

Prospective Trial

Verification of Sphenopalatine Ganglion Block Success Using Transcranial Doppler in Management of Patients with Postdural Puncture Headache

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Background: Sphenopalatine ganglion block (SPGB) is traditionally advised in the management of head and neck pain. Since SPGB is a minimally invasive, repeatable, and simple technique, SPGB should be tried first in the management of postdural puncture headaches (PDPH). Verification of the block's success in diagnostic, prognostic, and therapeutic nerve blocks, is of paramount importance in pain management.

Objectives: This study intends to prove the ability of SPGB in the management of PDPH. Transcranial Doppler (TCD) is utilized as an objective measure to assess the block's success by monitoring variations in the cerebral hemodynamics before and after the block procedure. Noninvasive intracranial pressure (nICP) was applied to support the theory which assumes that the vasodilation of the cerebral blood vessels is the precipitating cause of the PDPH, rather than intracranial hypotension.

Study Design: Prospective, triple blinded, controlled, clinical trial.

Setting: This clinical trial was conducted at Zagazig University.

Methods: In the present study, 123 patients were considered who had spinal and/or epidural anesthesia; 63 patients who developed PDPH joined treatment group A and received the SPGB block. The control group B included 60 patients with no PDPH. The patients in group A were evaluated preprocedure by a numerical pain score and at 30 minutes, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours postprocedure. Furthermore, patients in both groups were evaluated employing TCD before the transnasal block was given, then it was repeated to group A only within one hour after the block.

Results: Results analysis revealed that preprocedural pulsatility index (PI) and mean flow velocity (MFV) values in treatment group A were (mean \pm standard deviation [SD]) 0.63 ± 0.04 and 57.20 ± 4.85 cm s^{-1} , respectively. Values of PI and MFV were significantly increased up to (mean \pm SD) 0.87 ± 0.08 and 71.15 ± 7.686 cm s^{-1} , respectively after the block. The computed nICP values preblock and postblock were also within the normal range.

Limitations: Performing SPGB without standardized equipment may limit the results of the current study

Conclusions: SPGB should be considered as a first treatment modality for PDPH. Moreover, the results indicate that TCD is a successful objective tool in assessing a transnasal sphenopalatine ganglion block.

Key words: Noninvasive intracranial pressure, postdural puncture headache, sphenopalatine ganglion block, transcranial Doppler

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Postdural puncture headache (PDPH) is a major complication of regional anesthesia (spinal/epidural with iatrogenic dural puncture). The reported incidence of PDPH could be as high as 76%–85% after dural puncture using an epidural needle (1). More than 85% of PDPHs are relieved with conventional treatments, including bed rest, intravenous hydration, caffeine supplementation, and analgesic medication, gabapentinoids, and sumatriptan (2,3). In some patients, the headache lasts for months or perhaps years, and if not appropriately managed could progress into a chronic headache. A rare fatal sequelae of an untreated PDPH, caused by traction on bridging cerebral veins, is the development of intracranial subdural hematoma. Thus, given this fact, more interest in understanding its precise management is needed (4).

Sphenopalatine ganglion block (SPGB) is a developed procedure engaged in the management of patients who have head and neck pain. Transnasal sphenopalatine ganglion block (TN-SPGB) has been commonly used in patients with chronic conditions such as migraine, trigeminal neuralgia, and facial pain, and has produced valuable results in a recent case series to treat acute PDPH headache in postpartum patients (5,6). The sequelae accompanying the transnasal approach are mild and include mild discomfort during the technique, bleeding, infection, and numbness of the throat (4). Wasserman et al (7) performed a retrospective study to assess face temperature changes postblock and recommended further work is needed to assess autonomic changes that accompany SPGB. Kim et al (6) reported that there is a lack of objective methods for confirming the success of SPGB. They introduced facial temperature changes as an objective tool for validating the success of SPGB; unfortunately, their study had limitations such as the fact that it was a retrospective study without a control group and enrolled healthy individuals.

Using transcranial Doppler (TCD) to analyze the pulsatile cerebral blood flow velocity (CBFV) waveform of the intracranial arteries can provide information regarding various cerebrovascular changes (8). There have been great advances in TCD applications, as it was initially used for detecting vasospasm in subarachnoid hemorrhage and in brain stem death; more recently it has been used to predict the outcomes of patients with traumatic brain injury (9). The cerebral blood flow resistance can be measured by pulsatility index (PI) (10). Naqvi et al (11) also documented that low PI may be attributed to arteriolar vasodilation while blood vessel occlusion or constriction may increase the PI.

