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ORIGINAL RESEARCH

A comparative clinical study to assess the effectiveness of sphenopalatine ganglion block and oral caffeine in management of postdural puncture headache following lower segment caesarean section

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Abstract

Background and objective: Post dural puncture headache (PDPH) is most common complication of spinal an epidural anaesthesia. According to International Headache Society, PDPH is described as a headache occurring within 5 days of lumbar puncture and being aggravated when standing or sitting and relieved when laying flat and caused due to cerebrospinal fluid leak through the dural puncture.

Aim: To evaluate the efficacy of sphenopalatine ganglion block in management of PDPH and assess the efficacy of oral caffeine 300 mg in management of PDPH.

Material and methods: This randomize prospective, observational study will be carried out in patient scheduled for LSCS under spinal anaesthesia,30 patient in the age group of 20-50year belonging to ASA PS-1 AND 2 allocated to two groups,Group1 and Group2 ,who fulfill the criteria of PDPH. Group-APatient will receive oral caffeine 300mg and placebo block Group-BSphenopalatine ganglion block and placebo tablet. Patients were assessed for analgesia period using visual analogue scale (VAS). Hemodynamic parameters and time for first rescue analgesia was recorded.

RESULT – The mean VAS score at 72 hours after LSCS was 2.00+1.512 in Group-1, in Group-2 .67+.976, which was statistically significant ($p<0.05$). The patients in Group 2 showed positive outcome there was a statically significant reduction in visual analog scale (VAS) and mean duration of treatment. After applying unpaired t test for repeated measurement indicated that the interaction between time and group demonstrated that sphenopalatine ganglion block and placebo tablet($P>0.05$) was superior to oral caffeine 300mg and placebo block in pain reduction

Coclusion: SPGB could be used as an effective first line treatment modality for the management of post dural puncture headache .

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Key words: Sphenopalatine ganglion block, post dural puncture method ,cesarean section.

Introduction

Caesarean section is the most commonly performed surgeries in woman and neuroaxialanaesthesia is technique of choice for the procedure[1]. Post dural puncture headache (PDPH) is most common complication of spinal and epidural anaesthesia[2]. Dr. August Bier noted this adverse effect in the first patient undergoing successful spinal anaesthesia on August16 1898[3]. According to international Headache society, PDPH is describe as headache occurring within 5 days of lumbar puncture and being aggravated when standing or sitting and relieved when laying flat and caused due to cerebrospinal fluid leak through the dural puncture.

It usually accompanied by neck stiffness and subjective hearing symptoms.[4]Epidural blood patch was first given by DiGiovanni and Dunbar in 1970 for the management of PDPH.[7]An autologous epidural blood patch [EBP] is gold standard for treating PDPH when the headache is persistent even after conservative management and it has a success rate of around 68-98% in relieving PDPH[5]. Although the EBP is an effective way of treating PDPH, but procedure itself has a set of advantages and disadvantages. Problem using epidural blood patch include subdural hematoma, infection and neurological complication in some rare situation[6].The SPGB is simple, easy and can be done bedside or out patient department. SPGB provides a beneficial, less invasive treatment option with few side effect and can be effectively used in various situations. The sphenopalatine ganglion is collection of sympathetic, parasympathetic, and somatosensory nerve cells though commonly referred as parasympathetic ganglion and is located bilaterally close to sphenopalatine foramen posterior to the middle nasal concha[7-8.]

Aims and objectives

Aims

1. To evaluate the efficacy of sphenopalatine ganglion block in management of PDPH.
2. To assess the efficacy of oral caffeine 300 mg in management of PDPH.

Materials and method

This randomize prospective, observational study will be carried out in patient scheduled for LSCS under spinal anaesthesia.

30 patient in the age group of 20-50year belonging to ASA PS-1 AND 2 allocated to two groups, Group1 and Group2, who fulfill the criteria of PDPH.

The institutional ethical committee no: (66/IEC-GRMC/2020)
Registration in clinical trial registry India: (CTRI/2022/10/046747)
Sample size: 30
Formula used
n=
n= the sample size in each group
μ1 = population mean in treatment group 1
μ2 = population mean in treatment group 2
μ1–μ2 = the difference the investigator wishes to detect
σ2 = population variance
n=30

Patient who will give consent, aged between 20-50 years female and ASA physical grade I and II were included in the study.

