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REVIEW ARTICLE

# Trans-nasal sphenopalatine ganglion block for post-dural puncture headache management: a meta-analysis of randomized trials

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**KEYWORDS**
Post-dural puncture headache;
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Headache;
Pain management;
Conservative treatment

**Abstract**
*Objective:* To evaluate the efficacy and safety of trans-nasal Sphenopalatine Ganglion (SPG) block over other treatments for Post-Dural Puncture Headache (PDPH) management.
*Methods:* A systematic literature search was conducted on databases for Randomized Controlled Trials (RCTs) comparing trans-nasal SPG blockade for the management of PDPH over other treatment modalities. All outcomes were pooled using the Mantel-Haenszel method and random effect model. Analyses of all outcomes were performed as a subgroup based on the type of control interventions (conservative, intranasal lignocaine puffs, sham, and Greater Occipital Nerve [GON] block). The quality of evidence was assessed using the GRADE approach.
*Results:* After screening 1748 relevant articles, 9 RCTs comparing SPG block with other interventions (6 conservative treatments, 1 sham, 1 GON and 1 intranasal lidocaine puff) were included in this meta-analysis. SPG block demonstrated superiority over conservative treatment in pain reduction at 30 min, 1 h, 2 h, 4 h after interventions and treatment failures with "very low" to "moderate" quality of evidence. The SPG block failed to demonstrate superiority over conservative treatment in pain reduction beyond 6 h, need for rescue treatment, and adverse events. SPG block demonstrated superiority over intranasal lignocaine puff in pain reduction at 30 min, 1 h, 6 h, and 24 h after interventions. SPG block did not show superiority or equivalence in all efficacy and safety outcomes as compared to sham and GON block.

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*Conclusion:* Very Low to moderate quality evidence suggests the superiority of SPG block over conservative treatment and lignocaine puff for short-term pain relief from PDPH.
*PROSPERO Registration:* CRD42021291707.


## Introduction

Post-Dural Puncture Headache (PDPH) is an associated complication of spinal anesthesia.[1] The mechanism of PDPH involves leakage of cerebrospinal fluid (CSF) through the puncture site and subsequently, a decrease in CSF pressure, leading to traction on the pain-sensitive structures of the brain and reflex vasodilation of the vessels of meninges caused by the parasympathetic nervous system. The reported incidence of PDPH varies from 10% to 40% depending on age, gender, and needle size.[2-4] PDPH is managed with conventional treatments, including bed rest, intravenous hydration, abdominal binders, methylxanthines, analgesics, gabapentinoids, and sumatriptan.[5] Epidural Blood Patch (EBP) is considered the gold standard over other treatments. Those patients who do not respond to conservative treatment within 48 h may require an EBP, which is considered the treatment of choice for moderate and severe PDPH, with success rates of 61—98%.[6-8] However, EBP is contraindicated in coagulopathies and local site infection and can lead to neurological infection and sequelae such as meningitis, arachnoiditis, seizures, loss of hearing or vision, radicular pain, and neural deficits.[4,9] Therefore, several other interventions have also been practiced for the treatment of PDPH like Sphenopalatine Ganglion (SPG) block and Greater Occipital Nerve (GON) block.[10-13]

SPG is predominantly a parasympathetic ganglion positioned in the pterygopalatine fossa. In addition to parasympathetic fibers, the ganglion also receives sympathetic and sensory projections and en route to innervate the cerebral and meningeal vessels. Increased parasympathetic activity leading to vasodilation of these vessels has been postulated to be a cause of various headache disorders including PDPH. SPG is considered a target in the management of various headache disorders.[14,15] SPG block for managing PDPH was first published by Cohen et al. in 2001[16] and subsequently, various case reports, case series, retrospective and observational studies reported the efficacy of this superficial, noninvasive, and technically simple block for successful pain relief in PDPH[17-19] although the results were inconclusive due to the paucity of reviews and lack of evidence.[20] An earlier pilot meta-analysis of observational studies found no significant therapeutic advantage over conventional treatments.[21] The literature on the use of SPG block for the management of PDPH is now available in Randomized Controlled studies (RCTs). So, we planned a meta-analysis of randomized trials to compare the efficacy of trans-nasal SPG block using a cotton-tipped applicator with other modalities for the treatment of PDPH.

## Methods

The current systematic review was conducted as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[22] The study protocol was prospectively registered to PROSPERO: CRD42021262516.

### Study identification

Two investigators independently and systematically searched the databases (PubMed, PubMed Central, Scopus, LILACS, Google Scholar, trial registry clinicaltrial.gov, and Cochrane Database of Systematic Reviews). Bibliographies of relevant narrative review articles, systematic reviews, and meta-analyses were also hand-searched to retrieve additional eligible studies. A literature search was conducted using the Boolean operator "AND" to combine the search terms: (post-dural puncture headache OR dural puncture headache OR PDPH) AND (sphenopalatine ganglion block OR pterygopalatine ganglion block OR SPGB). The last search was conducted on October 20, 2022. No language or time restrictions were applied to include the studies. Initially, two investigators independently assessed titles and abstracts as per the selection criteria. Subsequently, the full texts of relevant studies were assessed to decide the eligibility of retrieved articles. Any disagreements or discrepancies were resolved by discussion and consensus among the authors.

### Selection criteria of studies

Inclusion criteria: RCTs comparing the analgesic efficacy of SPG block with local anesthetic via trans-nasal approach using cotton-tipped applicator versus placebo or other interventions used to treat post-dural puncture headache.

Exclusion criteria: Studies performing SPG block by other routes or methods, retrospective studies, case reports, case series, abstract-only papers, or conference presentations, review articles, single-arm studies, duplicate studies (in such cases, studies with the most up-to-date and largest data were included).

