was usually less during the research, with only a significant difference until the first two hours following the block when analgesia began more quickly and lasted longer. The hospital stay of the block group for EBP was substantially shorter and had higher patient satisfaction than the control group, which also had a much lower overall dose of the rescue analgesic in milligrams. Trans-nasal SPGB is a non-invasive, safe, simple, and effective treatment for post-dural puncture headache (PDPH) with a low complication rate.

Keywords Efficacy, Headache, Post-Dural Puncture Headache, Sphenopalatine Ganglion Block, Cesarean Section.

1. Introduction

The dural puncture has a strikingly greater severity and incidence of PDPH in the obstetric population than in other patient categories (1, 2). Pregnancy, young age, and gender have historically been seen as key risk factors for PDPH, even though there is an identical prevalence of headache following spinal anesthesia in both populations, ranging from 0.1 up to 36 percent depending on the gauge and type of needle utilized (3). It frequently exhausts the mother and makes it difficult for her to care for the new born. This results in prolonged hospital stays, increased healthcare costs, and frequent emergency room visits to assess and treat headaches (4). Additionally, a tiny study revealed that people with PDPH had a considerably higher risk of developing chronic headaches (5).

It is challenging to control PDPH, and conventional treatments like bed rest, painkillers, water, and caffeine alone are insufficient (6). However, EBP is regarded as the gold standard treatment for PDPH (7). Because of its invasiveness, it might cause significant side effects such as infection, hemorrhage, and neurological injury. It might make multiple dural punctures more likely (8). Adrenocorticotropic hormone (ACTH) is a natural hormone that increases aldosterone secretion from the adrenal cortex. Cosyntropin is an artificial version of this hormone

Corresponding author at: Iram Shehzadi
Email address: iramshehzadi.ajkmc@gmail.com

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(9). Through the active movement of the sodium ions, it might boost CSF synthesis. Additionally, there is a rise in β-endorphin, which could lessen pain perception (10). The medicine (CORTROSYN®) may be excreted in human milk; however, this is unknown. So, if cosyntropin for the injection is administered to the nursing mother, care must be exercised.

In 1908, Sluder first introduced the non-invasive topical trans-nasal SPGB procedure (8). Since then, it has been successfully utilised to treat various headache types, including cluster headaches, chronic migraine, postoperative analgesia, and refractory trigeminal neuralgia for endoscopic sinus surgery (11). The stimulation of the trigeminovascular system, results in inflammatory alterations in pain-sensitive.

2. Methodology

This study occurred at Sheikh Khalifa bin Ziad Hospital Muzaffarabad AJK and was a prospective, randomised, parallel-group clinical trial.

Prior to enrolment, each patient signed a written informed consent. The utilization of the NRS (numeric rating scale), which ranges from 0-10 and assigns a score based on the intensity of pain, was explained to the patients.

A researcher used a number table (computer-generated) containing numbers randomly placed in a sealed envelope to conduct simple randomization (SNOSE). Patients were evaluated for eligibility by a different researcher (not engaged in sequence generation or allocation concealment), who then assigned those who met the criteria to one group under study. The assigned treatment was recorded on a label or card and placed in numbered dense envelopes. Just before giving out the medication, these envelopes were unsealed.

The PASS 11th release programme computed sample size with power set to 90% and alpha error set to 5%. An earlier study showed that the mean pain score in two hours in group B cases was 1.7±2.3, while it was 4.1±1.4 in group A cases. Based on these findings, a sample size of 20 participating patients in each group will be required, allowing for a 20% dropout rate.

Patients refusing to participate in the study, those having a BMI greater than 35 kg/m^2 and an ASA greater than II, those with migraine or chronic headache, those carrying the known co-agulopathy, those having nasal-septal deviation, polyps, histories of nasal bleeding, and those with allergies to the local anesthetics were all excluded from the study.