Employing TCD to detect the effects of SPGB on cerebral hemodynamics has not yet been reported in the available literature. Thus, this study aimed to assess the TCD as a new objective tool for verifying SPGB. This paper also aims to explore whether the reflex vasodilatation mediated by parasympathetic fibers of the SPG, and the reversal of this vasodilation by SPGB, can be assessed by TCD. Results denoted that the preprocedure and postprocedure differences in PI and mean flow velocity (MFV) of the middle cerebral artery were significantly different. Consequently, TCD would be considered as an effective monitoring modality in the context of block success verification.

METHODS

This prospective nonrandomized clinical trial was approved by the Institutional Review Board in Zagazig University (IRB #6140), and the study was implemented in Zagazig University Hospitals. Informed consent was obtained from all patients after illustration of the procedures. It was also registered at ClinicalTrials.gov (NCT04401878, registration date May 23, 2020). The patients' enrollments were after the registration date (on May 24, 2020).

This study was performed in a postoperative orthopedic ward and included 123 patients divided into 2 groups: the treatment group (A) and the control group (B). Group A recruited 63 patients with a history of spinal and/or epidural anesthesia who complained of PDPH within 5 days after the dural puncture. Group B included 60 patients with a history of spinal and/or epidural anesthesia with no PDPH. Two patients were excluded at the start of the study, one due to his history of epistaxis and the other due to associated nasal fracture. One patient was also excluded during the study due to an inadequate acoustic temporal window, see Fig. 1.

Inclusion Criteria:

- Patients who have a history of spinal and/or epidural anesthesia within 5 days after the dural puncture.
- Patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II
- Patient's age ranged from 18 to 60 years of both genders.

Exclusion Criteria:

- Patients with any nasal deformity or epistaxis
- Patients who had recent nasal trauma or surgery (fewer than 3 months ago)

- Patients who had a fever (38°C)
- Known patients with coagulopathy
- Any facial lesion hindering appropriate TCD examinations
- Patients with cardiorespiratory diseases
- Patients with cerebrovascular diseases
- Uncooperative patients.

Sample Size

According to Vadhera et al (12), mean velocity before treatment was $79.8 \pm 11.8 \text{ cm s}^{-1}$ and $89 \pm 14.1 \text{ cm s}^{-1}$ after treatment. A total sample size of 14 (7 in each group) was sufficient to detect a power of 80% and a significance level of 5%. The number was increased to a total sample size of 17 to allow for use of a nonparametric test. To allow for 25% losses, the sample size was further increased to 22 patients (11 per group). Sample size estimation was performed by G*Power statistical package (Düsseldorf, Germany). This study considered 120 cases.

Patient Preparation

Prior to the procedure, the patient's nose was inspected for any obstruction, and xylometazoline 0.05% nasal drops (one drop in each nostril) were used to help open the nasal passages. A small amount of 2% lidocaine jelly was applied in each nostril for the patient's comfort. Standard ASA monitors were applied.

Procedure Steps

Patients in treatment group A received bilateral transnasal SPGB with 2% lidocaine when they were diagnosed as having PDPH. A long applicator was employed using a hollow cotton-tipped culture swab as an applicator, connected with a 21-gauge needle, which was also attached to a 3 mL syringe filled with 2% lidocaine, 1.5 mL for each nostril (Fig. 2). The applicator was soaked with 2% lidocaine, then inserted parallel to the floor of the nose until resistance was felt while the patients were lying supine. The swab was at the posterior pharyngeal wall superior to the middle turbinate. The applicator was kept in the nostril for the requisite 5 to 10 minutes with slow injection and the patient was instructed to inform the physician who perform the block if a bitter taste sensation is felt. The patient was slightly tilted to keep the side blocked in a dependent position. This procedure was repeated in the other nostril. The patient was then asked to remain in the same position for 10 minutes.