### Types of interventions

SPG block with local anesthetic performed via nasal cavity using a cotton-tipped applicator in patients with PDPH and compared with other interventions used for the management of PDPH.

### Outcomes

The primary efficacy outcome was the pooled assessment of the effect of interventions in improving headache i.e., reduction in pain score at different time intervals (e.g., 30 min, 1 h, 2 h, 4 h, 6 h, 8 h, 12 h, 24 hours, and 7 days) used by the authors of the primary studies. The secondary efficacy outcomes were need for rescue treatment and

treatment failures. The overall adverse events associated with the intervention were presented as safety outcomes. The subgroup analysis of each outcome was conducted based on the control arm. The studies that compared SPG block with noninvasive pharmacological treatment modalities were considered the Conservative Group. Other comparators in control arms were intranasal lignocaine puff, sham block and GON block.

## Data extraction

Two reviewers independently searched for all the clinical trials using retrieved titles and abstracts from the databases. The following data were extracted from the included studies: first author, publication year, study design, demographics, type of neuraxial block, type and size of the spinal needle used, type of surgery, technique of SPG block, contact time of cotton-tipped applicator, local anesthetic used (type, dose, and volume), pain rating scale, comparator technique, number of participants in each treatment arm, follow up duration, analgesic efficacy, and safety outcomes. For the extraction, data of pain scores provided in the median (range and/or interquartile range) were converted into mean (standard deviation) using an online tool[23] based on Luo et al.[24] and Wan et al.[25] The corresponding authors of included studies were contacted in case of missing data on efficacy and safety outcomes. The data were collected on an Excel sheet and cross-checked by another investigator to ensure quality. Trials being excluded were reviewed by both authors before the final agreement. Any disagreements regarding study selection and exclusion were resolved by discussion and consensus among the investigators or by a third investigator in the meta-analysis.

## Data synthesis

The effect sizes were summarized as a Standardized Mean Difference (SMD) with 95% CI (Confidence Interval) in case of continuous data (pain score at different time intervals) and as a Risk Ratio (RR) with 95% CI in case of dichotomous data (need for rescue treatment, treatment failure, and adverse events). The pooled meta-analytic summaries were estimated through the Mantel-Haenszel method using a random-effect model with the DerSimonian-Laird approach. Heterogeneity was assessed using the $I^2$ test. A forest plot was used for the graphical display of the results of individual studies and meta-analytic summaries of each outcome.

SPG block and control interventions were considered "equivalent" when the RR (95% CI) of the meta-analytic summary was within the range of a clinically significant difference of 20% (0.80−1.20) in the case of dichotomous outcomes. More than 20% difference was considered as 'superiority' of SPG block over control interventions.[26] In the case of continuous outcomes, a meta-analytic summary (SMD [95% CI]) should be within the range of a clinically significant difference of 20 units (-0.20 to 0.20) to demonstrate the "equivalence" of interventions. More than a 20-unit difference was considered as "superiority" of SPG block over control interventions.[26]

## Risk of bias assessment of included studies

The risk of bias was assessed in the included RCTs by using the ROB-II scale. Two investigators used the ROB-II tool to assess the methodological quality of the included RCTs.[27] Each study was assessed for the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selective outcome reporting. The studies were categorized into "low risk", "high risk" or having "some concerns" in the risk of bias assessment.[27] The disagreements in the assessment were resolved through discussion and consensus among the authors. The sensitivity analysis of outcomes was performed based on the risk of bias assessment.

## Publication bias

Publication bias was assessed through a visual inspection of the "funnel plot" for asymmetry. It was plotted using (log [OR]) of effect size and standard error of each outcome.

## Certainty of the evidence

The GRADE approach was used to rate the certainty of the evidence for each efficacy and safety outcome. They were rated based on the risk of bias, imprecision, inconsistency, indirectness, and other factors (publication bias, magnitude of effect size, plausible confounding, and dose-response gradient). Each outcome was categorized into "high", "moderate", "low", or "very low" quality of evidence. The summary of findings table was created using GRADEpro software.[28,29]

The meta-analysis was conducted through the Review manager software version 5.4.1.

# Results

## Study characteristics

From the literature search, we retrieved 1748 references and assessed 29 full-text articles. A total of 9 RCTs with 381 patients fulfilling the selection criteria were included in the analysis (Fig. 1).[30-38] Among the included studies, eight studies performed bilateral SPG block and one study.[37] assessed unilateral SPG block. The block was performed using lidocaine 2%,[34-36,38] 4%[30-33] and 10%[37] along with ropivacaine 0.5%[32] or dexamethasone 4 mg[34,38] or adrenaline 1/2000000.[30] Among 9 included studies, there were 4 different modalities of interventions in the control group: sham SPG block using saline,[32] SPG block with 2 puffs of intranasal lidocaine 10%,[35] bilateral GON block,[38] and conservative measures which included noninvasive pharmacological methods (acetaminophen, diclofenac, tramadol, magnesium sulfate, theophylline, codeine and caffeine in various combinations along with intravenous fluids, abdominal binders and bedrest in 6 studies).[30,31,33,34,36,37] Regarding the dural puncture proceeding the PDPH, all studies included patients developing PDPH after spinal anesthesia except[31] Bohara et al. and Jespersen et al.[32] who included patients developing a headache after lumbar puncture and epidural anesthesia. The surgical procedure in 6 studies[31,34-38] was Lower