We included the 40 post-C-section patients with active PDPH in the 7 days of the subarachnoid block who underwent spinal anesthesia with a 25-G spinal needle, the ASA II or I status, a BMI less than 35 kg/m^2, and who were not eased (NRS greater than 4) with the standard treatment. Patients were divided into two equal groups by chance after giving their informed consent. The anesthesiologist and the patients were not blinded, but blinded the data collector:

For one day, patients got one gram of paracetamol intravenously three times each day. Rescue analgesia was administered as the injection of ketorolac intravenous 30 mg and a daily maximum dose of 120 mg if sufficient analgesia (NRS < 4) had not been attained after two hours.

Block group (SPGBG): 20 participants in each nostril, patients get the bilateral SPGB with a 3ml mixture of 2% lignocaine and 1 ml of dexamethasone. The same anaesthetist performed all blocks.

A cotton-tipped applicator performed bilateral SPGB in the ward while the patient was monitored with a non-invasive blood pressure and oxygen saturation device. The patient's neck was stretched as they lay supine. We looked for polyps, tumours, and considerable septal deviation in the anterior nares. Using a trans-nasal technique, SPGB was completed. There were a few lidocaine drops (2% in each anterior nare). Then, until resistance is felt, a long applicator with a cotton swab at the tip is inserted parallel to the floor of the nose. The mixture is 3 mL of 1 mL dexamethasone + 2 mL lidocaine at 2 percent. The swab should be placed above the posterior pharyngeal wall, above the middle turbinate. The applicator was left in the nostril for five minutes before being removed. The process is similarly done in the opposite nostril.

The mucous membrane and connective tissue covering aid in the drug's diffusion and penetration. The patients of the B-group were asked to sit up after 5 minutes so that a numerical pain score could be used to determine whether or not there was a headache (NRS). After two hours following the successful block (NRS greater than 4), rescue analgesia in intravenous ketorolac 30mg was administered, with a daily maximum dose of 120mg. After 24 hours from the start of the study, patients in both groups who had not received enough pain relief were given consideration for EBP.

Normal patient monitoring measurements, including the mean arterial blood pressure and heart rate, were taken prior to the block. A pain score was recorded for 5 minutes, 15 minutes, 30 minutes, 1, 2, 4, 6, 8, and 24 hours following the procedure. The beginning of the analgesia (NRS < 4), the length of the analgesia, the adverse effects related to block, the total amount of the ketorolac administered in the period of study in mg, the satisfaction of the patient, hospital discharge after the 24 hours or hospital stays for EBP were recorded as well. Twenty-four hours after enrolling subjects in the experiment, our study ended.

The main objective was to ascertain whether SPGB was successful in treating PDPH based on a decrease in pain score to or below 4.

The secondary goals included evaluating the effectiveness of the block by measuring the duration and onset of analgesia, any side effects that might have developed as a result of block, the overall dose of the ketorolac, the length of stay in hospital for EBP or the discharge from hospital after 24 hours, and the satisfaction of the patient. Using SPSS software, version 26.0, the gathered data are coded, tabulated, and statistically evaluated.

Quantitative variables were checked for normality using the Shapiro-Wilk test, and if they were, they were described as mean, and SD and compared using an independent t-test; for variables with modest, expected numbers, qualitative data were presented as percentages and numbers were compared using the tests (chi-square and Fisher's exact); for ordinal variables, linear by linear connections were utilised. The rate of morphine analgesia was compared using the long rank test. P values below 0.050 were considered significant, while values over this threshold were considered non-significant.

3. Results

In comparison to the IV analgesias by paracetamol without or with ketorolac, this prospective clinical trial compares the effectiveness and efficiency of the SPGB in treating PDPH in pregnant patients who have undergone cesarean sections under spinal anesthesia.

Sixty-nine people were evaluated to see if they were eligible for this study. 40 patients were randomly assigned to undergo either the PG (where n = 20) or the SPGBG (n = 20) between March and December 2022 after 29 individuals were eliminated (Figure 1).

