Effect of Sphenopalatine Ganglion Block With Bupivacaine on Postoperative Pain in Patients Undergoing Endoscopic Sinus Surgery

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Abstract
Background: Postoperative pain is one of the most complications in endoscopic sinus surgery. We aimed to evaluate the effect of the sphenopalatine ganglion block (SPGB) with bupivacaine on postoperative pain in patients undergoing endoscopic sinus surgery.

Methods and Materials: In this clinical trial, 40 patients who indicated functional endoscopic sinus surgery were selected and then divided into 2 parallel groups as intervention and control. The intervention group was received 1.5 mL of bupivacaine 0.5% (injected to sphenopalatine ganglion) and while control was injected 1.5 mL of normal saline at the same injection site. Also, the visual analogue scale (VAS) was recorded immediately after anesthesia, along with 6, 12, 24, 48 h, 7 days, and 21 days after the operation for all patients.

Results: Immediately after anesthesia, as well as 6, 12, and 24 h after the operation, VAS in the intervention group was significantly lower than in the control group (\(P<.05\), for all). However, there were no significant differences between the 2 groups regarding VAS 48 h as well as 7 and 21 days after surgery (\(P>.05\), for both). Also, the rescue analgesia in the intervention group was significantly lower than in the control group (\(P=.01\)).

Conclusion: SPGB with bupivacaine 0.5% (1.5 mL) was a simple, effective, safe, and noninvasive method for the management of postoperative pain in the patients undergoing endoscopic sinus surgery.

Keywords endoscopic sinus surgery, postoperative pain, sphenopalatine ganglion block, bupivacaine

Introduction
Known as a safe technique, functional endoscopic sinus surgery (FESS) is a treatment of choice in a category of conditions, particularly nasal polyps and rhinosinusitis.¹⁻⁶ This technique has proved advantageous in improving the patients’ postoperative symptoms by 86.3% while treating chronic inflammatory paranasal sinus diseases.⁷ Postoperative pain is an important issue to be dealt with after any surgery and managing it challenging. It is suggested that 86% of patients who undergo a surgical event would experience pain, and 75% of them suffers moderate to extreme levels of pain.⁸⁻⁹ Despite high demands for effective pain management and availability of potent and rapidly acting analgesic agents, postoperative pain has remained undertreated.⁹ Difficulties in management coupled with the association between slowed functional recovery and different levels of pain may result in displeasure of surgical procedure and failure in returning to normal life activities.¹⁰ Sphenopalatine ganglion block (SPGB) is known to be a comfortable, efficient, and safe method for managing craniofacial pains. The ganglion is made of both sensory and autonomic nerves, with sensory neurons innervating the nasal cavity, palate, and some

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regions in nasopharynx and oropharynx. The noninvasive techniques involve injecting antianalgesic agents into the nasal cavity, with the endoscopic approach introduced considering the difficulties of transnasal injection. Radiofrequency ablation and pulsed radiofrequency are known as more invasive methods for nerve blockade. This method is used to treat different conditions with pain in crania such as a cluster headache, trigeminal neuralgia, migraine, pain syndromes of the face, and cancer pains, with many positive effects reported in different studies. Some complications such as postoperative epistaxis, cheek hematoma, and hypoesthesia of the palate have occurred after performing the blockade with endoscopic intervention, though they have been temporary. It has also been reported that SPGB might help to alleviate symptoms of trigeminal neuralgia. Some studies have been conducted to evaluate the effects of the sphenopalatine block in endoscopic sinus surgery. They suggest that postoperative pain in patients undergoing the ganglion block might be reduced with general anesthesia compared to a placebo group. Also, these studies suggested that SPGB is a safe, simple, noninvasive, and an effective method of short-term pain. In Iran, no study has examined the effect of SPGB with bupivacaine on postoperative pain in patients undergoing endoscopic sinus surgery. Furthermore, considering the increasing usage of the endoscopic sinus surgery and importance of its postoperative complications, we aimed to evaluate the effect of sphenopalatine nerve block technique with bupivacaine on postoperative pain in patients undergoing endoscopic sinus surgery and its subsequent complications.

