Section: Miscellaneous

Original Research Article

EVALUATION OF INTRANASAL LIGNOCAINE SPRAY VERSUS CONVENTIONAL SPGB IN THE MANAGEMENT OF POST-DURAL PUNCTURE HEADACHE: A PROSPECTIVE STUDY

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ABSTRACT

Background: Post-dural puncture headache is a well-recognised complication of spinal and epidural procedures, often resulting in significant patient discomfort and prolonged recovery. Sphenopalatine ganglion block is an emerging treatment strategy for PDPH. This study evaluates the efficacy of intranasal lignocaine spray versus conventional SPGB using cotton applicators in managing PDPH. **Materials and Methods:** In this prospective, randomised, double-blind controlled trial, 90 patients with PDPH were enrolled and equally divided into two groups. Group S received 10% lignocaine spray intranasally, followed by saline-soaked cotton swabs, while Group B received saline spray followed by 2% lignocaine-soaked cotton swabs applied to the posterior nasal cavity. Pain scores were assessed using the Visual Analogue Scale at baseline, 30 minutes, 1 hour, 2 hours, 24-, 48-, and 72-hours post-intervention. Hemodynamic changes and adverse effects were also recorded. **Result:** Group S showed significantly greater reductions in VAS scores at 30 minutes and 1 hour post-procedure compared to Group B ($p = 0.043$ and $p = 0.0001$, respectively). Both groups had similar pain scores beyond 2 hours. Repeated measures ANOVA demonstrated significant effects of treatment group ($F = 39.87$, $p = 0.001$), time ($F = 196.76$, $p = 0.001$), and their interaction ($F = 4.76$, $p = 0.009$). Hemodynamic parameters remained stable in both groups, and no serious adverse events were reported. **Conclusion:** Intranasal lignocaine spray is a safe, effective, and non-invasive alternative to conventional SPGB for managing PDPH, offering faster analgesic onset and superior early pain control. Its simplicity and ease of administration make it an attractive first-line option in clinical situations.

INTRODUCTION

Post-dural puncture headache is a debilitating and distressing difficulty encountered predominantly after neuraxial anaesthesia, lumbar puncture, or unintentional dural puncture during epidural procedures. Characterised by a severe fronto-occipital headache, typically postural, PDPH arises from cerebrospinal fluid leakage through the dural tear, leading to reduced intracranial pressure and compensatory cerebral vasodilation, which contributes to pain generation. The frequency of PDPH varies based on needle size and type, patient factors, and procedural conditions, ranging from 0.16% to 1.3% in spinal anaesthesia and up to 76% in diagnostic lumbar puncture using large-bore needles.[1,2]

Mechanism of Post-Dural Puncture Headache: The most extensively accepted theory for PDPH is the Monro-Kellie doctrine, which emphasises the fixed intracranial volume shared among brain tissue, CSF, and blood. Loss of CSF reduces intracranial volume, triggering compensatory cerebral vasodilation to maintain equilibrium. This vasodilation, along with brain sagging due to gravity, uses traction on pain-sensitive structures, leading to the hallmark orthostatic headache.[3] The trigeminal and upper cervical nerves mediate the pain sensation. Sphenopalatine ganglion, located in the pterygopalatine fossa, is an important parasympathetic hub for cranial vasculature, and its blockade helps mitigate this reflex vasodilation, thus offering symptomatic relief in PDPH.[4]

Conventional SPGB and the Rationale for Alternative Methods: Sphenopalatine ganglion

block is a minimally invasive, effective, and increasingly utilised technique in managing PDPH, particularly when conservative treatments like hydration and analgesics fail. Traditionally, SPGB is performed transnasally using cotton-tipped applicators soaked in local anaesthetic and inserted posteriorly through the nasal cavity to reach the ganglion. While generally safe, this method has drawbacks such as discomfort, nasal bleeding, and patient noncompliance due to the invasive nature of the applicator-based technique.[5]

To discourse these limitations, intranasal lignocaine spray has emerged as a promising non-invasive alternative. The concept leverages the ability of atomised local anaesthetics to reach the posterior nasal cavity and exert pharmacologic effects on the sphenopalatine ganglion region without the need for direct mechanical contact. Lignocaine, an amide-type local anaesthetic, is highly effective due to its rapid onset of action, good mucosal absorption, and ability to block voltage-gated sodium channels, thereby inhibiting nerve conduction.[6]

