Original Article

A randomized control study to assess the efficacy of the sphenopalatine ganglion block in patients with post dural puncture headache

ABSTRACT

Background: Post dural puncture headache (PDPH) delays discharge from hospital. We studied the efficacy of sphenopalatine ganglion (SPG) block, a novel technique in management of PDPH using 0.25% Ropivacaine.

Methodology: Forty patients presenting with PDPH after urological procedures under spinal anaesthesia were randomized into two groups: Group C and Group S. Group C received conservative treatment with bed rest, adequate hydration and caffeine 200 mg 6th hourly. Group S patients received SPG block (packing bilateral nostril for 10 minutes with 0.25% Ropivacaine). Inj Paracetamol 1 g IV was given as primary analgesic. Intravenous Diclofenac 75 mg was administered as rescue analgesic. Patients were monitored for 72 hours. Total analgesic requirement, time to attain adequate pain relief, headache pain score, patient satisfactory score were compared between the two groups. We compared the PDPH severity score for headache using 5-point scale method and patient satisfaction score using Likert-type scale.

Results: Demographic data, onset of PDPH, needle size, intervention time were statistically insignificant. Total paracetamol consumption was significantly reduced in SPG group. Headache pain score was significantly low in Group S up to 54 hours. Patient satisfaction score was statistically better in Group S. Mean block onset time was 12 minutes. One patient in Group C required Epidural blood patch.

Conclusion: SPG block is an effective alternative in managing patients with PDPH. The need for epidural blood patch is greatly reduced using SPG block. Procedural safety, immediate and sustained pain relief make it an evolving treatment modality for PDPH.

Key words: Epidural blood patch, headache, post dural puncture headache, ropivacaine, spinal anaesthesia

Introduction

Post dural puncture headache (PDPH) is a severe and disabling complication of neuraxial anaesthesia posing challenging management with the incidence around 1–2%.[1] It affects post-operative course by affecting day-to-day activities, extends hospital stay. Conservative treatment includes fluid therapy, caffeine and analgesics.[2] Epidural blood patch (EBP)

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with 75% success rate[3] has its own complications. This lacuna has been resolved by sphenopalatine ganglion (SPG) block, which has sparse literature evidence on its analgesic potency and efficacy.[4] We studied the efficacy of SPG block in management of PDPH using 0.25% Ropivacaine.

Subjects and Methods

We conducted a randomized control study after institutional ethical committee approval (1854/IEC/2019) and CTRI registration (CTRI/2020/06/025834). Forty patients aged between 18 and 60 years presenting with PDPH after urological procedures performed under subarachnoid block were enrolled in our study. Informed written consent was obtained from all the patients. The patients not willing for procedure, presence of nasal polyp/anomaly/infection, allergy to NSAIDs, previous spine surgeries, patients with migraine/chronic headache, patients on antidepressants were excluded [Flow chart 1].

The primary objective was to compare the requirement of analgesics between the groups and secondary objectives were to compare the Headache Score and Patient satisfaction with the treatment between two groups, time of onset of analgesia following SPG Block, incidence of associated nausea and vomiting.

Patients were randomly allocated into two equal groups (Group C and Group S) by computer-generated random numbers. Group C: Conservative treatment, Group S: SPG block. All patients with PDPH were advised conservative management as soon as patient c/o headache. The conservative treatment includes bed rest, T. Caffeine 200 mg 6th hourly, oral fluids 1.5–2 litres/day + Intravenous fluids (IVF) 20 mL/kg/day. For patients on nil oral were given IVF 3 L/day. After providing conservative management, patients in Group C were not given block, whereas patients in Group S were given SPG block with gauze soaked in 10 mL of 0.25% Ropivacaine and bilateral nasal packing was done. They were monitored for 10 minutes and later which the pack was removed.