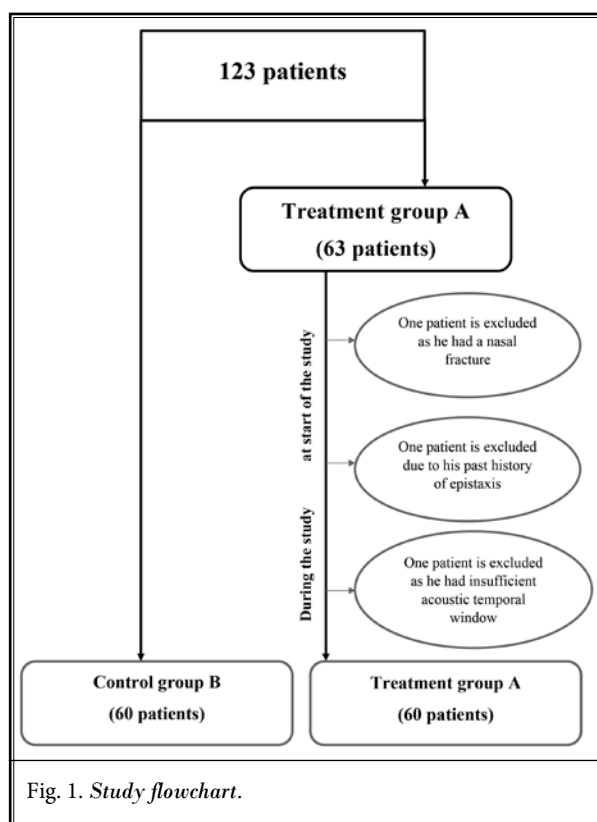


Fig. 1. Study flowchart.

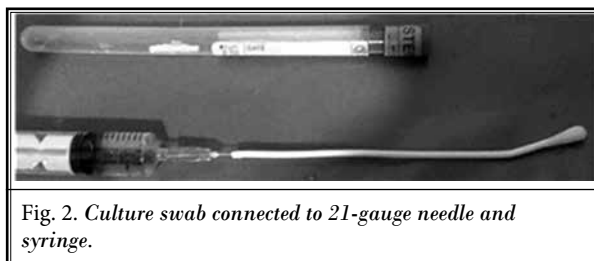


Fig. 2. Culture swab connected to 21-gauge needle and syringe.

Pain was assessed by healthcare providers who were unaware of patient groups or design of the study at preprocedure (T0), 30 minutes (T1), 2 hours (T2), 4 hours (T3), 6 hours (T4), 12 hours (T5), and 24 hours (T6) postprocedure using a numeric rating scale (NRS), where 0 is no pain and 10 is the worst pain imaginable. Pain relief is considered when $\text{NRS} < 4$.

All patients in group A were instructed to have conservative treatment such as bed rest while supine, to maintain good hydration, and to drink caffeine beverages. If the pain score remained ≥ 4 at T1, the block was repeated in parallel with another TCD examination. No pain assessment was performed in group B as the enrolled patients in this group had no headache after neuraxial anesthesia.

TCD Technique

TCD measurements were performed in both groups, before the block was given, then it was repeated in group A only within one hour after the block. A single experienced operator, who was unaware of the patient groups, performed all TCD measurements. Color Doppler-Ultrasound equipment (Siemens Acuson X300 ultrasound machine, Siemens Medical Solutions USA Inc., Malvern, PA) with P 4-2 phased array 2MHz probe was utilized. For all patients, both middle cerebral arteries were insonated through the transtemporal window over the zygomatic arch in front of the tragus of the ear at a depth of 50-60 mm. Tracings were also recorded for at least 10 cardiac cycles according to the technique described by Aaslid et al (13). Noninvasive intracranial pressure (ICP) was calculated using PI by applying the formula of Bellner et al (14).

Statistical Method

Data were analyzed using Statistical Package for Social Sciences version 21 (IBM Corporation, Armonk, NY). Numerical data were described as mean and standard deviation, and categorical data were labeled as number and percent. Independent sample t-test was applied to compare numerical variables between cases and the

control group, while paired t-test was applied to compare numerical variables before and after treatment. χ^2 test was employed to compare categorical data between patients and controls. A P value ≤ 0.05 was considered statistically significant and all tests were 2-tailed.

RESULTS

The results revealed no significant difference between groups A and B regarding demographic data: age, gender, weight, and height, as well as patients' characteristics (hemoglobin, temperature, mean arterial pressure, and heart rate) (Table 1).

Referring to Table 2, the values of PI and MFV were significantly different between patients in treatment group A before performing SPGB (mean \pm standard deviation [SD]: 0.63 ± 0.04 and 57.20 ± 4.85 cm s⁻¹, respectively) and patients in control group B (mean \pm SD: 0.89 ± 0.09 and 69.71 ± 4.25 cm s⁻¹, respectively).