Pharmacology of Lignocaine: Lignocaine is an extensively used local anaesthetic and antiarrhythmic drug. Its mechanism of action involves reversible blockade of sodium ion influx into nerve cells, thus preventing depolarisation and the propagation of action potentials. It has a rapid onset and is metabolised in the liver by cytochrome P450 enzymes.[7] Its favourable pharmacokinetics and minimal systemic absorption when used intranasally make it ideal for SPGB. Atomised lignocaine provides a uniform spray to the mucosa of the posterior nasal cavity, reducing procedural discomfort and improving patient compliance.

Emerging Evidence for Intranasal Lignocaine Spray: Numerous recent studies have explored the efficacy of intranasal lignocaine spray for SPGB, demonstrating significant symptomatic relief in PDPH, with outcomes comparable to the conventional method. A study by Jespersen et al. (2021) found that 2% lignocaine spray provided rapid headache relief in over 80% of patients with minimal side effects.[8] Another pilot study conducted by Bala et al. (2022) supported these findings, reporting better patient satisfaction scores and procedural simplicity using spray-based SPGB.[9] However, comparative prospective data remain limited, and further robust studies are needed to determine the efficacy and safety of intranasal spray compared to conventional SPGB methods.

This study was designed to compare the clinical efficacy, patient satisfaction, and procedural ease of intranasal lignocaine spray versus conventional cotton applicator-based SPGB in patients suffering from PDPH. The primary endpoint was the reduction in headache intensity as measured by the Visual Analogue Scale at predefined intervals. Secondary endpoints included time to onset of relief, need for rescue therapy, recurrence, and adverse effects. Specified the increasing incidence of PDPH in anaesthetic and diagnostic practices and the need for non-invasive, patient-friendly interventions, this study aims to address a significant clinical question and potentially redefine the standard approach to SPGB in PDPH.

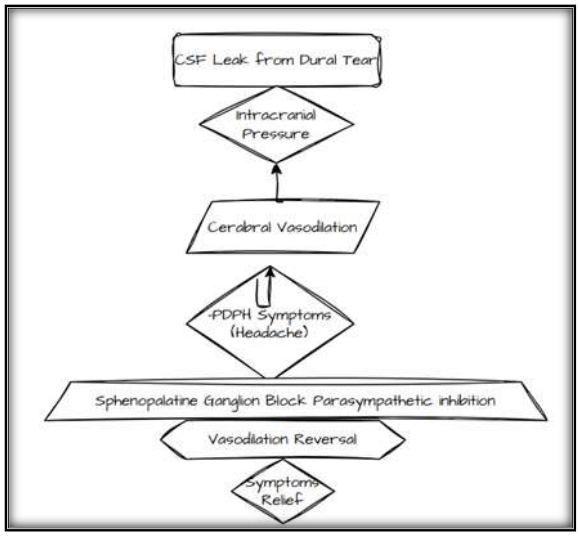

Figure 1: Mechanism of PDPH and SPGB Action

MATERIALS AND METHODS

Research Design: This double-blind, randomised controlled trial was conducted at a tertiary care university hospital between December---- and March ----. Ethical clearance was obtained from the Institutional Ethics Committee. All participants provided written informed consent before enrolment. The trial was prospectively registered with the Clinical Trials Registry – India. Patients were randomly allocated to two equal groups using a block randomisation method with sealed, opaque envelopes to ensure allocation concealment. The study employed a double-blind design; both patients and outcome assessors were blinded to group allocation. Drug preparation and administration were carried out by a clinician not involved in outcome assessment. All patients received xylometazoline nasal drops in both nostrils five minutes before the procedure to reduce mucosal congestion. Patients in Group S (Spray group) were administered two puffs of 10% lignocaine spray intranasally in each nostril, followed by insertion of cotton swabs soaked in normal saline. In difference, Group B (Block group) received two puffs of saline spray intranasally, followed by placement of cotton swabs soaked in 2% lignocaine. In both groups, the patient was positioned supine with the neck extended. The cotton applicator was inserted parallel to the nasal floor until mild resistance was felt. The swab was placed near the posterior pharyngeal wall, above the level of the middle turbinate, corresponding anatomically to the location of the sphenopalatine ganglion. The procedure was then repeated in the contralateral nostril. An insulin syringe was used to deliver both the lignocaine and placebo sprays identically. If a patient reported inadequate pain relief at 1 hour post-intervention, the

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same block was repeated once. Failure to achieve important improvement after the second attempt was categorised as treatment failure, and conventional pharmacologic management was initiated.