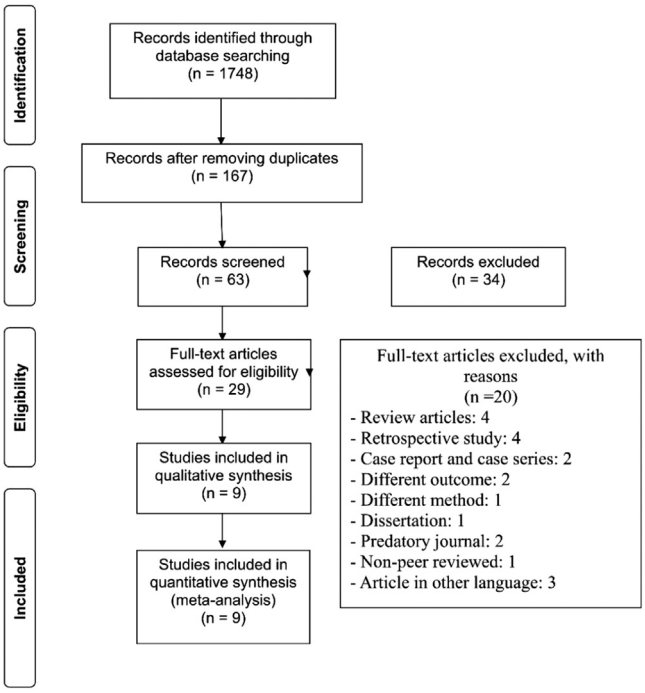


**Figure 1** PRISMA flow diagram showing the study selection process.

Segment Cesarean Section (LSCS), while 3 studies included patients with various surgeries and procedures conducted under spinal anesthesia.[30,32,33] Two studies reported pain score data in median (interquartile range).[30,34] One study used median (range) to report pain score data.[32] These outcome data were calculated to mean (standard deviation) using the online tool.[23] The general characteristics of the included studies are summarized in Table 1.

## Risk of bias in included studies

The risk of bias assessment in individual randomized controlled trials is presented in the Supplementary Data File: Figure 1. In the overall risk of bias assessment, six studies were considered to have "some concern" as per the ROB-II tool[27] and three randomized controlled studies were considered to have a "low" risk of bias.

## Efficacy outcomes

### Pain score at 30-min after intervention

A total of six studies (n = 271 patients) reported a "pain score at 30 min after intervention". As shown in Figure 2, SPG block significantly decreased pain score when compared to control interventions (SMD = -1.99 [95% CI-3.88, -0.10]; $I^2$ = 97%) in the pooled analysis. Subgroup analysis showed the superiority of SPG block over conservative treatment (SMD = -3.85 [95% CI -4.42, -3.17]; $I^2$ = 0%) and intranasal lignocaine puff (SMD = -1.70 [95% CI -2.76, -0.64]). The GRADE approach suggested "low" quality of evidence for the comparison of SPG block and control interventions (Table 2).

The SPG block arm did not show a significant difference as compared to sham and GON block. Their comparisons did not fulfill the criteria of equivalence.

### Pain score at 1 hour after intervention

A total of six studies (n = 271 patients) reported a "pain score at 1 hour after intervention". SPG block significantly decreased the pain score as compared to control interventions (SMD = -1.56 [95% CI -2.65, -0.48]; $I^2$ = 93%) in the pooled analysis. Subgroup analysis also revealed the superiority of SPG block over conservative treatment (SMD = -2.71 [95% CI -4.24, -1.18]; $I^2$ = 86%) and intranasal lignocaine puff (SMD = -1.52 [95% CI -2.54, -0.50]) (Supplementary Data File: Fig. 2). The GRADE approach suggested "moderate" quality of evidence for the comparison of SPG block and control interventions (Table 2).

No difference between the SPG block and other control interventions was observed. They did not fulfill the criteria of equivalence.

### Pain score at 2 hours after intervention

A total of four studies (n = 211 patients) reported a "pain score at 2 hours after intervention". As shown in Figure 3, no significant difference was observed in the overall pooled effect (SMD = -1.23 [95% CI -3.06, 0.59]; $I^2$ = 97%), however in subgroup analysis, SPG block significantly decreased pain score as compared to conservative treatment (SMD = -2.01 [95% CI -2.65, -1.36]; $I^2$ = 46%). The superiority of the SPG block was demonstrated over conservative treatment. The GRADE approach suggested "very low" quality of evidence (Table 2).

There was no significant difference between the SPG block and the GON block. They did not fulfill the criteria of equivalence.

### Pain score at 4 hours after intervention

Four studies (n = 271 patients) comparing SPG block and conservative treatment reported a "pain score at 4 hours after intervention". As shown in Figure 4, SPG block significantly decreased pain score as compared to conservative treatment (SMD = -1.16 [95% CI -1.91, -0.40]; $I^2$ = 70%). The superiority of the SPG block was demonstrated over conservative treatment. The GRADE approach suggested "moderate" quality of evidence (Table 2).

### Pain score at 6 hours after intervention

A total of five studies (n = 231 patients) reported a "pain score at 6 hours after intervention". No significant difference was observed between SPG block and control interventions (SMD = -0.29 [95% CI -0.99, 0.41]; $I^2$ = 83%) in the pooled analysis. In subgroup analysis, SPG block significantly decreased pain score as compared to intranasal lignocaine puff (SMD = -1.58 [95% CI -2.62, -0.55) (Supplementary Data File: Fig. 3). The comparison demonstrated superiority. However, the SPG block arm did not show a significant difference as compared to other control interventions. Both comparisons did not fulfill the criteria of equivalence.

### Pain score at 8 hours after intervention

The three studies (n = 98 patients) comparing SPG block and conservative treatment reported a "pain score at 8 hours after intervention". No significant difference in pain score was observed between the study arms (Supplementary Data File: Fig. 4). GRADE approach suggested a "very low" quality of evidence (Table 2).