The study's findings imply that SPGB could be utilised to manage and quickly control PDPH. It was discovered that the SPGB could provide acceptably control of pain throughout the trial with a quicker onset, longer duration, and less analgesic intake. In the SPGB group, no patients experienced severe side effects from the block. The block group required fewer hospital stays for EBP, while the SPGB group had significantly higher patient satisfaction.

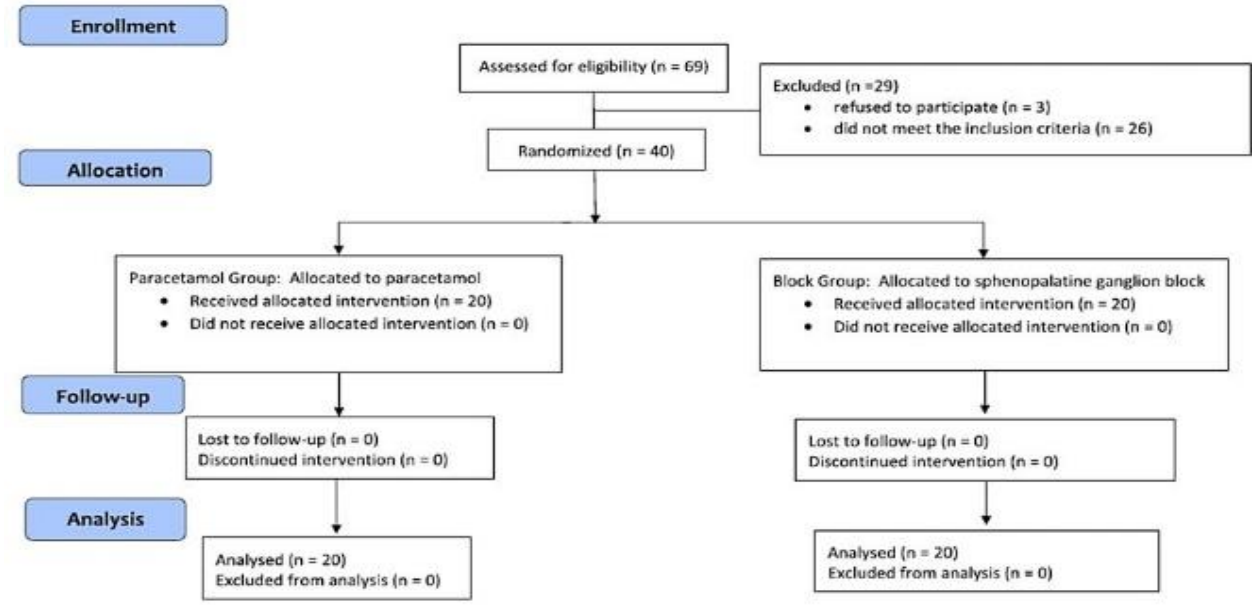

Figure 1: Trial flow sheet

Table 1: Comparison of Characteristics (Demographic)

Vars.	PG (N = 20)	SPGBG (N = 20)	p-value^
ASA 1 (%)	100%	100%	NA
BMI	28.7±1.6	29.4±1.8	0.198
Age	27.5±3.0	28.7±3.7	0.25
Weight	80.5±6.8	82.9±5.0	0.199

Table 2: Pain Perception Comparison

Time	PG (N = 20)	SPGBG (N = 20)	p-value^
24-Hour	2	2	0.832
12-Hour	1.5	1	0.564
8-Hour	2	1	0.124
6-Hour	1	1	0.466
4-Hour	1.5	1	0.093
2-Hour	4	2	<0.001
1-Hour	4	2	
30-Minutes	4.5	2	
15-Minutes	5	2	
5-Minute	5	4	0.151
Base line	5	5	0.456

Table 3: Comparison of the duration of analgesia, onset, and total dose of the rescue analgesia

Time	PG (N = 20)	SPGBG (N = 20)	p-value	Effect of SPGBG with respect to PG	
				CI 95%	Mean±SE
Overall dose of rescue analgesic	94.6±29.6	52.5±28.7	^0.024	-78 to -6.2	-42.1±16.8
Duration	253±92.5	582±76.7	<0.001	274.6 - 383.4	329±26.9
Onset	127.5±55	10.3±4.1	<0.001	-142.2 to -92.3	-117.3±12.3

In our study, the SPGB group experienced a few self-limited adverse effects such as dizziness, bitter taste, lacrimation, nasal congestion, and epistaxis. Therefore, it is regarded as a safe procedure. In contrast to the seven patients in the control group, only one in our block group required EBP.