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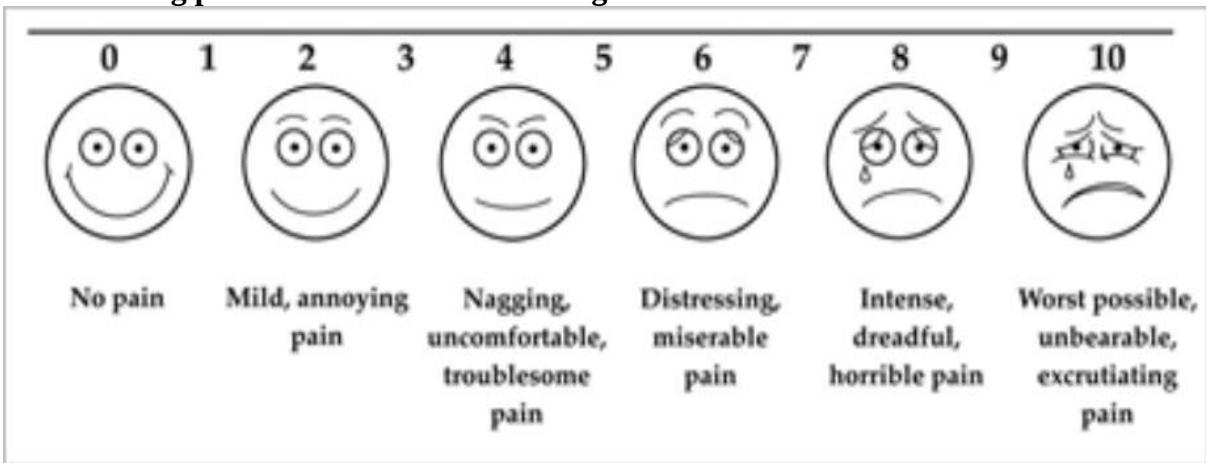
Patients who refused participation from the study, uncooperative patients, history of facial trauma, coagulaopathy or bleeding diathesis, severe hypovolemia, neurologic disease like multiple sclerosis, symptomatic herniated lumbar disc, spinal stenosis and headache other than PDPH were excluded from the study.

Group1
Patient will receive oral caffeine 300mg and placebo block.

Group2
Sphenopalatine ganglion block and placebo tablet.
A written informed consent of the patient was taken .they were explain about procedure and technique for sphenopalatine Ganglion block.
After institutional ethics committee approval and informed written consent,30 ASA 1-2 patient selected for study based on inclusion and exclusion criteria. In sphenopalatine ganglion block, the patient need to be in supine position with neck extended, the extension can be facilitated with pillow or a folded sheet under both shoulder. A long applicator with a cotton swab at the tip is soaked with 2-4% lidocaine or viscous lidocaine. It is then inserted parallel to the floor of the nose until resistance is encountered. The swab will be at the posterior pharyngeal wall superior to middle turbinate.
The applicator should be retained in the nostril for 5-10 min and then removed. This procedure is similarly repeated to other nostril. The swab does come into direct contact with ganglion. However, the local anesthetic infiltrate around it in that position. The connected tissue in mucous membrane facilitate the spread and penetration of drug.
In the ward, all patient who underwent LSCS under subarachnoid block are followed from 6 hour post procedure until 3 days after surgery.
First visit was made 6 hour after surgery and every 12 hour for 3 days. All the patient were questioned about any subjective symptoms of headache, nausea and vomiting.
Those complaining of headache were ask about location, nature and severity of headache, whether by sitting, coughing and relieved by lying down. They were asked to mark on visual analogue scale, the intensity and severity of headache. The degree of pain was assessed with the help of visual analogue scale (VAS).

Assessment of pain
Various scales are being used for assessment of pain of which most sensitive scale is visual analogue scale (VAS).
The following picture show the visual analogue scale:



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Interpretation of pain using visual analogue scale

Marking of visual analogue scale	Degree of pain
0-3	Mild
4-7	Moderate
>7	Severe

Results

Table 1: showing group distribution according to study drugs

Groups	No. of Patients	Study Drugs and its Doses
Group I	15	Oral caffeine 300 mg and placebo block
Group II	15	Sphenopalatine ganglion block and placebo tablet

In our study, out of the 30 patients 15(50%) patients received Oral caffeine 300mg &placebo block and 15(50%) Patients received Sphenopalatineganglion block &placebo tablet.