**Table 1** General characteristics of included studies.

| Study | Study design | Total number of patients | Age in Mean (SD) SPGB/ Comparator | Gender (% female) SPGB/ Comparator | Trans-nasal SPG Block group: (n), drug, quantity, contact time | Comparator group: (n) treatment | Type of neuraxial anesthesia/ surgery | Type/ size of needle for neuraxial block | Rescue treatment | Treatment failure | **Outcomes** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Abotaleb et al. 2022[30] | RCT (Open labelled) | 60 | 38.53 (13.55)/ 41.67 (12.53) | 43.3%/ 36.7% | (30) B/L SPGB with applicator saturated with Lignocaine 4% + adrenaline (1/ 2000000) in each nostril, NA, 5-min | (30) (Conservative) PCM 1 gm IV QID × 3day | SA/ Lower limb surgeries | NS/NS | IV PCM 1 gm followed by IV Diclofenac 75 mg/12h if NRS > 4 after 2h | Inadequate pain relief after 72h | VAS (0–10 cm) after 30 min, 1h, 2h, 6h, 12h, 24h, rescue treatment, treatment failure, adverse effects |
| Bohara et al. 2022[31] | RCT (Open labelled) | 40 | 24.1 (3.09)/ 24.25 (2.59) | NS/NS | (20) B/L SPGB with applicator saturated with Lignocaine 4%, NA, 5-min | (20) (Conservative) oral codeine+ paracetamol X TDS + caffeine + oral fluid + bed rest + abdominal binder | SA and epidural/ LSCS | NS/NS | IV tramadol if NRS > 7 | NS | NRS (0–100) after 10 min, 4h, 8h |
| Jespersen et al. 2020[32] | RCT (Triple blind) | 40 | 35.24 (26.32)/ 36.42 (23.94) | 70%/70% | (20) B/L SPGB with Lignocaine 4% + Ropivacaine 0.5% (1:1), 1 mL, 10-min | (20) B/L SPGB with Saline | LP/ SA/ epidural/ Surgical or non-surgical procedure | Traumatic/ atraumatic or both/ 18–27G | Repeat SPG block if VAS ≥ 30 mm | Not relieved after rescue block | VAS (0–100 cm) after 30 min and NRS (0–100) at 1h and 7 days, rescue treatment, treatment failure, adverse effects |
| Kumar et al. 2021[33] | RCT (Open labelled) | 40 | 35.50 (12.16)/ 36.58 (12.91) | NS/NS | (20) B/L SPGB with Lignocaine 4%, 1.5 mL, 10-min | (20) Conservative (PCM+ tramadol+ caffeine + oral fluid+ bedrest) | SA/ Various surgeries | Quincke needle/ 26G | Respective treatment repeated if pain not relieved after 1h of SPG Block | Not relieved after repeat treatment | VAS (0–10 cm), treatment failure |
| Mowafi et al. 2022[34] | RCT (Open labelled) | 40 | 28.7 (3.7)/ 27.5 (3.0) | 100%/ 100% | (20) B/L SPGB with Lignocaine 2% + dexamethasone 4 mg, (2 mL + 1 mL), 5-min | (20) (Conservative) PCM 1 gm IV TDS × 1day | SA/LSCS | NS/26 G | IV Ketorolac 30 mg with a maximum dose of 120 mg. $day^{-1}$ if NRS > 4 after 2h | Inadequate pain relief after 24h | NRS (0–100) after 30 min, 1h, 2h, 4h, 6h, 8h, 12h, 24h, treatment failure, adverse effects |
| Nazir et al. 2021[35] | RCT (Single blind) | 20 | 28 (NS)/ 27.5 (NS) | 100%/100% | (10) Applicator saturated with Lignocaine 2% in posterior nasopharynx followed by B/L SPGB with Lignocaine 2%, 1 mL, 10-min | (10) Two puffs of Lignocaine 10% in each nostril | SA/LSCS | NS/NS | Injection Diclofenac IV 75 mg if VAS ≥5 | Not relieved after treatment (VAS ≥8) | VAS (0–10 cm) after 30 min, 1h, 6h, 12h, 24h, rescue treatment, treatment failure, adverse effects |

**Table 1** (*Continued*)

| Study | Study design | Total number of patients | Age in Mean (SD) SPGB/ Comparator | Gender (% female) SPGB/ Comparator | Trans-nasal SPG Block group: (n), drug, quantity, contact time | Comparator group: (n) treatment | Type of neuraxial anesthesia/ surgery | Type/ size of needle for neuraxial block | Rescue treatment | Treatment failure | **Outcomes** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Puthenveettil et al. 2018[36] | RCT (Open labelled) | 20 | NS/NS | 100%/ 100% | (10) B/L SPGB with Lignocaine 2%, NA, 5-min | (10) (Conservative) PCM 1 gm TDS for 1day followed by addition of inj. Diclofenac 75 mg BD | SA/LSCS | NS/ NS | Conservative treatment (PCM 1 gm and Diclofenac 75 mg) if NRS > 4 | Inadequate pain relief after conservative treatment for 3 days. | NRS (0-–10) after 30 min, 1h, 2h, 4h, 6h, 8h, 12h, 24h |
| Yilmaz et al. 2020[37] | RCT (Open labelled) | 21 | 26.9 (5.2)/ 28.4 (5.8) | 100%/ 100% | (10) U/L SPGB with 10% Lignocaine, 2 mL, 15-min | (10) (Conservative) normal saline 1000 ml over 4h, $MgSO_4$ 1500 mg, Theophylline 200 mg, PCM 1000 mg) | SA/LSCS | NS/NS | NS | NS | VAS (0–10 cm) after 12 h, 24 h, adverse effects |
| Youssef et al. 2021[38] | RCT (Single blind) | 100 | 31.5 (5.8)/ 30.9 (5.8) | 100%/ 100% | (46) Applicator with Lidocaine 2% in posterior nasopharynx followed by B/L SPGB with Lignocaine 2% + dexamethasone 4 mg (2 mL + 1 mL), 10-min | (47) B/L GON block with same drug composition | SA/LSCS | Quincke needle/ 26G | PCM 1g IV Followed by 2nd rescue block after 24 hours | Inadequate pain relief after 2nd block (NRS ≥4) | NRS (0–100) after 30 min, 1h, 2h, 6h, 12h, 24h, rescue treatment, treatment failure, adverse effects |