A significant difference between PI and MFV values in group A before performing the block (mean \pm SD) were 0.63 ± 0.04 and 57.20 ± 4.85 cm s⁻¹, respectively and after performing the block (mean \pm SD) were 0.87 ± 0.08 and 71.15 ± 7.69 cm s⁻¹, respectively, as presented in Table 3. Samples of TCD readings for both groups are depicted in Fig. 3.

Pain was assessed by NRS at preprocedure (T0) and at 30 minutes (T1), 2 hours (T2), 4 hours (T3), 6 hours (T4), 12 hours (T5), and 24 hours after the procedure (T6). As seen in Table 4, the pain significantly decreased after the block between T0 preprocedure (mean \pm SD ; 8.12 ± 1.14) and at T1 (mean \pm SD; 1.62

Table 1. Comparison between group A and group B regarding demographic data and patients' characteristics.

Variables	Group A		Group B		t-Test/ χ^2 test	P value
	Mean \pm SD n = 60		Mean \pm SD n = 601			
Age (years)	31.3 \pm 9.3		33.1 \pm 10.1		-0.608 T	0.547
Gender	No.	%	No.	%		
Male	7.00	35.0%	12.00	42.9%	2.02 χ	0.160
Female	13.00	65.0%	9.00	57.1%		
Height (cm)	171.3 \pm 7.3		171.0 \pm 8.6		0.100 T	0.921
Weight (kg)	73.4 \pm 9.8		71.5 \pm 13.1		0.520 T	0.606
BMI (kg m ⁻¹)	24.94 \pm 2.18		24.26 \pm 2.68		0.902 T	0.373
Hematocrit (%)	40.45 \pm 5.16		39.77 \pm 4.23		0.468 T	0.642
MAP (mm Hg)	89.7 \pm 3.8		90.1 \pm 3.6		-0.384 T	0.703
Heart rate (bpm)	85.9 \pm 11.3		85.3 \pm 8.8		0.194 T	0.847
Temperature (°C)	36.9 \pm 0.3		36.7 \pm 0.2		2.530 T	0.017

Numerical data are presented as mean \pm SD, categorical data are labeled as number and percent, independent sample t-test; (T), Chi square test (χ^2), P value ≤ 0.05 was considered statistically significant.

Table 2. Comparison between group A and group B regarding Pulsatility index, mean flow velocity, and noninvasive ICP before performing SPGB.

Variables	Group A	Group B	t-Test	P value
	Mean \pm SD n = 60	Mean \pm SD n = 60		
Pulsatility index (before block)	0.63 ± 0.04	0.89 ± 0.09	20.847 T	< 0.001
Mean velocity (cm s ⁻¹) (before block)	57.20 ± 4.85	69.71 ± 4.25	-8.792 T	< 0.001
non-invasive ICP	5.59 ± 0.48	8.48 ± 0.96	20.847 T	< 0.001

Numerical data are described as mean \pm SD, categorical data were labeled as number and percent, independent sample t-test; (T), P value ≤ 0.05 was considered statistically significant.

± 1.83) postprocedure; also there was a second pain peak that occurred at T5 (mean \pm SD; 2.67 ± 1.46) as seen in Fig. 4. In group A, 55 of 60 patients showed pain relief 5 minutes after the block. Only 5 patients showed no pain relief at T1 in parallel with no significant change in MFV and PI after the block. Accordingly, the block was successfully repeated. Another 2 patients indicated no significant changes in TCD readings after the block, although they showed significant pain relief. The pain returned to 6 patients at T4 and T5. Thus, the block was also successfully repeated.

DISCUSSION

PDPH is thought to be due to cerebral vasodilatation, which is mediated by parasympathetic nerve fibers that have synapses in the SP ganglion. This parasympathetic activity can be blocked by TN-SPGB (15). The SPG also has a dual sympathetic innervation via both the vidian nerve and the maxillary artery nerve plexus. Therefore, the block of the sympathetic fibers initially overrides the parasympathetic block, hence, clinical signs such as lacrimation and face temperature changes have been noticed after SPGB (7,16).