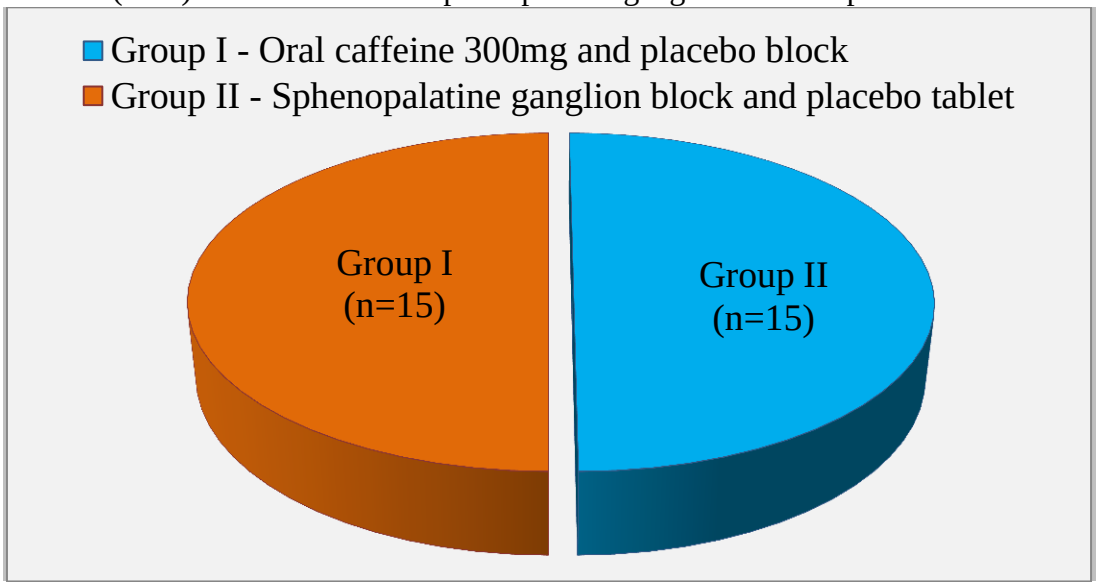

Table 2: Distribution of patients according to age in both the groups

Age Group (years)	Group				Total	
	Group I		Group II			
	No.	%	No.	%	No.	%
≤ 21 years	1	6.7%	1	6.7%	2	6.7%
22-24 years	7	46.7%	9	60.0%	16	53.3%
25-27 years	6	40.0%	3	20.0%	9	30.0%
28-30 years	1	6.7%	2	13.3%	3	10.0%
Total	15	100.0%	15	100.0%	30	100.0%
Mean±SD	24.60±1.92		24.47±2.38		24.53±2.12	
P value	.867					

Unpaired 't' test applied. P value <0.05 was taken as statistically significant*

Above table showing statistical analysis of demographic data regarding Mean +SD of age in year showing no statistically significant difference among the both group(p>0.05). The mean age was 24.53±2.12.

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Table3: Comparison of Visual Analogue Scale Score before and after the intervention between both the groups

VAS	N	Group 1 Mean±SD	Group 2 Mean±SD	T value	95% Confidence Interval of the Difference		P value
					Lower	Upper	
Before treatment	30	6.13±1.598	6.00±.000	.323, df=28	-.712	.978	.749
After 6 hours	30	5.73±2.120	5.20±2.111	.690, df=28	-1.049	2.116	.496
After 12 hours	30	4.53±2.446	4.93±2.120	-.479, df=28	-2.112	1.312	.636
After 24 hours	30	4.13±2.200	3.73±2.120	.507, df=28	-1.216	2.016	.616
After 36 hours	30	3.33±1.952	2.80±1.971	.745, df=28	-.934	2.001	.463
After 48 hours	30	3.20±1.821	1.60±1.352	2.733 df=28	.401	2.799	.011*
After 60 hours	30	2.40±1.724	1.20±1.014	2.324, df=28	.142	2.258	.028*
After 72 hours	30	2.00±1.512	.67±.976	2.870, df=28	.382	2.285	.008*

Unpaired 't' test applied. P value <0.05 was taken as statistically significant*

It is evident from the above table showing statistical analysis of VAS score between the groups at different time interval.

Significant reduction in VAS score was observed in both the groups at different time intervals but the difference between the two groups was statistically insignificant (P>0.05) at 6 hours ,12 hours, 24 hours ,36 hours . The decline in VAS score in group 2 was statistically significant (p>0.05) after 48 hours, 60 hours and 72 hours of block as compared to group 1.