Materials and Methods

Subjects

This randomized clinical trial was registered in the Vice-presidency of Research, Isfahan University of Medical Sciences, Isfahan Province, Iran, and also recorded in Iranian Registry of Clinical Trial. For this research, 53 patients who had endoscopic sinus surgery indication were referred to Amin Hospital of Isfahan province, Iran, in 2016–2017. Then, 40 patients were selected according to inclusion and exclusion criteria. The patients were diagnosed based on physical examination, clinical, para-clinical, imaging (computed tomography scan in axial and coronal views) and endoscopic findings. The inclusion criteria were patients with refractory or resistant chronic rhinosinusitis or polyposis with endoscopic sinus surgery indication (with general anesthesia), aged over 18 years, American Society of Anesthesiologists (ASA) physical status I or II and informed consent. The patients with pregnancy or breastfeeding, needed concurrent septoplasty or turbinate reduction history of allergy to local anesthesia such as lidocaine, uncontrolled hypertension, cardiovascular or cerebrovascular diseases, alcohol or opioids consumption, diabetes, and chronic renal disease did not meet the inclusion criteria. The exclusion criteria included severe complication with the injection of bupivacaine, severe bleeding, changing the anesthesia technique, and using medication 24 h before surgery such as corticosteroid sprays (mometasone spray). After enrollment and according to inclusion and exclusion criteria, the patients were randomly divided into 2 parallel groups as intervention (SPGB) and control (no SPGB). The randomization was performed using Random Allocation Software. Before the surgery, clinical information of patients including age, gender, body mass index (BMI), ASA status, and clinical findings was recorded in a checklist.

Anesthesia and Blocking Methods

In the operating room, hemodynamic data of the patients were recorded, and all patients underwent general anesthesia with 2.5 mg of propofol 1% and 2 µg/kg of Fentanyl. With body weight considered, tracheal intubation was performed by a muscle relaxant intravenously. Also, isoflurane in oxygen (1%–2.5%) was administrated as the maintenance dose. All patients were ventilated mechanically for keeping end-tidal carbon dioxide between 35 and 36 mm Hg. A surgeon performed the whole operation, and the surgical technique was according to our institute. The nasal cavities were soaked by 1:100,000 adrenaline as a decongestant. The patients were placed in reverse Trendelenburg position with an angle of 15° for the blockage. An intravenous flange of 18 gauges was introduced using an endoscope between the middle and lower turbinates with the needle bent at 25 mm from the tip at an angle of 45° for the injection to pterygopalatine fossa. Then, 1.5 mL of bupivacaine 0.5% (intervention) or 1.5 mL of normal saline (control) was injected (after aspiration) into the nasal cavity mucosa, the posterior and over the middle turbinates tail in the pterygopalatine fossa. After removing from the needle, a cotton applicator was inserted to prevent bleeding at the injection site. In this way, bilateral sphenopalatine ganglia were blocked. In the patients with heart rate (HR) >100 per/min, 0.2 mg propofol was administered, and 200 µg of Atropine was administered for patients with HR <45 during the operation. The patients underwent maxillary antrostomy, frontal sinusotomy, sphenoidotomy, and an ethmoidectomy. Also, the blood loss was estimated based on the difference of the amounts of blood in the suction device and consumed normal saline. The duration of anesthesia and operation were recorded for both groups.
Postoperation

After the operation, the patients were transferred to the recovery room, and their hemodynamics including HR, respiratory rate (RR), systolic and diastolic blood pressures (SBP and DBP), and oxygen saturation (SPO2) were monitored. The patients were discharged from the recovery room based on Alderete criteria. The postoperative pain of patients was measured according to visual analogue scale (VAS) (0 [without pain] and 10 [severe pain]) immediately after anesthesia, 6, 12, 24, 48 h, 7 days, and 21 days after the operation. Also, paracetamol 1g/stat/IV infusion was performed for the patients with a VAS ≥ 4. If the pain (VAS ≥ 4) remains unchanged after 30 min of receiving analgesia, the dose of the drug was repeated. The satisfaction of patients scored between 0 and 20, and the adverse effects were also recorded in both groups within 48 h. Furthermore, if the hemostatic agent was removed 24 h after the operation, and patients were treated with cephalexin 500 mg/Qd for 10 d and nasal steroids spray/TDS for 1 month.

Statistics

The sample size was based on a confidence level of 95% and power detection of 80%. Also, standard deviations (SDs) of VAS were 1.4 and 2.8, and the mean of difference (mean1 = 3.4 and mean2 = 1.6) was 1.8. Accordingly, the sample size was calculated at least 20 for each group based on a previous study.19 All data were entered and analyzed by Statistical Package for the Social Sciences (SPSS, Chicago, IL) software version 22. Using this software, independent T test, χ2, and Mann–Whitney U test were used to compare the groups. Also, repeated measure analysis of variance (ANOVA) test was used to assess VAS variations in both groups. The data were shown as frequency (percentage) and mean ± SD. Also, P value less than .05 was considered as significant.

