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Original Research Article

Analgesic Efficacy and Safety of Medical Therapy Alone vs Combined Medical Therapy and Extraoral Glossopharyngeal Nerve Block in Glossopharyngeal Neuralgia

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Abstract

Objective. The aim of this study is to compare medical therapy alone and medical therapy with add on extraoral glossopharyngeal nerve block in terms of analgesic efficacy and hemodynamic safety in patients with glossopharyngeal neuralgia (GPN). As GPN is a rare disease, our secondary targets were to review the demographic profile of the disease, clinical profile, and any associations with the disease.

Design. This was a randomized, prospective, active-controlled, parallel group study conducted from 2007 to 2009 to determine the safety and efficacy of extraoral glossopharyngeal nerve block in GPN and compare it with pharmacological intervention. After institutional ethics committee approval and patient's consent, GPN patients were randomly allocated into two groups. Group A (N = 15) received standard medical therapy (gabapentin 300 mg, tramadol 50 mg TDS, methylcobalamin 500 μgm PO) and group B (N = 15) patients received extraoral glossopharyngeal nerve block together with standard medical therapy. Patients were analyzed for analgesic outcome using numerical pain scale (NPS) and brief pain inventory (BPI) assessing both analgesic effect and degree of interference in quality of life (QOL) during 3-month follow-up. They were also evaluated for any significant hemodynamic alterations.

Results. Over the follow-up of 90 days, the mean NPS in group A decreased from 6 ± 2 to 3 ± 2 and in group B from 5 ± 1 to 2 ± 2. From the mean NPS scores, it can be interpreted that both the modalities were effective clinically in treating GPN. However, NPS scores were statistically similar by the end of 90 days. Improvement from baseline in BPI measurement of QOL (mood, interpersonal relationship, and emotion) was earlier in group B (1, 2, and 1 months, respectively) compared with group A (2, 3, and 2 months, respectively). However, there were no significant hemodynamic adverse outcomes after administration of the block.

Conclusion. This study found that patients in both the groups had significantly lower pain intensities, improved pain relief, and reduced pain interference with QOL, which was especially evident on fourth visit (2 months) after the initiation of treatment regimen. Both were safe and well tolerated. The study advocates rational polypharmacy approach (oral and block) in difficult to treat painful conditions. Further controlled trials are warranted to further define the impact of such a combination therapy.

Key Words: Pain; Neuralgia; Glossopharyngeal Neuralgia; GPN; Extra Oral Glossopharyngeal Nerve Block; Multidimensional Pain Assessment

Introduction

The diagnosis and management of cranial neuralgias like glossopharyngeal neuralgia (GPN) can be either most frustrating or most rewarding challenges for pain interventionists. The International Association for the Study of Pain (IASP) defines GPN as sudden, severe, brief, recurrent pain in the anatomical distribution of the glossopharyngeal nerve [1]. It must be emphasized that GPN is not as uncommon as reported in the literature in view of underestimated frequency of styalgia [2].

Over the years, many modalities for treating pain have emerged, but GPN treatment still remains underdeveloped. The commonly available treatment modalities are

medical therapy and nerve blocks. Medical therapy includes antidepressants, opioids, antiepileptics, steroids, membrane-stabilizing agents, etc [3–10]. However, the nerve blocks can be performed with either non-neurolytic agents (local anesthetic agents) with or without additives (steroid, ketamine, etc.) or neurolytic agents (phenol, alcohol, glycerol, etc). The other available techniques are: radiofrequency nerve ablation [11], balloon compression [12], proton beam therapy [13], gamma knife ablation [14], implantable motor cortex stimulation [15], microvascular decompression, and decompression surgery [16].

In numerous clinical study reports, medical therapy has been shown to improve pain scores in patients with GPN [3,4,6,7,17]. However, there are very few individual clinical reports documenting the analgesic efficacy of nerve block [18,19], thus it is not routinely used in clinical practice. Hence, the present study was undertaken to evaluate extraoral glossopharyngeal nerve block in terms of analgesic efficacy and hemodynamic safety along with conventional medical therapy. Patients were followed up for 3 months, evaluating for pain intensity and pain induced daily activity limitation and their subsequent improvement after treatment.

This study was planned at our institution, a tertiary care center that has been successfully dealing with at least 200 cases of GPN in a year for more than 20 years with minimal complications and good results in terms of pain relief.

Materials and Methods

This study was a randomized, prospective, active-controlled, parallel-group study conducted from 2007 to 2009 to determine the safety and efficacy of extraoral glossopharyngeal nerve block in GPN. Ethical approval for this study (Ref No. T-02/29/08.08) was provided by the Ethical Committee of AIIMS (Chairperson: Prof. Ravinder Kumar Batra). Written and informed consent was obtained from the participants after detailed description of procedure and associated risks/benefits. Forty adult patients (20–70 years) of either sex, American Society of Anesthesiology (ASA) grades I and II, with history of pain suggestive of GPN were enrolled in the study. They were assessed thoroughly for their pain (duration of pain, previous treatment taken, side involved, and trigger factors) and associated comorbidity if any. Those enrolled were randomly divided into two groups using a computer-generated random number table. Group allocation was concealed in sealed opaque envelopes that were not opened until patient consent had been obtained.