Kim et al (6) followed Wasserman et al (7) using face temperature changes assessment as an objective measure for validation of SPGB success. In their retrospective study they recommended that the assessment of the cranial autonomic changes after SPGB needs further investigations

Although lacrimation is a reliable sign of block success (17), it is not a frequent sign to rely on, as demonstrated by Cady et al (18) in a placebo-controlled

study. They reported that lacrimation occurred in only 29% of patients after SPGB in the bupivacaine group.

A significant difference between PI and MFV values in group A before and after performing the block was attributed to the reversibility that occurred in cerebral

Table 3. Difference in PI, MFV, and noninvasive ICP for patients in group A before and after performing SPGB.

Variables	Before SPGB (n = 60)	After SPGB (n = 60)	Paired-Test	P value
Pulsatility index	0.63 \pm 0.04	0.87 \pm 0.08	-19.569	< 0.001
Mean velocity (cm s ⁻¹)	57.20 \pm 4.85	71.15 \pm 7.69	-9.152	< 0.001
non-invasive ICP	5.59 \pm 0.48	8.31 \pm 0.88	-19.569	< 0.001

Numerical data are presented as mean \pm sd, P value \leq 0.05 was considered statistically significant.

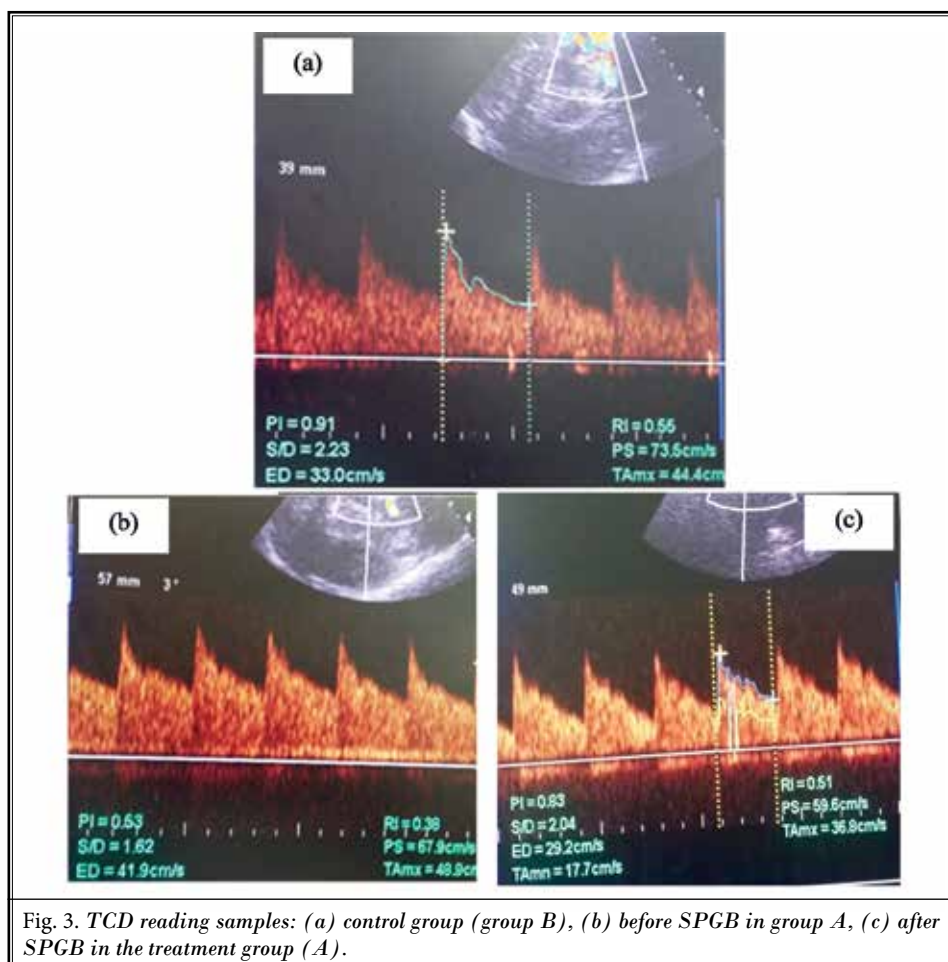


Fig. 3. TCD reading samples: (a) control group (group B), (b) before SPGB in group A, (c) after SPGB in the treatment group (A).

Table 4. Distribution of pain scores throughout the study period.