n, Number of patients; SPGB, Sphenopalatine Ganglion Block; LP, Lumbar Puncture; SA, Spinal Anesthesia; VAS, Visual Analog Scale; NS, Not Specified; PCM, Paracetamol; LSCS, Lower Segment Caesarean Section; NRS, Numerical Rating Scale; GON, Greater Occipital Nerve.

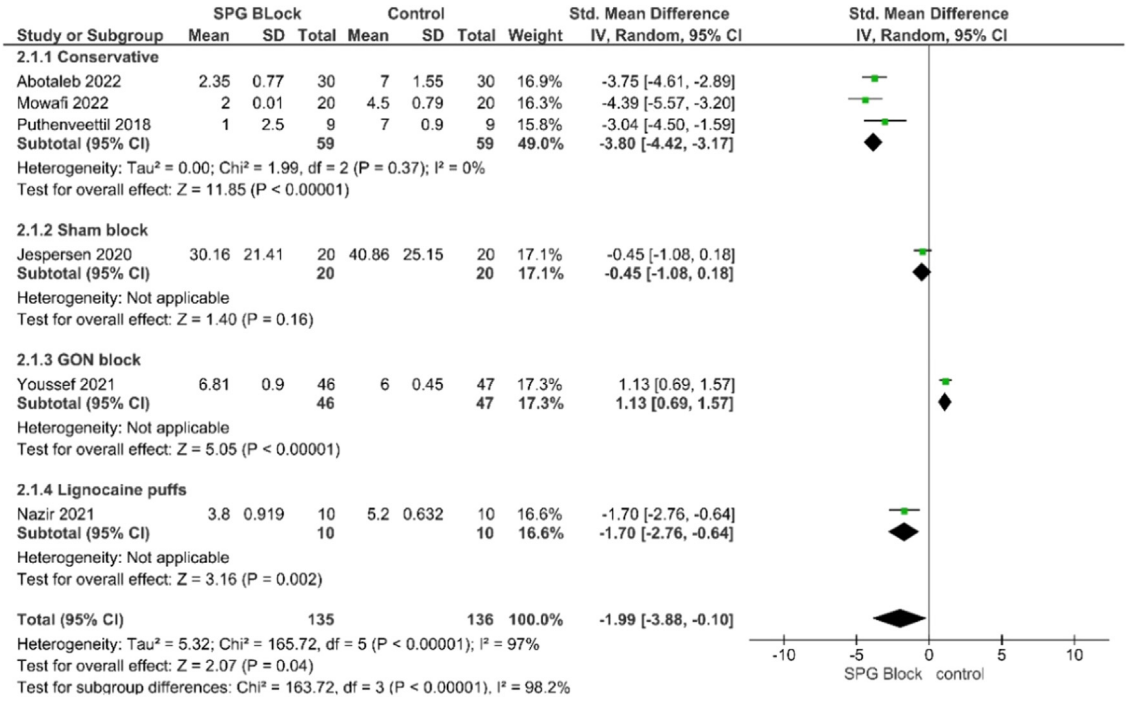


**Figure 2** Forest plot of the outcome pain score at 30-min after intervention.

### Pain score at 12 hours after intervention

Six studies (n = 231 patients) reported a "pain score at 12 hours after intervention". SPG block did not show an overall significant difference as compared to control interventions (SMD = -0.30 [95% CI -0.67, 0.06]; $I^2$ = 45%] in the pooled analysis. In subgroup analysis, SPG block significantly decreased pain score as compared to intranasal lignocaine puff (SMD = -1.07 [95% CI -2.03, -0.12). However, the comparison did not the fulfill criteria of superiority. SPG block did not show any significant difference in pain score as compared to conservative treatment and GON block (Supplementary Data File: Fig. 5). Both comparisons did not fulfill the criteria of equivalence.

### Pain score at 24 hours after intervention

A total of six studies (n = 251 patients) reported a "pain score at 24 hours after intervention". Overall effect was observed as insignificant between SPG block and control interventions (SMD = -0.40 [95% CI -0.85, 0.06]; $I^2$ = 63%) in the pooled analysis although SBG block significantly decreased pain score as compared to intranasal lignocaine puff (SMD = -1.79 [95% CI -2.86, -0.72) (Supplementary Data File: Fig. 6). The criteria of equivalence could not be demonstrated due to the wide confidence interval.

### Pain score at 7 days after intervention

Only two studies (n = 133 patients) comparing SPG block with a procedure group (sham block and GON block) reported "pain score at 7 days after the intervention". No significant difference was observed between the two groups (Supplementary Data File: Fig. 7). This comparison did not fulfill the criteria of equivalence.