Inclusion Criteria

- American Society of Anaesthesiologists physical status I to III
- Occurrence of post-dural puncture headache within seven days of spinal or epidural puncture
- Visual Analogue Scale pain score of ≥3 at the time of intervention
- Willingness to participate and provide informed consent

Exclusion Criteria

- A history of nasal pathology such as septal deviation, nasal polyps, rhinitis, or sinusitis
- Known hypersensitivity or allergy to any study medications (lignocaine or saline)
- Refused consent for participation

Statistical Analysis: Data analysis was performed using Stata version 10. Continuous variables were presented as means with 95% confidence intervals if normally distributed, or as medians with interquartile ranges if not. Repeated Measures Analysis of Variance was used to compare changes in VAS scores over time within and between groups. At each time point, intergroup comparisons of VAS scores were conducted using the Mann–Whitney U test. The Kruskal–Wallis test assessed the median VAS scores across all time intervals. Paired t-tests were applied to evaluate changes in hemodynamic parameters within each group pre- and post-intervention. A p-value of <0.05 was considered a significant difference.

RESULTS

The mean age of patients in Group S was 35.8 years (±14.85), while that in Group B was somewhat lower at 33.85 years (±16.05), with overlapping 95% confidence intervals, suggesting no significant age difference between the groups. Gender distribution was identical across both groups, with 64.4% females and 35.6% males, indicating a female-predominant study population. The body mass index data showed a high prevalence of obesity in both groups: 71.1% in Group S and 75.6% in Group B, while normal BMI was observed in 24.4% of patients in both groups. Only Group S had a small percentage (4.4%) of patients with below-normal BMI, while Group B had none. Regarding the ASA physical status classification, the majority of patients in both groups were ASA I (80% in Group S and 64.4% in Group B), indicating a predominantly healthy study population. However, a higher percentage of Group B patients fell into the ASA II and ASA III categories, signifying a somewhat higher comorbidity burden in that group [Table 1].

Table 1: Demographic and Clinical Characteristics of Patients in Group S and Group B

Variable	Group S (n = 45)	Group B (n = 45)
Age (years)	35.8 ± 14.85	33.85 ± 16.05
	(95% CI: 28.85–42.74)	(95% CI: 26.33–41.36)
Gender, n (%)		
Male	16 (35.6%)	16 (35.6%)
Female	29 (64.4%)	29 (64.4%)
BMI (kg/m²), n (%)		
Below normal	2 (4.4%)	0 (0%)
Normal	11 (24.4%)	11 (24.4%)
Obese	32 (71.1%)	34 (75.6%)
ASA Physical Status, n (%)		
ASA I	36 (80.0%)	29 (64.4%)
ASA II	7 (15.6%)	11 (24.4%)
ASA III	2 (4.4%)	5 (11.1%)

The Mann-Whitney U test revealed a statistically significant reduction in VAS scores for Group S compared to Group B at 30 minutes ($p = 0.043$) and more prominently at 1 hour postoperatively ($p = 0.0001$). This demonstrates the superior early analgesic efficacy of Bupivacaine. Even though the median VAS scores at later time points (2 hours to 72 hours) were consistently low or zero in both groups, the differences were not significant. The Kruskal-Wallis test confirmed overall important variation in pain scores across time points in both groups ($\chi^2 = 106.240$ and 106.269; $p = 0.0001$), indicating a dependable trend of pain reduction over time postoperatively [Table 2].