Table 4: Severity of pain after 48 hours

Severity	Group				Total	
	Group I		Group II			
	No.	%	No.	%	No.	%
No Pain	3	20.0%	5	33.3%	8	26.7%
Mild	2	13.3%	8	53.3%	10	33.3%
Moderate	10	66.7%	2	13.3%	12	40.0%
Severe	0	0.0%	0	0.0%	0	0.0%
Total	15	100.0%	15	100.0%	30	100.0%

Pearson Chi-Square = 9.433, df = 2, p value = .009, Significant

It is evident from the above table showing severity of pain at 48 hours reflecting statistically significant difference in the groups. (p=.009)

Table 5: Severity of pain after 60 hours

Severity	Group				Total	
	Group I		Group II			
	No.	%	No.	%	No.	%
No Pain	4	26.7%	6	40.0%	10	33.3%
Mild	4	26.7%	9	60.0%	13	43.3%
Moderate	7	46.7%	0	0.0%	7	23.3%

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Severe	0	0.0%	0	0.0%	0	0.0%
Total	15	100.0%	15	100.0%	30	100.0%

Pearson Chi-Square = 9.323, df = 2, p value = .009, Significant

It is evident from the above table showing severity of pain at 60 hours reflecting statistically significant difference with the groups. (p=.009)

Table 6: Severity of pain after 72 hours

Severity	Group				Total	
	Group I		Group II			
	No.	%	No.	%	No.	%
No Pain	4	26.7%	10	66.7%	14	46.7%
Mild	7	46.7%	5	33.3%	12	40.0%
Moderate	4	26.7%	0	0.0%	4	13.3%
Severe	0	0.0%	0	0.0%	0	0.0%
Total	15	100.0%	15	100.0%	30	100.0%

Pearson Chi-Square = 6.905, df = 2, p value = .032, Significant

It is evident from the above table showing severity of pain at 72 hours reflecting statistically significant within the groups.(p=.032)

Discussion

The present study entitled "A comparative clinical study to assess the effectiveness of sphenopalatine ganglion block and oral caffiene in management of postdural puncture headache following lower segment caesarean section" prospective, randomized,observational study including 30 patients (ASA grade 1 and 2) divided into 2 groups as group 1 and group 2 with 15 patients in each group. Group 1 received the conventional treatment in the form oral caffeine and placebo block where as Group 2 received Transnasal Sphenopalatine ganglion block and placebo tablet as the treatment for PDPH.

We compared the efficacy of oral caffeine and Transnasalsphenopaltine ganglion block for the treatment of PDPH in obstetric patients who underwent LSCS under subarachnoid block.

Intergroup comparison of vas score

In the present study we observed the difference in VAS score at different time duration in between the groups.

As shown in table no.7 reduction in VAS score was more in group 2 as compared to group 1 at all the time interval except at 12 hours .The difference in reduction in VAS score was statistically insignificant up to 36 hours($p>0.05$). Statistically significant reduction in VAS score observed thereafter at 48 hour, 60 hours and 72 hour ($P<0.05$). Similar study conducted by Kumar et al[9] in there study compared the efficacy of sphenoapaltine ganglion block and conservative treatment in management of PDPH. There was statistically significant reduction in VAS score in the SPGB group as compared to conservative group($P=0.001$). At 72 hours of treatment, 95% of patients of SPGB group and 5.26% patients of conservative group were found ready to discharge. Results of our study are in accordance withKhanoojaet al[10]who also conducted a randomized study in which they compared conservative treatment alone and conservative treatment along with SPGB for PDPH. They found that VAS scores were significantly lower in SPGB group when compared to conservative group at 0.5, 4, 24, 48 and 72 hours with p value of <0.001. In our study also, VAS scores were significantly lower in SPGB group when compared to the caffeine group at 48 hour,60 hour and 72 hours (P value < 0.05). The result of our study also correlated with the finding of study conducted by Boharaet al[11]a study comparing the efficacy of SPG block and conservative treatment in obstetrics patient suffering from PDPH. They found a significant lower pain scores in SPGB

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group when compared to conservative group and concluded that SPG block could be used effectively in management of PDPH.

Putheveettilet al[12]alsoconducted a similar study to assess the efficacy of sphenopalatine ganglion block for treatment of PDPH and they concluded that SPG block was found to be significantly better ($p<0.01$) than conservative treatment for the treatment of PDPH. Another study conducted by Schaffer et al[13] conducted study to compare effectiveness of bupivacaine and normal saline in SPG block for management of acute headache in emergency department also showed similar result as our study results. Cohen et al [14] conducted a retrospective study of 81 patients comparing SPG block with EBP and found larger no. of patients with significant pain relief at 30 and 60 min after SPG block than with EBP. SPG block was found to be cost effective treatment which could be done as outpatient procedure without need for a OT room.