### Rescue treatment

Three studies (n = 153 patients) reported the need for "rescue treatment" among patients with inadequate pain relief after an intervention. Rescue treatment was given as diclofenac IV 75 mg (if VAS ≥ 5),[27] acetaminophen 1 g IV followed by a second rescue block (after 24 h),[29] repeat SPG block (if VAS ≥ 30 mm).[30] No data were available for comparison between the SPG block and the conservative treatment group. SPG block did not show an overall significant difference (RR = 0.72 [95% CI 0.36, 1.44]; $I^2$ = 52%) as compared to sham block (RR = 1.00 [95% CI 0.63, 1.58]), GON block (RR = 0.71 [95% CI 0.34, 1.49]) and intranasal lignocaine puffs (RR = 0.17 [95% CI 0.02, 1.14) (Supplementary Data File: Fig. 8). The comparisons did not fulfill the criteria of equivalence. The GRADE approach suggested "low" quality of evidence.

### Treatment failure

Six studies (n = 293) reported "treatment failure" which was defined as "no relief (NRS ≥ 4) after rescue block[28,29,34] or VAS ≥ 8 after treatment[31] inadequate pain relief after 24 h[30] and after 72 h.[26,32] Overall effect showed significantly less patients with treatment failure in the SPG block group as compared to other interventions (RR = 0.40 [95% CI 0.18, 0.91]; $I^2$ = 66%). Subgroup analysis also showed a significantly lower number of patients with treatment failure after SPG block as compared to conservative treatment [RR = 0.22 [95% CI 0.10, 0.49]; $I^2$ = 18%). The superiority of the SPG block was demonstrated over conservative treatment. The GRADE approach suggested "low" quality of evidence (Table 2).

**Table 2** GRADE approach for comparison of SPG block with control interventions for PDPH.

| Certainty assessment | | | | | | | N° of patients | | Effect | | Certainty |
|---|---|---|---|---|---|---|---|---|---|---|---|
| N° of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | SPG block | control | Relative (95% CI) | Absolute (95% CI) | |
| Pain score at 30-min after intervention | | | | | | | | | | | |
| 6 | Randomized trials | Serious[a] | Not serious | Not serious | Not serious | Publication bias strongly suspected[b] | 135 | 136 | – | SMD 1.99 SD lower (3.88 lower to 0.1 lower) | ⊕⊕◯◯ Low |
| Pain score at 1 hour after intervention | | | | | | | | | | | |
| 6 | randomized trials | serious[a] | Not serious | Not serious | Not serious | publication bias strongly suspected strong association[b] | 135 | 136 | - | SMD 1.56 SD lower (2.65 lower to 0.48 lower) | ⊕⊕⊕◯ Moderate |
| Pain score at 2 hours after intervention | | | | | | | | | | | |
| 4 | randomized trials | Serious[c] | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 105 | 106 | – | SMD 1.23 SD lower (3.06 lower to 0.59 higher) | ⊕◯ Very low |
| Pain score at 4 hours after intervention | | | | | | | | | | | |
| 4 | randomized trials | Serious[c] | Not serious | Not serious | Not serious | Publication bias strongly suspected strong association[b] | 59 | 59 | – | SMD 1.16 SD lower (1.91 lower to 0.40 lower) | ⊕⊕⊕◯ Moderate |
| Pain score at 6 hours after intervention | | | | | | | | | | | |
| 5 | Randomized trials | Serious[e] | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 115 | 116 | – | SMD 0.29 SD lower (0.99 lower to 0.41 higher) | ⊕◯◯◯ Very low |
| Pain score at 8 hours after intervention | | | | | | | | | | | |
| 3 | Randomized trials | Serious[f] | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 49 | 49 | – | SMD 0.65 SD lower (2.38 lower to 1.08 higher) | ⊕◯◯◯ Very low |
| Pain score at 12 hours after intervention | | | | | | | | | | | |
| 6 | Randomized trials | Serious[g] | Not serious | Not serious | Not serious | Publication bias strongly suspected[b] | 125 | 126 | – | SMD 0.3 SD lower (0.67 lower to 0.06 higher) | ⊕⊕◯◯ Low |
| Pain score at 24 hours after intervention | | | | | | | | | | | |
| 6 | Randomized trials | Serious[g] | Not serious | Not serious | Not serious | Publication bias strongly suspected[b] | 125 | 126 | – | SMD 0.4 SD lower (0.85 lower to 0.06 higher) | ⊕⊕◯◯ Low |
| Pain score at 7 days after intervention | | | | | | | | | | | |
| 2 | Randomized trials | Not serious | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 66 | 67 | – | 0 (0 to 0) | ⊕⊕◯◯ Low |
| Rescue treatment | | | | | | | | | | | |
| 3 | Randomized trials | Not serious | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 23/76 (30.3%) | 32/77 (41.6%) | RR 0.72 (0.36 to 1.44) | 116 fewer per 1,000 (from 266 fewer to 183 more) | ⊕⊕◯◯ Low |
| Treatment failure | | | | | | | | | | | |
| 6 | Randomized trials | Serious[a] | Not serious | Not serious | Not serious | Publication bias strongly suspected[b] | 24/146 (16.4%) | 58/147 (39.5%) | RR 0.40 (0.18 to 0.91) | 237 fewer per 1,000 (from 324 fewer to 36 fewer) | ⊕⊕◯◯ Low |
| Adverse events | | | | | | | | | | | |
| 6 | Randomized trials | Serious[a] | Not serious | Not serious | Serious[d] | Publication bias strongly suspected[b] | 53/136 (39.0%) | 42/137 (30.7%) | RR 1.19 (0.60 to 2.38) | 58 more per 1,000 (from 123 fewer to 423 more) | ⊕◯◯◯ Very low |

CI, Confidence Interval; RR, Risk Ratio; SMD, Standardized Mean Difference.
Explanations:
[a] 3 out of 6 studies had some concern in risk of bias assessment;
[b] Less than 10 studies;
[c] 2 out of 4 studies had some concern in risk of bias assessment;
[d] Wide confidence interval;
[e] 3 out of 5 studies had some concern in risk of bias assessment;
[f] 1 out 3 studies had some concern in risk of bias assessment;
[g] 4 out of 6 studies had some concern in risk of bias assessment.