Group A—Patients were given standard medical therapy. Group B—Patients were given extraoral glossopharyngeal block in addition to standard medical therapy.

Standard medical therapy included:

1. gabapentin 300 mg, PO HS for first 3 days, if patient tolerated the drug without excessive sedation; dose was stepped to 300 mg BD;
2. tramadol 50 mg PO, TDS; and
3. methylcobalamine 500 μgm PO, OD

Patients in Group B were initially planned to be given glossopharyngeal block under fluoroscopy (guided to the styloid process), but because of limited degree of success to visualize the styloid process in the first few cases, we continued to use the classical landmark technique for the block in the subsequent cases.

All patients underwent X-ray (panoramic view) to look for styloid process enlargement, magnetic resonance imaging (MRI) brain to rule out any brain pathology, and an otorhinolaryngology checkup to rule out any ear and throat pathology. Patients with local injection site infection, sepsis, coagulopathy, behavior abnormalities, diabetes, known sensitivity to local anesthetics, no response to the first injection *(not true GPN cases)*, and those lost to follow-up were excluded from the study.

The primary objective of study was to evaluate the efficacy of block in addition to medical therapy in terms of analgesia. Due to reported arrhythmias associated with the block, we also set our secondary target to evaluate the safety of the block in terms of any hemodynamic changes. The study not only focused on the analgesic outcomes but also evaluated the degree of limitation in daily activities caused by the pain and their subsequent improvement in a follow-up of 3 months. Exploratory objective included evaluation of the time of onset of clinically significant symptomatic relief.

Blocks and Dosing

Patient's landmark technique was used for giving the block at a depth of 3.5–4.5 cm [20]. This proved to be reliable technique, which was evaluated by onset of numbness in glossopharyngeal nerve area subsequent to the block, and it showed a fairly acceptable level of clinical accuracy. A total of six blocks were given to group B patients with first being a diagnostic block using 5 mL of 1% lidocaine to assess if it relieved the pain or not. If patient reported no or nonsignificant relief, the patient was excluded from the study and was evaluated for alternate causes of pain. Second block was given with 40 mg of depomedrol added to 5 mL of 0.25% bupivacaine. Third and fourth blocks were given with 20 mg depomedrol in 5 mL of 0.25% bupivacaine. Fifth and sixth blocks were given with 5 mL of 0.25% bupivacaine.

These blocks were given on alternate day basis under monitoring that included continuous electrocardiogram, noninvasive blood pressure, heart rate, and pulse oximetry being monitored before and after giving the block at 2, 5, 10, 15, 20, and 30 minutes intervals after the procedure. Patients were looked for any adverse events associated with GPN and glossopharyngeal block like cardiac dysrhythmia, bradycardia, hypotension, asystole, and syncope.

Table 1 Distribution of subjects according to demographic profile and treatment taken

	Group A	Group B	Total
Mean age (years)	41.33 ± 8.2	37.13 ± 7.3	39.23 ± 7.9
Mean weight (kg)	61.06 ± 5.39	58.80 ± 7.51	59.93 ± 6.52
Sex (M/F)	9 (60)/6 (40)	6 (40)/9 (60)	15 (50)/15 (50)
ASA grade (I/II)	11/4	10/5	21/9
Enlargement of styloid process (yes/no)	12 (80)/3 (20)	15 (100)/0 (0)	27 (90)/3 (10)
Side involved (right/left/both)	6 (40)/4 (26.67)/5 (33.33)	5 (33.33)/8 (53.33)/2 (13.33)	11 (33.67)/12 (40)/7 (23.33)
Previous treatment history (yes/no)	12 (80)/3 (20)	10 (66.67)/5 (33.33)	22 (73.33)/8 (26.67)
Duration of pain (months)	22.93 ± 17.19	25.07 ± 31.88	20.67 ± 17.47

Parametric data expressed as mean ± standard deviation. Categorical data expressed as frequency (%).
P value < 0.05 is statistically significant.

Pain Assessment

The pre- and postprocedure pain scorings were done using both unidimensional and multidimensional assessment of pain. Unidimensional assessment was done by standard numerical pain scale (NPS) score ranging from 0 to 10 (where 0 meant no pain and 10 meant worst possible pain). Multidimensional assessment of pain was done with Brief Pain Inventory Questionnaire (BPI) [21,22]. All patients were assessed for the worst pain, minimal pain, average pain, pain at the time of recording the response, and relief since last visit using BPI. Simultaneously, a comparison was made between the quality of life (QOL) parameters (interference in general activity, mood, walking ability, relationship, sleep, and enjoyment of life) using the standard questions included in BPI attached in the appendix section. Each pain parameter in BPI was rated from 0 to 4 (0 = does not interfere, 4 = completely interferes). These items were asked on a 0–4 scale "Circle the one number that describes how, during the past 24 hours, pain has interfered with your:"

Follow-Up Evaluation

Each patient was followed up for a period of 3 months with subsequent visits scheduled on day 15, 1 month, 2 months, and 3 months from the start of therapy. The patients were reassessed using both the NPS and BPI on each visit. All patients continued their other medications during the course of their treatment.