As shown in table no.4 at 48 hours out of 15 patients only 5(33.3%) patients of group 2 and 3(20.0%) patient in group 1 had complete relief of pain. No patients had severe pain in both the groups. 10(66.66%) patients had moderate pain relief in group 1 while 2(13.3%) in group 2. 2 (13.3%) patient had mild pain relief in group 1 and 8(53.3%) in group 2.The difference in result between the groups is statistically significant ($P>0.05$).

As shown in table no.5 at 60 hours out of 15 patients only 6 (40.0%) patients of group 2 and 4(26.7%) patient in group 1 had complete relief of pain. No patients had severe pain in both the groups. 7(46.7%) patients had moderate pain relief in group 1 while 0(0%) in group 2. 4(26.7%) patient had mild pain relief in group 1 and 9 (60%) in group 2.The difference in result between the groups is statistically significant ($P>0.05$).

As shown in table no.6 at 72 hours out of 15 patients only 10(66.6%) patients of group 2 and 4(26.7%) patient in group 1 had complete relief of pain. No patients had severe pain in both the groups. 4(26.7%) patients had moderate pain relief in group 1 while 0(0%) in group 2. 7(46.7%) patient had mild pain relief in group 1 and 5(33%) in group 2.The difference in result between the groups is statistically significant ($P>0.05$). As the time duration increase the effective of SPG block improve and no. patient with complete pain relief also increase.

Khanoojaet al[10]who also conducted a similar randomized study in which they compared conservative treatment alone and conservative treatment along with SPGB for PDPH. They found that VAS scores were significantly lower in SPGB group when compared to conservative group at 0.5, 4, 24, 48 and 72 hours with p value of <0.001. In our study also, VAS scores were statistically significantly lower in SPGB group when compared to the caffeine group at 48 hours 60 hours and 72 hours (P value < 0.05). 91.66% patients were ready to discharge at 72 hours in SPGB group. Result of our study are similar to those of Puthenveettil et al[12] who conducted a observation study to assess the efficacy of NASIDs and sphenopalatine ganglion block for the treatment of PDPH in obstetric patients . They found out that 88.88% patients in SPGB group had complete pain relief and statistically significant difference ($P<0.001$). They also conclude that SPGB is an effective modality for management of PDPH.

Kumar et al[1] in there study compared the efficacy of sphenoapaltine ganglion block and conservative treatment in management of PDPH. There was statistically significant reduction VAS score in SPG block group in comparison to conservative treatment group. At 72 hours of treatment 95% of patients group SPG block and 5.26% of patients' conservative group were found ready to discharged.

Summary

The present prospective randomized comparative study was undertaken to evaluate the efficacy of sphenopalatine ganglion block and oral caffeine in management of postdural puncture headache in patient undergoing lower segment cesarean section under subarachnoid

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block in G.R. medical college and J. A. Group of Hospitals. 30 obstetric patients in the age group of 18-40 years belonging to ASA grade I & II, who developed PDPH after undergoing Lower segmental caesarean sections were enrolled based on the inclusion and exclusion criteria.

In present study in group 1 intragroup statistical analysis showed statistically significant reduction in VAS score starting from 12 hours post treatment and it continued till 72 hours post treatment (VAS score=2.00+1.512 and p value=0.000), while in group 2 statistically significant effect was observed from 24 hours post treatment which also continued till 72 hours post treatment(VASscore=0.67+0.976and p value 0.000).

In present study the inter group statistical analysis of both the groups showed Significant reduction in VAS score which was observed in both the groups at different time intervals but the difference between the two groups was statistically insignificant (P>0.05) at 6 hours ,12 hours, 24 hours ,36 hours . But, the decline in VAS score in group 2 was statistically significant (p>0.05) after 48 hours, 60 hours and 72 hours of block as compared to group 1

Conclusion

For our clinical comparative study, it can be concluded that

1. The time of onset of SPGB is faster than oral caffeine 300 mg in treatment of PDPH.
2. The efficacy of SPGB in treatment of PDPH is superior than oral caffeine 300 mg.
3. None of the treatment modalities used in the study have any serious adverse effects.
4. The transnasal SPGB can be used as an effective And safe modality for treatment of PDPH.

Limitations

1. The study sample size was smaller.
2. The first assessment after giving treatment was done at 6 hours, while in some patients might had experienced pain relief earlier than 6 hours.
3. The study was carried out only on obstetric patients.
4. It was not blinded study as patients anaesthetist performing the block and person collecting data were aware of group allocated.

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