Pain score	Mean \pm SD	Test *	P value
T0	8.12 \pm 1.14		
T1	1.62 \pm 1.83	207.8	< 0.001
T2	1.63 \pm 0.96		
T3	1.80 \pm 0.95		
T4	2.42 \pm 1.42		
T5	2.67 \pm 1.46		
T6	2.65 \pm 0.66		

*Friedman's test, post hoc test showing the significance present among all variables.

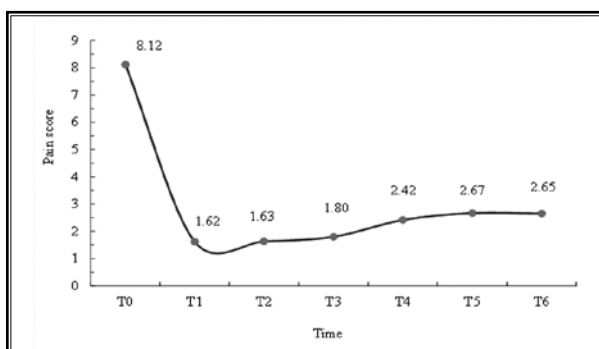


Fig. 4. Distribution of numerical pain score before and within 24 hours after the block.

blood vessel resistance after blocking the parasympathetic fibers that have a synapse in the SPG. When the arterial lumen diameter increased as a result of the activity of parasympathetic fibers in the SPG, the blood flow velocity subsequently decreased. After these parasympathetic fibers were blocked, the normal caliber of cerebral vessels was restored; this coincided with an increase in MFV values in middle cerebral arteries.

The factors that affect MFV and thereby PI are cardiac output, partial pressure of carbon dioxide, hematocrit, cerebral vascular compliance, and body temperature changes (19). With these facts in mind, the current study is based on exclusion of patients with cardiorespiratory diseases as well as patients with central vasculature diseases. Regarding patient characteristics, patients who suffered from fever were also excluded. Hematocrit levels were within normal range in the enrolled patients in both groups, additionally, the difference between the groups regarding patients' characteristics was not significant.

The role of TCD in postpartum patients with PDPH, who were managed by evidence-based practice (EBP), sumatriptan, and caffeine, was examined by Vadhera

et al (12). They believed that TCD is a useful tool for monitoring treatment effectiveness as TCD detects the reversal of cerebral vasodilation after medical management in those patients. However, Vadhera et al (12), in their study, considered only the effect of cerebral vascular resistance on PI and ignore the effect of ICP.

The current results indicate that the preprocedural MFV in group A were (mean \pm SD) 57.2 \pm 4.9 cm s⁻¹. These results are lower than the outcomes of (12) where the values of pretreatment MFV, before initiation of any patient's management, were (mean \pm sd) 79.8 \pm 11.8. Besides that, the preprocedural PI values (mean \pm SD; 0.59 \pm 0.08) in the current investigation were higher than the pretreatment PI values of (12) (mean \pm SD; 0.63 \pm 0.04). This may be due to the different demographic data of patients in both investigations, as they considered only postpartum patients with an age range lower than the one selected for the current study (18 - 60 years old, in both genders). As documented in the literature, changes in values of PI and MFV occur along with changes in age and gender. Tegeler et al (20) accomplished a comprehensive study on 364 healthy individuals aged 18 to 80 years. They demonstrated that MFV was decreased with the aging process and a higher MFV was observed in women than in men. Their results were also confirmed by Arnolds and von Reutern (21).

The cerebral resistance resumed after the block as the PI and the MFV values were significantly higher than before the block. Also, a significant difference regarding the TCD parameters between group A who have headache and group B with no headache, was observed. These findings proved the theory that the cerebral vasodilation was the cause of PDPH. Vadhera et al (12) reported that the significant difference was only between PI values before and after the patients' management (either by medical treatment or epidural blood patch), and no significant change was noticed with MFV. The current findings showed a significant change with both PI and MFV; it is worth noting that the discrepancy between the 2 studies was initially attributed to the difference in the used treatment modality in between the 2 investigations, along with the relatively larger sample size enrolled in the present study.

De Riva et al (22) illustrated that PI is a representative parameter of varied hemodynamic values such as ICP and cerebral vascular resistance. Bellner et al (14) introduced a formula for calculating ICP noninvasively (nICP) using PI as follows: n ICP = (10.93 \times PI) - 1.28 (1)

In contrary to the theory that supposes that cerebral hypotension is the cause of headache (23), the findings

of the current study revealed that the values of the computed nICP pre- and postblock in group A were within the normal range (mean \pm SD; 5.59 ± 0.48 mm Hg, and 8.31 ± 0.88 mm Hg, respectively). Thus, it is assumed that the changes in PI values before and after the block mainly mirror the changes in a cerebral vessel's caliber.