The initial appointed team completed the analysis (each had 20 patients). Age, weight, BMI, and ASA do not statistically differ across the groups under study, according to Table 1.

In contrast to other measurements, Table 2 reveals that perception of pain (NRS) in SPGBG was typically less throughout the research, with the sole highly significant difference occurring from 15 minutes to the first two hours following the block.

Table 3 demonstrates that SPGBG had a quicker start, a highly significant difference in analgesia duration, and fewer needs for rescue analgesics.

Table 4: Patients' satisfaction, hospital stay, and adverse effects comparison

Time		PG (N= 20)	SPGBG (N = 20)	p-value	Effect of SPGBG with respect to PG	
					CI 95%	Mean±SE
Nasal congestion		0	3	0.231		NA
Epistaxis		0	0	NA		NA
Hospital Stay for EBP		7	1	0.044	0.02-1.06	RR:0.14
Lacrimation		0	1	0.999		NA
Dizziness		0	0	NA		NA
Bitter taste		0	5	0.047		NA
Satisfaction	Satisfied	6	13	0.019	1.03-4.55	RR:2.17
	Unsatisfied	6	1			
	Borderline	8	6			For satisfaction

Table 4 demonstrates that the SPGBG has a much shorter stay in the hospital, significantly higher patient satisfaction, and very few adverse effects, with the bitter taste only showing a significant difference.

4. Discussion

The first work, which was published, described how to manage PDPH using SPGB blocks (22). Pregnant women who experienced low backaches, tension headaches, migraines, and neck pain used the block. They placed cotton-tipped applicators drenched with EMLA cream in each nostril for ten minutes. Only two individuals could not tolerate applicators; the nasal spray cetacaine was used. None of the patients reported any negative side effects, which were proven beneficial. It was advised to be utilised for treating PDPH following this encounter. The 3 parturients with moderate to severe PDPH were included in Cohen's study, and SPG block was performed using a cotton tipped applicator and topical lignocaine (4%) ointment. In contrast to the other two patients, eleven out of the 13 experienced adequate pain relief without needing an EBP (18).

Three patients with proven PDPH were treated with SPG blocks in the emergency room by Kent and Mehaffey. The lignocaine used was vicious and 2 percent (21). After the block, the three patients said their discomfort was sufficiently relieved. They proposed that the technique may be used accurately and safely in the emergency room. Another instance with three parturients with PDPH was published by Kent and Mehaffey (21). Trans-nasal SPGB was carried out in the Delivery and Labor Suite using cotton-tipped applicators and 2 percent viscous lidocaine. All patients said their pain was quickly and adequately relieved, and none required EBP.

In their trial comparing the effectiveness of block in treating post-spinal headaches to the traditional treatment, Puthenveettil et al. included 20 pregnant women (23). Patients in the SPGB group received the block in the intensive care unit using a cotton-tipped applicator dipped in 2% lignocaine. The second group gets 1 g of paracetamol intravenously three times per day. They noted that the SPGB provided long-lasting and effective pain reduction throughout the research. Still, the effective pain relief of the traditional procedure did not start until 4 hours later.

Participants in the Jespersen et al. trial received a 1 ml injection of either a placebo or local anaesthetic (lidocaine 4 percent and ropivacaine 0.5 percent) for the bilateral sphenopalatine ganglion block (saline) (20).