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Table 2: Comparison of Postoperative Pain Scores Between Group S (Bupivacaine) and Group B (Lignocaine) at Different Time Intervals

Time	Group S Median (IQR)	Group B Median (IQR)	P-value (Mann-Whitney U test)
Baseline	7 (6–7.5)	6.5 (6–8)	0.5
30 minutes	4 (4–5)	6 (4–6)	0.043
1 hour	2 (0–2)	4 (2–4)	0.0001
2 hours	0 (0–2)	2 (2–4)	0.77
24 hours	0	0 (0–2)	0.645
48 hours	0	0 (0–2)	0.575
72 hours	0	0	0.55
Kruskal-Wallis χ^2 with ties	$\chi^2 = 106.240$; df = 6; P = 0.0001	$\chi^2 = 106.269$; df = 6; P = 0.0001	–

There was a statistically significant difference between the two treatment groups (F = 39.87, P = 0.001), indicating that one intervention was more effective than the other in reducing pain scores. A highly significant effect of time was observed (F = 196.76, P = 0.001), reflecting substantial changes in pain scores over the observation periods, irrespective of the group. The interaction between group and time was also significant (F = 4.76, P = 0.009), suggesting that the change in pain scores over time differed between the treatment groups, indicating differential treatment effects at various time points. The overall model was highly significant (F = 96.08, P < 0.0001), confirming the robustness of the observed effects [Table 3].

Table 3: Two-Way Repeated Measures ANOVA for VAS Score – Comparing Group and Time Effects

Source	Type III SS	df	Mean Square	F Value	P-value
Model	1557.97	13	119.84	96.08	<0.0001
Group	49.72	1	49.72	39.87	0.001
Time	1472.62	6	245.43	196.76	0.001
Group × Time	35.62	6	5.93	4.76	0.009
Residual Error	331.8	266	-	-	-

The group variable had a statistically significant impact on pain relief, with an F-value of 39.87 and a p-value of 0.001. This suggests that the treatment modality itself significantly influenced the patients' pain scores, confirming a difference in efficacy between the two interventions. The pain scores changed significantly over the 6 time points assessed, as shown by an F-value of 196.76 and a p-value of 0.001. This indicates that both groups experienced substantial time-related variation in pain relief, which is expected as the analgesic effect evolves post-treatment. The interaction between treatment group and time was also significant (F = 4.76, p = 0.009), suggesting that the trajectory of pain relief over time differed between the two groups. In other words, the pattern and speed of symptom resolution varied depending on whether the patient received intranasal lignocaine or conventional SPGB [Table 4].

Table 4: Comparison of Hemodynamic Parameters and Adverse Symptoms Before and After Intervention in 90 Patients with PDPH and Adverse Symptoms Reported Post-Intervention

Variable	Group S (n = 45)	Group B (n = 45)	Between-Group t-test P-value	P-value
Heart Rate (beats/min)				
Before	100 ± 17.77 (91.7–108.3)	95.15 ± 20.0 (85.7–104.5)		
After	96.55 ± 12.7 (90.6–102.5)	94.8 ± 16.2 (87.2–102.4)	0.35	
Paired t-test P-value	0.19	0.86		
Systolic BP (mmHg)				
Before	122.7 ± 13.4 (116.4–128.9)	125.35 ± 16.9 (117.4–133.3)		
After	119.3 ± 14.2 (112.7–125.9)	124.7 ± 16.4 (117.0–132.4)	0.275	
Paired t-test P-value	0.08	0.69		
Diastolic BP (mmHg)				
Before	75.2 ± 13.1 (69.0–81.3)	78.2 ± 13.1 (72.0–84.3)		
After	77.2 ± 10.8 (72.2–82.2)	75.9 ± 11.3 (70.6–81.2)	0.12	
Paired t-test P-value	0.316	0.236		
Symptom	Group S (n = 45)	Group B (n = 45)	Chi-square	
Nausea	0	1	$\chi^2 = 3.12$	0.47
Vomiting	3	1		
Stiff Neck	1	0		
None	41	43		

DISCUSSION

This prospective evaluation comparing intranasal lignocaine spray to conventional SPGB via cotton swab applicator provides valuable insights into the evolving landscape of PDPH management. The study's main finding, that lignocaine spray (10%) offers significantly greater pain relief within the first two hours post-intervention compared to the applicator route without notable adverse effects, suggests a promising, non-invasive alternative for rapid symptom control.