Puthenveettil et al (4) documented that adequate pain relief had occurred within 5 minutes and the recovery rate was 88.89% in 20 postpartum obstetric patients who were managed with SPGB. In this study, we support the findings of (4) as SPGB proved to be effective in the management of PDPH. The recovery rate was 91.7% of patients, including in the treatment group (A) at T1. The current results also revealed that pain relief was continued for 24 hours in 54 patients, and for 6 to 12 hours in the other 6 patients. This attributed to initiation of the conservative management considered earlier in the present investigation. All patients were instructed to maintain good hydration, drink caffeine beverages, and get bed rest in a supine position. Another contributing factor that may have affected the results is that this study was carried out in already nonambulant orthopedic patients, not in postpartum patients; bed rest is well tolerated in these orthopedic patients but not tolerated in postpartum patients who have the burden of caring for a baby.

Evaluation of the severity of the headache was done by NRS 30 minutes after the block (T1). Fifty-five patients showed a significant pain improvement after the block at T1, only 5 patients had a pain score ≥ 4 at T1, and their TCD examination revealed no change in cerebral vascular resistance after the block. Thus, the block was considered technically failed and it was repeated a second time. The pain score decreased to less than or equal to 3 when the block was repeated for those 5 patients, which coincides with TCD parameters changes this time. Another 2 patients showed no changes in TCD parameters after the block throughout the study; their pain score surprisingly decreased to ≤ 3 at T1. The pain reduction in such cases may be attributed to many assumptions. One of them is the mechanical stimulation of the SPG as introduced by Schaffer et al (24). They conducted a randomized placebo-controlled trial of SPGB for management of frontal headache. They believed that there was no significant difference between the groups in their study (bupivacaine 0.5% group versus saline group) in achieving pain relief postblock. Pain reduction may also be due to sensory stimulation of the ganglion, if the ganglion is at an unusual or inaccessible location. The latter assumption was supported by Majedi et al (25) who documented their observations in a case report of a 33-year-old patient

with chronic headaches. This patient was prepared for radiofrequency (RF) denervation of the SPG. Majedi et al (25) faced a technical problem while they advanced the RF needle in the SP fossa, as the ganglion was found at an unusual location. However, this patient showed a satisfactory response after transnasal injection of a local anesthetic. So, future examinations are required in this specific situation.

Standardized instruments for TN-SPGB are not available in our institute, which placed certain limits on the current investigation. In order to compensate for the defect in resource availability, the technique offered by Grosh and Ayubcha (26) was followed due to the availability of its components at our hospitals. The flexible culture swab was angled nearly to 45° to ensure reaching the SP ganglion posteriorly to the middle turbinate; slow administration of local anesthetic by the attached syringe can then take place. Thus, avoiding pooling of local anesthetic at the oropharynx guarantees a controlled delivery of the medication and a hold on the injection of the drug when a bitter taste sensation was felt by the patient.

The execution of TCD depends on the operator's experience and can be a challenge in nearly 10% - 20% of patients with an inadequate temporal window. With this fact in mind, a single experienced operator performed all TCD assessments. But it is still noted that the procedure showed an intraobserver variation that may affect the results of the current study (27). Another limitation of the present investigation was performing SPGB without standardized equipment. This was due to a shortage in these instruments at our hospital.

The current study recommends using SPGB in the management of PDPH, as well as using TCD as an objective tool in assessing the success of the block. SPGB can be assessed by TCD, which identifies the difference in CBFV and PI values in the major cerebral arteries pre- and postblock. This study also recommends that further studies in this context are needed, using standardized instruments for transnasal SPGB. Follow-up assessment of patients by NRS is also advised to last for a longer period.

CONCLUSIONS

The current study proved the effectiveness of SPGB in pain relief, which was maintained for 24 hours, in PDPH immediately after the block. Therefore, transnasal SPGB can be considered an attractive, rapid, and efficient treatment modality in PDPH. Analysis of the obtained data by TCD monitoring of the cerebral hemodynamics during SPGB also revealed that PI and MFV can be relied upon to verify the block's success.

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