Inj Paracetamol 1 g IV was given as primary analgesic if patients don't respond to primary treatment. Inj Diclofenac 75 mg in 100 mL NS was given as a rescue analgesic in both the groups, for patients not responding to Inj Paracetamol. For refractory PDPH not settling with the above management, Epidural blood patch was considered and those patients were noted as cases of treatment failure. PDPH severity score for headache assessed using 5-point scale: No headache–0, mild–1, moderate–2, severe–3, unbearable–4. Patient satisfaction was assessed using Likert-type scale (very satisfied–5, somewhat satisfied–4, neither satisfied nor dissatisfied–3, somewhat dissatisfied–2, very dissatisfied–1).

Sample size estimation

Based on study by Puthenveetil, Rajan *et al*.,[5] we took into account their primary objective: Comparison of onset of analgesia between groups.

FORMULA = $2(\alpha + \beta)\ 2^{*}[(s1)\ 2 + (s2)\ 2]/(m1 - m2)\ 2$, (95% Confidence Interval and 80% Power).

We obtained 14.19 as sample size, but for better statistical analysis we have included 20 subjects in each group.

Statistical analysis

Data were entered in MS-Excel spreadsheet (2010) and were analysed using the statistical package for social sciences version 22 (trial version). Descriptive statistics including proportions, measures of central tendency and measures of dispersion were used to describe the data. Further, Student's *t*-test was used to compare means between the groups and Chi-square test, Anova test was used to compare proportions. Mann Whitney U test was used for data's showing not normal distribution. A $p < 0.05$ was considered to be statistically significant. A $p < 0.001$ was considered highly significant.

Results

Age, gender, BMI distribution, onset of PDPH and needle size were comparable between the groups [Table 1]. The total paracetamol consumption(mg) was 3465 ± 0.201 in Group C and 1072 ± 381.64 in Group S with *P* value 0.001 (unpaired t-test) [Table 1]. Inj Diclofenac was required in five patients of Group C. Headache pain score when analysed using

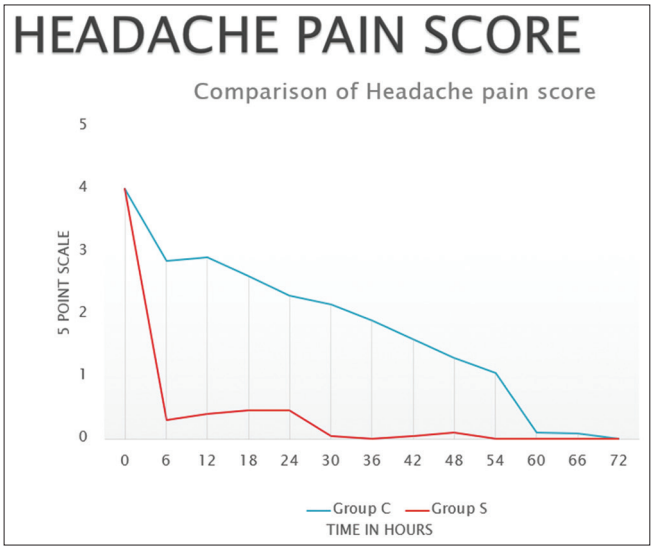


Figure 1: Comparison of headache pain score

Mann Whitney U test, there was statistical reduction in pain score in Group S till 54 hours, after which both groups had insignificant results [Figures 1 and 2]. Patient satisfaction score was better in Group S with *P* value <0.0001 (Anova test) [Table 1]. The mean SPG block onset time was 12 minutes. Four patients in Group C had nausea and vomiting. One patient required epidural blood patch in Group C.

Discussion

Post dural puncture headache (PDPH) turns to be the most persistent complication of neuraxial anaesthesia.[6] It results from inadvertent puncture of the dura membrane while performing neuraxial anaesthesia[7] or after myelography and diagnostic lumbar puncture. Purpose of early ambulatory procedures gets affected. It restrains patients from doing daily activities, delayed recovery and hospital stay.[8] Serves to be one of the reason for patients to refuse procedures under neuraxial anaesthesia.