They demonstrated the effectiveness of SPGB by showing that in half of the patients in both block groups (local anaesthetic and the saline groups), the pain was lowered, and EBP was averted. This shows a significant benefit not necessarily connected to the local anaesthetics. Saline placebo also alleviated pain, suggesting that the mechanism may be related to the mechanical stimulation of the sphenopalatine ganglion.

In four obstetric patients with PDPH, Furtado et al. applied a sphenopalatine block using 4 mL of ropivacaine at 0.75 percent (25). For 12-24 hours, these individuals said their discomfort was under control. This longer-lasting pain alleviation may be attributed to the administration of ropivacaine, a long-lasting local anaesthetic.

Takmaz et al. included 26 non-obstetric individuals with PDPH in their study (24). They discovered that trans-nasal SPGB quickly alleviated PDPH in all patients and that the therapeutic benefit persisted for 48 hours after surgery. A VAS score of three was obtained for all the patients, and nearly half reported being free of pain 24 hours after the treatment.

For SPGB, Candido et al. administered 0.5 mL of 0.5 percent ropivacaine and 2 mg of dexamethasone via a nasal applicator to 3 patients who suffered from trigeminal neuralgia, post-herpetic neuralgia, and chronic migraine headache, respectively (17). Two of the three trial subjects experienced significant pain reduction, which persisted during the 28-day follow-up period. All three patients reported high levels of satisfaction with this method.

In the Candido et al. research, one patient experienced little post-treatment nasal bleeding that stopped independently in less than five minutes (17). According to Cohen et al., no block-related negative effects were reported by patients in their studies (19). Takmaz et al. reported that following SPGB, people experienced nasal discomfort, throat numbness, and nausea, all disappearing entirely within 24 hours. 24 most investigations revealed a decrease in the requirement for the EBP and generally good patient satisfaction (18, 20).

It appears that the majority of the linked investigations tested the impact of the SPGB or even the stimulation on the PDPH using only lignocaine, and occasionally only saline. In our trial, we have used the combination/mixture of dexamethasone and lignocaine to allow our patients to experience less intense pain, a quicker start of block, a longer block, and a longer pain-free time. Additionally, some research was carried out in the ICU, the ER, or the delivery room. It was simpler because we conducted our research in the hospital ward. Conversely, some studies have employed a special apparatus (Tx360®) for nasal applicators. We also used a cotton-tipped applicator, which was easily accessible even in areas with limited resources (26).

Finally, while the pain score was recorded in every study, few studies captured the start and length of the block, while others captured the adverse effects, requirement for the EBP, and/or patient satisfaction. Data was gathered for our investigation.

Our study had some drawbacks, including that it was not triple-blinded. By utilising a longer-acting local anaesthetic like bupivacaine or raising the concentration of lignocaine, we may have extended the duration of analgesia. The block might have been repeated as soon as the pain returned.

5. Conclusion

Trans-nasal SPGB can, in the end, be used to treat PDPH quickly and successfully. With a low rate of complications, a protracted analgesic effect, and high patient satisfaction, it is a non-invasive, secure, and simple procedure. Additionally, fewer hospitalizations and EBP are required.

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. H.H. Shaikh Khalifa Bin Zayed Al Nahyan Hospital CMH Muzaffarabad, AJK issued approval DME-490. This is to certify Dr. Iram Shahzadi (PMDC Registration Number. 1768-AJK), working as a consultant Anesthesiologist in the Anesthesiology Department of this hospital, has submitted a study titled “Efficacy of sphenopalatine block in patients with post dural punctual headache after cesarean section at Tertiary Care Hospital SKBZ/AK CMH Muzaffarabad, Azad Kashmir” to the ethical review committee for review. The study has been scrutinized and found ethically sound, as all ethical issues have been addressed in this study. Furthermore, this study has no conflicts of interest or financial disclosure. Dr. Tahir Aziz- Chairman, Ethical Committee SKBZ/ AK CMH Muzaffarabad, AJK.

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue.

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 no other relationships or activities could appear to have influenced the submitted work.

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