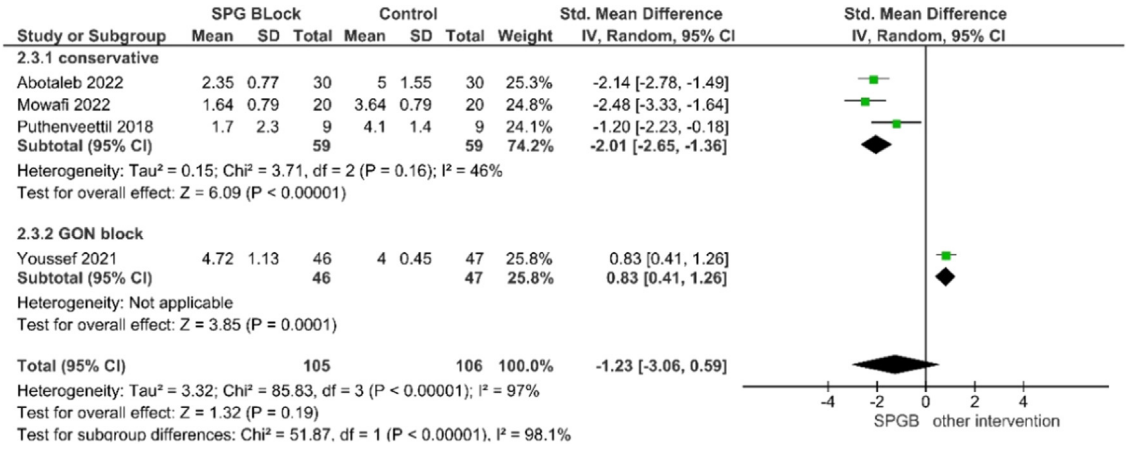


**Figure 3** Forest plot of the outcome pain score at 2 hours after intervention.

No difference between SPG block and other control groups was observed. It did not fulfill the criteria of equivalence (Supplementary Data File: Fig. 9).

## Safety outcomes

Adverse events were reported in 6 studies (n = 273) in the form of nasal discomfort, seizures, blood-stained applicator, throat numbness, photophobia, dizziness, tinnitus, etc. No significant difference was observed among the groups (Supplementary Data File: Fig. 10). The GRADE approach suggested "very low" quality of evidence for the comparison of SPG block and conservative treatment (Table 2). The comparisons did not fulfill the criteria of equivalence.

## Sensitivity analysis

Among 6 studies using conservative treatments as a comparator, only one study had a "low" risk of bias, while 2 studies of the sham group and GON block had a "low" risk of bias in the risk of bias assessment. The sensitivity analysis of the low risk of bias studies suggests a similar trend for conservative treatment, sham and GON block (Supplementary Data File: Table 1). However, it was not possible to perform sensitivity analysis of all outcomes for the lignocaine puff based on the risk of bias assessment.

## Discussion

In this meta-analysis, outcome data from 9 RCTs were pooled to assess the efficacy and safety of SPG block as compared to other treatments for PDPH. We analyzed the included studies in four subgroups: conservative, intranasal lignocaine puffs, sham block and GON block because three studies compared SPG block with intranasal lignocaine puffs,[35] sham block[32] and GON block[38] while six studies compared SPG block with non-invasive conservative treatments.[30,31,33,34,36,37] Efficacy was assessed in terms of changes in pain scores at various intervals after intervention (30 min, 1 h, 2 h, 4 h, 6 h, 8 h, 12 h, 24 h, and 7 days), need for rescue treatment or rescue block and treatment failure. We also analyzed adverse events reported in the intervention groups.

We observed that SPG block is more effective in relieving PDPH than conservative treatments. The meta-analytic summary of the overall pooled effect showed lower pain scores in patients treated with SPG block as compared to other interventions for 30 min, 1 h and 4 h. The subgroup analysis of SPG block with the conservative group found that SPG block-treated patients had significantly decreased pain scores at 30 min, 1 h, 2 h, and 4 h after the intervention. Also, there were significantly less patients with treatment failures with SPG block. The superiority was demonstrated as these outcomes fulfilled the criteria of more than a 20% difference in RR or 20 units of SMD. GRADE evidence was