Results

In this study, the patients were divided into intervention (14 males and 6 females, 41.65 ± 15.31 years) and control (11 males and 9 females, 44.90 ± 10.61 years) groups. Also, there were no significant differences between the groups in terms of age (P = .12), gender (P = .32), BMI (P = .87), ASA (P = .60), anesthesia duration (P = .15), surgery duration (P = .35), and blood loss (P = .75) (clinical information of patients were summarized in Table 1). In the recovery room, there were no significant differences between the groups regarding RR (P = .64), HR (P = .75), SBP (P = .27), DBP (P = .58), and SPO2 (P = .22). After the operation, the VAS score was recorded immediately after anesthesia (recovery room), as well as after 6, 12, 24, and 48 h, 7 days, and 21 days. VAS scores in the intervention group were significantly lower than in the control group immediately after anesthesia, along with 6, 12, and 24 h after the operation (P < .05). However, there were no significant differences between the groups regarding VAS after 48 h and 7 and 21 days (P > .05) (Table 2). Based on the repeated measure ANOVA test, the variations of VAS were significant in intervention and control (P < .001, for both). Specifically, 20% of the intervention group and 60% of the control group had rescue analgesia, where the rescue analgesia in the intervention group was significantly lower than in the control group (P = .01). There was no significant relationship between the groups regarding complications including nausea and vomiting (P = .21), headache (P = .39), bleeding (P = .54), and visual disturbances (P = .29). Furthermore, the satisfaction of patients in the intervention group was

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| Table 1. Clinical Information of Patients in the SPGB and Control Groups. |
|-----------------------------|-------------|-------------|---|
| Characteristics            | SPGB       | Control     | P  |
| Number                      | 20         | 20          | -  |
| Age (years) (mean ± SD)     | 41.65 ± 15.31 | 44.90 ± 10.61 | .12a |
| Gender                      |            |             |    |
| Male                        | 14 (70%)   | 11 (55%)    | .32b |
| Female                      | 6 (30%)    | 9 (45%)     |    |
| BMI (mean ± SD) (kg/m²)     | 24.55 ± 3.27 | 23.65 ± 3.68 | .87a |
| ASA (mean ± SD)             | 1.50 ± 0.51 | 1.60 ± 0.50 | .60c |
| Anesthesia duration (min)   | 112.75 ± 14.28 | 103.80 ± 17.47 | .15c |
| Surgery duration (min)      | 90.65 ± 15.06 | 85.95 ± 16.44 | .35c |
| Blood loss (mL)             | 63.40 ± 30.56 | 67.30 ± 24.45 | .75c |

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; SPGB, sphenopalatine ganglion block.

aIndependent t test.

bχ2 test.

cMann–Whitney test.

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| Table 2. VAS Scores in Different Times of Study in the SPGB and Control Groups. |
|-----------------------------|-------------|-------------|
| VAS Scores After Operation (Mean ± SD) | SPGB       | Control     |
| Immediately after anesthesia | 1.95 ± 0.88 | 5.05 ± 1.09 | <.001 |
| 6 h                          | 2.15 ± 0.98 | 4.40 ± 0.99 | <.001 |
| 12 h                         | 1.68 ± 0.87 | 3.20 ± 1.19 | <.001 |
| 24 h                         | 1.05 ± 0.60 | 2.30 ± 1.03 | <.001 |
| 48 h                         | 0.65 ± 0.67 | 0.80 ± 0.41 | .27  |
| 7 days                       | 0.36 ± 0.49 | 0.52 ± 0.51 | .41  |
| 21 days                      | 0.15 ± 0.37 | 0.10 ± 0.31 | .79  |
| P times                      | <.001       | <.001       |
| P group times                | <.001       |             |

Abbreviations: SPGB, sphenopalatine ganglion block; VAS, visual analogue scale.

*Mann–Whitney test.
who had pterygopalatine blockade and the group who
there was no significant difference between the group
had pterygopalatine blockade. However, in our study,
blood loss was significantly lower in the group who

importantly, the patients were not given any medica-
tions before the surgery. Kesimci et al. 18 stated that

an hour, 50 mg of Diclofenac was orally administered.

if VAS remained unchanged after half
more than 4, they would receive 75 mg of IM
was 2 mL, and if postoperative VAS was equal to or
in either group. The injection dose for each substance
was significantly lower VAS scores as opposed to the control
after the operation, patients who had bupivacaine
was effective in shortening the hospitalization time and
decreasing the need for opiates following the surgery.
They, however, indicated that after the first day, there
would be no verifiable benefits concerning pain management.

our findings might support the results of the previous
studies, as the incidence of complications and effectiveness
of SPGB for postoperative analgesia has been con-
sistent with many of the previous results. Notably, our
study was a first study on the effect of SPGB on pain,
surgery, anesthesia duration, and bleeding loss.
Nevertheless, further studies are required to determine
the efficacy of different analgesics on pain duration and
quality after sinus surgery such as examining short and
long-acting narcotics used in the same technique.