Post dural puncture headache is throbbing in nature and is a constant pain that involves the bilateral frontal, occipital or retro-orbital areas. It is sometimes associated with photophobia/nausea/vomiting. Pain increases on sitting position and decreases on lying down supine. The onset of headache is usually 12–72 hours post procedure and lasts for 4–5 days.[9] In rare cases, it may last for several weeks. Current non-invasive treatment like bed rest, fluids, analgesics, caffeine only minimize discomfort. It doesn't produce complete pain relief.[4]

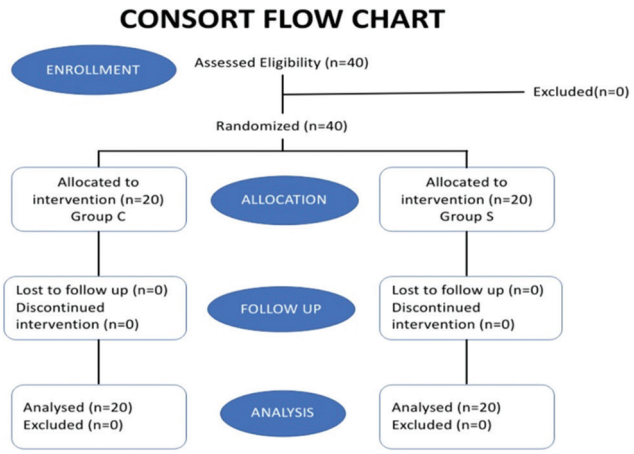
Gold standard treatment was epidural blood patch, which may again lead to inadvertent subarachnoid insertion of needle and infection.[4,10] Complications include meningitis, cauda equina syndrome, paraparesis, epidural infection.[5,11] If first epidural blood patch was ineffective, second patch is kept 24–48 hours after the first procedure. Recent modality of approach to PDPH is SPG block. It is a simple, non-invasive bed side procedure. Low-risk technique, easier to learn and decreases pain at faster time.[4]

PDPH results from loss of cerebro spinal fluid via dura which creates traction on pain-sensitive intracranial structures as the brain loses support and sags. Loss of CSF is compensated by painful intracerebral vasodilatation to offset reduction in intracranial pressure.

HRS	GROUP C	GROUP S	P-VALUE (By Mann Whitney U Test)
0	4(0)	4(0)	0.99#
6	3(0)	0(2)	<0.00001*
12	3(0)	0(1)	<0.00001*
18	3(1)	0(1)	<0.00001*
24	2(1)	0(1)	<0.00001*
30	2(1)	0(1)	<0.00001*
36	2(0)	0(0)	<0.00001*
42	2(1)	0(1)	<0.00001*
48	1(1)	0(1)	<0.00001*
54	1(1)	0(0)	<0.00001*
60	0(1)	0(0)	0.596#
66	0(1)	0(0)	0.794#
72	0(0)	0(0)	0.992#

* Statistically significant, # not significant

Figure 2: Comparison of headache pain scores



Flow Chart 1: Consort flow chart

Table 1: Comparison of demographic data, PDPH onset time, risk factors, total analgesic consumption and complications

Parameter	Group C	Group S	Type of test	*P*
Age (years)	35.5±13.327	32.15±10.342	Unpaired *t* test	0.380#
Gender (Male/Female)	7/13	6/14	Chi square test	0.735#
BMI (kg/m2)	25.55±1.709	26.39±3.896	Unpaired *t* test	0.382#
PDPH Onset (hours)	59.95±14.787	65.5±16.978	Unpaired *t* test	0.277#
Needle size (25G/26G/27G)	14/4/2	13/5/2	ANOVA	0.743#
Paracetamol consumption (mg)	3465±0.201	1072±381.64	Unpaired t test	0.0001*
Headache Pain score (5-point scale)			Mann Whitney *U* test	<0.00001*
Patient satisfaction score (Likert scale)			ANOVA	<0.00001*
Diclofenac requirement	5/20	0/20	25% in Group C, 0% in Group S	
Need for EBP	1/20	0/20	5% in Group C, 0% in Group S	
Nausea and Vomiting	4/20	0/20	20% in Group C, 0% in Group S	

*Statistically significant, #not significant

This vasodilatation brings out the headache after dural puncture. It is mediated by parasympathetic activity via neurons that have connections in SPG.