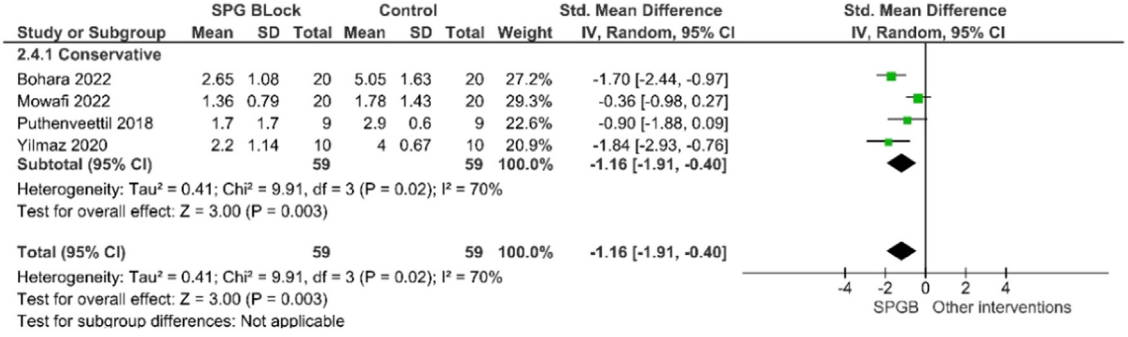


**Figure 4** Forest plot of the outcome pain score at 4 hours after intervention.

"very low" to "moderate" for these parameters as the outcomes were based on open labels and a small number of studies. We found that the effect of SPG block was immediate and short-lasting in the treatment of PDPH. This is because SPG block failed to demonstrate superiority in pain score assessment at 6 hours and beyond in this meta-analysis. GRADE evidence was "very low" for these outcomes. These findings highlight trends for faster relief from headache after block.[39] Similar findings were reported in previous retrospective studies comparing SPG block with EBP[18,19,40] where effective pain relief was noted within 30 min of a block. In our analysis, no significant difference was observed for later time intervals (6 h, 8 h, 12 h, 24 h, and 7 days), which is in line with previous studies.[41-43] Patients treated with SPG block may require repeat blocks for the recurrence of pain.

The mechanism of pain relief after SPG block is still not exactly known, although as described in the literature, either mechanical stimulation of sphenopalatine ganglion[31,44,45] or absorption of local anesthetic through the mucous membrane overlying the ganglia, finally block the parasympathetic mediated vasodilation and relieve headache.[46] The short-term effectiveness of the block can be attributed to the short-lasting mechanical stimulation or pharmacological profile of the local anesthetic used for the SPG block. All included studies used lidocaine, and only one study used lidocaine with ropivacaine.[32] Adjuvants like adrenaline and dexamethasone were also included in one and two studies, respectively, which may affect the duration of the block.[30,34,38]

SPG block through the application of local anesthetic using a cotton tip applicator could be more effective than trans-nasal local anesthetic spray or puffs. Various approaches are practiced for SPG block like trans-nasal, trans-oral, sub-zygomatic, and lateral infratemporal approaches. The trans-nasal SPG block is a simple, noninvasive technique,[47] which can be achieved by local anesthetic administration through a hollow cotton tip applicator, trans-nasal local anesthetic spray or puffs,[48] trans-nasally inserted cotton gauze soaked in local anesthetic[49] and nasal drops of local anaesthetic,[50] although, the last three methods cannot ensure adequate concentration of local anesthetic reaching the effective site to be blocked. In this meta-analysis, one study compared SPG block with local anesthetic spray (lignocaine puffs) and subgroup analysis of the same observed superiority of SPG block over lignocaine puff for pain relief at 30 min, 1 h, 6 h, 12 h, and 24 h. However, this data was from only one study with a small sample size of 20 patients, therefore more studies with large sample sizes are needed for evaluating potential advantage of using local anesthetic spray or puff over trans nasal block with cotton tip applicator. Like the intranasal lignocaine puff, SPG block was compared with sham block and GON block in only one study each and there is insufficient evidence to interpret the superiority, inferiority, or equivalence between the efficacy of SPG block and sham or GON block in the treatment of PDPH.

There is insufficient evidence regarding the safety of SPG block in the treatment of PDPH. This is also based on "low" to "very low" quality evidence. Common adverse effects associated with SPG block are local, mostly procedure-related or because of local anesthetic. The trans-nasal approach may cause mild discomfort during the technique, bleeding, infection, and numbness of the throat which are usually short-lasting. Changes in face temperature and lacrimation due to sympathetic blockade can also occur and are considered reliable signs of block success,[51,52] although these are not frequent findings. We did not observe any life-threatening adverse events among the included studies and all groups were comparable regarding the safety of trans-nasal SPG block.

Several limitations exist in this meta-analysis. It included only 9 RCTs with a small sample size. Six out of nine included studies had "some concerns" in risk of bias assessment due to open labelled design. There was significant heterogeneity because of sample composition (e.g., demography, type of surgery, and anesthesia) and different interventions in the control group (conservative, sham, GON block, intranasal lidocaine puff). Each study used different cut-off points for pain relief and the rescue treatment regimen was also non-similar among the groups. Similarly, the definition of treatment failure was also different among the studies. Different pain measuring tools were used among studies (VAS 0−10 cm, VAS 0−100 cm, NRS 0−10, NRS 0−100), therefore we used Standardized Mean Difference (SMD) to present the meta-analytic summary The block technique was also not uniform in studies, as different drugs with a wide range of strength and doses were chosen for performing the block. Therefore, interpreting study data included in this meta-analysis requires caution concerning heterogeneity across the trials due to small sample size of studies (< 30 patients/group) and small number of studies (≤ 5 studies). Considering this, we preferred random-effect models for our meta-analysis. Publication bias was observed in all outcomes, and it may have affected precision. Also, we could not extract and analyze data regarding the duration of block effect, overall analgesic consumption, patient satisfaction. and its impact on the long-term recovery of patients as limited data were available in the included studies.

In conclusion, very low to moderate quality evidence suggests that SPG block provides pain relief in PDPH, but it does not last till 6 hours or afterwards. The superiority of SPG block over conservative treatment and lignocaine puff was demonstrated. This meta-analysis failed to provide directions regarding comparisons of SPG blocks with sham and GON blocks. Further large-scale RCTs are required to assess the definite role of SPG block with its effect on overall patient recovery, analgesic consumption, and satisfaction.

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The study was not funded.

## Conflicts of interest

The authors declare no conflicts of interest.

## Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjane.2023.06.002.

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