Conclusion

Utilization of bupivacaine is associated with decreased
postoperative pain and more satisfaction with the sur-
gery for patients. The complications following usage this
method were not observed to be considerable.

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room of Amin Hospital.

Table 3. The Rescue Analgesia, Complications, Satisfaction in the
SPGB and Control Groups.

| Variables                     | SPGB   | Control | P   |
|-------------------------------|--------|---------|-----|
| Rescue analgesia              | 4 (20%)| 12 (60%)| .01 |
| Complications                 |        |         |     |
| Nausea and vomiting           | 2 (10%)| 5 (25%) | .21 |
| Headache                      | 1 (5%) | 3 (15%) | .29 |
| Bleeding                      | 1 (5%) | 2 (10%) | .54 |
| Visual disturbances           | 1 (5%) | 3 (15%) | .29 |
| Satisfaction (mean ± SD)      | 17.95 ± 1.70 | 16.25 ± 1.97 | .007 |

Abbreviation: SPGB, sphenopalatine ganglion block.

* Mann–Whitney U test.

significantly higher than in the control group (P = .007)
(Table 3). Also during the study, 1 patient of the inter-
vention and 1 patient of the control groups (did not follow up) were excluded from the study.

Discussion

The study results suggested that during the first 24 h
after the operation, patients who had bupivacaine
injected into their sphenopalatine ganglion had significa-
cantly lower VAS scores as opposed to the control
group. They additionally required smaller amounts of
rescue analgesia and were more satisfied with their
pain management after the operation as compared
with the group taking normal saline. The occurrence of
difficulties such as nausea and vomiting, bleeding, head-
ache, or visual disturbances was almost the same in both
groups. A few studies have been conducted to assess the
effectiveness and examine the complications following
the sphenopalatine ganglion nerve block. Most of them
have indicated that the use of this procedure might bring
statistically significant results in diminishing pain in
patients undergoing endoscopic sinus surgery. Kesimci
et al. compared 3 groups of patients undergoing FESS
who had their sphenopalatine ganglion injected with
bupivacaine, levobupivacaine, and saline. 18 They con-
cluded that the analgesic groups had significantly lower
VAS scores, and the complications were not significant
in either group. The injection dose for each substance
was 2 mL, and if postoperative VAS was equal to or
more than 4, they would receive 75 mg of IM
Diclofenac; and if VAS remained unchanged after half
an hour, 50 mg of Diclofenac was orally administered.
Importantly, the patients were not given any medica-
tions before the surgery. Kesimci et al. 18 stated that
blood loss was significantly lower in the group who
had pterygopalatine blockade. However, in our study,
there was no significant difference between the group
who had pterygopalatine blockade and the group who

received placebo concerning the blood loss, and the
cause might be the fact that a same surgeon performed
the surgeries, and the cases were adjusted for variables
such as blood loss in our study.

In a study conducted by Cho et al., 29 patients
had SPGB with bupivacaine alongside epinephrine,
and 27 had normal saline injected. 10 The injection dose
was 2 mL. No premedication was used before the surgi-
cal operation. Postsurgical pain management regimen
composed of oral Vicodin (1–2 tabs every 4–6 h), plus
an adjusted dose of orally taken tylenol PRN. Vicodin
was substituted with Percocet if it could not be tolerated.
They suggested that if bupivacaine was used during the
operation instead of normal saline, postoperative pain
might have been lower, but statistically significant results
were not achieved through their study, and larger studies
might be required to support their findings. DeMaria
et al. studied 70 patients to evaluate post-sinus surgery
analgesia after using bilateral sphenopalatine block tech-
nique. 22 They used 1 mL of Lidocaine 1% with epineph-
rine during the procedure, with Oxymetazoline nasal
spray administered 30 min before the surgical operation,
and Oxymetazoline-soaked pledgets were placed into the
patients’ nasal cavity. Also, 25 to 50 μg of Fentanyl was
allowed to be administered by instructed nurses if the
numeric pain score was ≥4 and patients needed pain
medications. The study results suggested that sphenopa-
latine ganglion nerve block during the general anesthesia
was effective in shortening the hospitalization time and
decreasing the need for opiates following the surgery.
They, however, indicated that after the first day, there
would be no verifiable benefits concerning pain management.

Abbreviation: SPGB, sphenopalatine ganglion block.

* Mann–Whitney U test.
Ethical Approval
This study was approved by our institutional review board.

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