SPGB brings out pain relief by blocking the preganglionic parasympathetic nerve fibres.[12]

Sphenopalatine/Meckel/nasal/pterygopalatine ganglion

It is one of the four parasympathetic ganglion of head and neck; 5 mm in size[13] situated in pterygopalatine fossa posterior to middle turbinate and anterior to pterygoid canal. It has connecting tissue and mucous membrane surrounding it which makes passage of drug easier.

Sphenopalatine ganglion is formed by

Pre ganglionic parasympathetic axons, post ganglionic sympathetic axons, afferent sensory branches of maxillary division of trigeminal nerve. Blocking this leads to blockade of all three. This can lead to parasympathetic blockade, which in turn tackles the vasodilation caused by the CSF loss.[14,17-18]

The local anaesthetic we provide doesn't directly contact with the ganglion, but seeps in through the mucosa and connective tissue to reach the ganglion. Ropivacaine is a long-acting amide local anaesthetic and pure (s) enantiomer. Similar to bupivacaine but butyl group is replaced by propyl group. Maximum dose being 3.5 mg/kg. Effects of cardiovascular system and central nervous system effects seen with bupivacaine are minimized with use of ropivacaine.[15,18-20] Unique features being lower toxicity, less intense motor block. 0.25% concentration provides equal sensory analgesia as that of 0.25% Bupivacaine with prolonged duration of action.

Analgesic consumption

In our study, the paracetamol consumption (mg) for 72 hours in Group S was 1072.5 ± 381.64 compared to Group C 3465 ± 0.201. The analgesic consumption was greatly reduced in SPGB group with *P* value of 0.0001. The Diclofenac requirement was seen with five patients of Group C, where none of the patients in Group S required diclofenac. A study by Youssef *et al*.[3] found that the mean paracetamol consumption was 2.87g in patients receiving SPGB.

Headache pain score

Before intervention, both the groups pain scores were statistically insignificant in our study. After intervention upto 54 hours there was significant reduction in pain score in Group S compared to Group C (*P* value < 0.00001). After which both the groups became insignificant.

Akin *et al*.[16] through their retrospective study on 26 non-obstetric patients observed that from 15 minutes post block till 48 hours there was significant pain reduction in patients who had SPGB. The VAS was <3 in all patients with 100% success rate.

Time of onset of analgesia following SPGB

The mean onset time of pain relief following SPGB with 0.25% Ropivacaine was 12 minutes in Group S. The reduction in headache score from 4 to 0 was observed in majority of patients in Group S following block. Puthenveetil *et al*.[5] in their study observed that the mean onset of analgesia in SPGB using 2% lignocaine was 4.1 minutes and 206 minutes in patients who received conservative management.

Patient satisfaction score

We analysed Patient satisfaction with treatment using Likert-type scale. The patients who received SPGB had better satisfaction with the treatment provided than Group C. The *P* value was <0.0001. Akin *et al*.[16] observed patient satisfaction using Patient Global Impression of Change (PGIC) scale. It is a 7-point self-reported scale, where among 26 patients 19 of them rated after SPGB as 'much improved' and 7 of them reported as 'very much improved'.

In a study done by Youssef *et al*.[3] patient satisfaction level after giving SPGB was found to be similar to patients receiving GONB (Greater Occipital Nerve Block).

Need for EBP

Limited to one patient in Group C of our study. Santos *et al*.[1] compared SPGB–early (<24 hours) intervention with 20 patients and late (>24 hours) intervention with 21 patients presenting with PDPH. One patient in late intervention had the need for EBP. They also quoted that both groups had equal effectiveness in pain reduction.

Side effects

The side effects such as nausea and vomiting were observed in four patients of Group C whereas no such effects were seen in Group S. In a study comparing GONB and SPGB by Youssef *et al*.,[3] the side effects were insignificant between two groups.

Limitations

All the patients included in our study were young and healthy.

Patients with extremes of age and other uncontrolled systemic illness were not included in our study.

Conclusion

SPG block is found to be an effective alternative in managing patients with PDPH. The need for epidural blood patch is greatly reduced using SPG block. Procedural safety, immediate

and sustained pain relief make it an evolving treatment modality for PDPH.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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