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Comparative Efficacy: The randomised trial by Smita et al. demonstrated that patients receiving lignocaine spray had markedly lower VAS pain scores up to two hours post-procedure compared to those undergoing SPGB via swab, and no significant side effects were observed in either group.[10] This result underscores the spray's efficacy in immediate analgesia, especially in a critical early window when patient discomfort is often most intense. In difference, the broader data on SPGB's efficacy show mixed results. A pilot meta-analysis found no statistically significant advantage of SPGB over conventional treatments, such as epidural blood patch or paracetamol, for headache relief at 30 minutes or adverse events.[11] This suggests that while SPGB may benefit certain patients, it does not consistently outperform standard therapies across the board.

Numerous observational and prospective studies support the efficacy of SPGB. In obstetric patients unresponsive to conservative treatment, direct application of 2% lignocaine via SPGB yielded pain relief in nearly 89% of cases within five minutes, and sustained benefit up to eight hours.[12] Meanwhile, a randomised study using 0.25% ropivacaine packing into the nostrils showed significantly reduced analgesic requirements, lower headache scores, and better patient satisfaction than conservative treatment alone; only one patient required EBP.[13] Another angle involves timing. An observational study comparing early versus late SPGB with ropivacaine found that earlier application resulted in reduced hospital stay and lower symptom recurrence, though pain relief was comparable between groups.[14] Thus, timing may augment the utility of SPGB, even if the analgesic mechanisms are similar.

Mechanistic and Practical Considerations: Anatomical factors underpin both involvements' potential efficacy. The sphenopalatine ganglion lies beneath a thin mucosal layer in the pterygopalatine fossa, facilitating anaesthetic penetration via topical application, whether by spray or swab. The spray offers a important advantage in ease of delivery, requiring only a few simple steps, minimal use of equipment, and the ability to be administered by nursing staff or possibly self-administered by patients.[15]

Moreover, the applicator method, though minimally invasive, is less tactful in certain patients, particularly those with nasal pathologies or anticoagulation concerns. The spray circumvents these tasks as the nozzle does not directly engage tissue, lowering the risk of mucosal trauma or bleeding.[16]

Limitations and Future Directions: In spite of promising early results with lignocaine spray, broader limitations must be acknowledged. Smita et al.'s trial, while robustly designed, focused on a small cohort (n≈40) and only tracked outcomes through 72 hours. Its strength lies in demonstrating early analgesic superiority; long-term outcomes beyond 72 hours, need for rescue involvements, or comparisons to EBP were not fully addressed.[17]

Similarly, for SPGB, the mixed results across studies, randomised, observational, and meta-analytic, variability in technique, anaesthetic agent dosage, timing, and patient populations. The pilot meta-analysis specifically cited heterogeneity in study design as limiting its conclusions.[18] Therefore, to clarify the relative roles of spray versus applicator SPGB versus EBP, larger randomised trials should extend follow-up, compare functional results, and explore patient preferences and cost effectiveness. Additionally, investigations into optimal timing and combined strategies could further refine clinical algorithms for PDPH.

Clinical Implications: Given its ease of use, favourable safety profile, and apparent efficacy in early pain reduction, intranasal lignocaine spray could serve as first-line therapy for PDPH in appropriate settings, especially when immediate symptom control is desired, and when avoidance of invasive procedures is preferable. Where spray is unavailable or contraindicated, applicator-based SPGB remains a less invasive alternative to EBP, especially if applied early.[19] Ultimately, widespread adoption of either method will depend on clinicians' familiarity, institutional protocols, and further evidence from large, controlled trials.

CONCLUSION

This prospective, randomised study established that intranasal lignocaine spray provides significantly superior early pain relief compared to the conventional cotton applicator-based sphenopalatine ganglion block in patients suffering from post-dural puncture headache. The analgesic benefit was most pronounced within the first hour of administration, with both groups showing similar pain relief at later time points. Prominently, the lignocaine spray was associated with minimal adverse effects and no hemodynamic instability, indicating an excellent safety profile. Specified its ease of administration, non-invasive nature, and clinical effectiveness, intranasal lignocaine spray may be considered a viable first-line intervention for PDPH, especially in settings where rapid symptom relief is desired and invasive procedures such as epidural blood patch are not preferred or feasible. These results support the integration of lignocaine spray into routine clinical practice for PDPH management, although larger multi-centre trials with extended follow-up are recommended to confirm long-term efficacy and establish standardised protocols.

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