Statistical Analysis

Statistical analyses were performed using SPSS (version 15.0; SPSS, Inc., Chicago, IL, USA) software, and graphs were produced using Microsoft Excel for MAC 2011 (version 14.1.2). In this study, parametric data were recorded as arithmetic mean ± standard deviation. Chi-square analysis was used for nonparametric measurement and to compare the hemodynamic effects. Independent *t*-test was applied for NPS in both the groups with significant confidence interval of 9%. Intergroup comparison in different parameters of BPI (worst pain, minimal pain, average pain, pain at the time of recording, pain relief since last visit, and QOL [interference in general activity, mood, walking ability, relationship, sleep, and enjoyment of life]) was done using Mann–Whitney test. Repeated major analysis was used to assess the mean change from baseline to 3-month follow-up of different BPI parameters. A *P* value of <0.05 was accepted as statistically significant.

Observations and Results

Thirty of 40 potential subjects were included in the study with 15 subjects in each group. The two groups were comparable in terms of demographics (age, weight, sex, ASA grade, side involved, associated styalgia, previous treatment taken, and duration of treatment prior to enrollment in the study) (Table 1). Of these 40 enrolled patients, four patients were not true GPN, two patients did not give consent to participate, one patient was referred to neurosurgery department because of vascular compression of glossopharyngeal nerve root, and three patients were lost in the follow-up, and thus these 10 patients were subsequently eliminated from the study analysis.

Demography

The age of patients ranged from 29 to 61 years with mean age being 39.23 ± 7.9 years. The disease was equally distributed among males and females with ratio being 15:15. One of the significant finding in the study was that out of 30 patients, 27 had an associated enlarged styloid, which was evident on the MRI and an X-ray (panoramic view). Hence, stalgia was the most comment cause of GPN. In our study 7/30 (23%) patients had bilateral pain, 11 patients (36.6%) had pain on right side, and 12 patients (40%) on the left side of face, hence no specific gender or side predilection was seen for the disease. Commonest presentations were earache (93%), pain at angle of mandible (63%). The precipitating factors for pain in this study were swallowing (73%), eating (66%), speaking (60%), and laughing (27%).

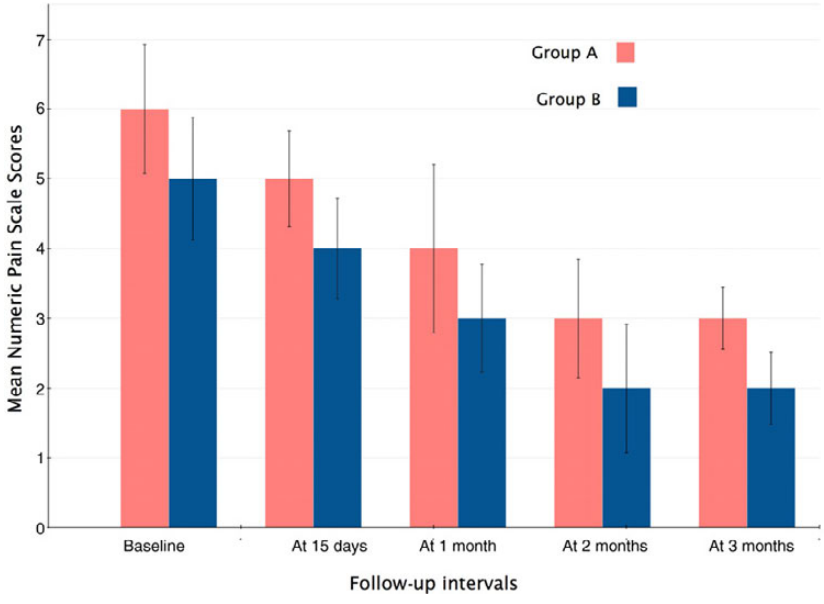

Figure 1 Bar diagram of NPS in both the groups at different time intervals. NPS = numerical pain scale.

Efficacy

NPS

During the follow–up, both groups showed improvement in their pain scores. The unidimensional mean of NPS at the beginning of the study was 6 and 5 in groups A and B, respectively, which reduced to 3 and 2 (groups A and B) by the end of 90 days, which was statistically nonsignificant (Figure 1).

Brief Pain Inventory (BPI)

Intergroup comparison: BPI scores (pain and QOL) were statistically comparable in both the groups (T Figures 2,3). The only statistically significant difference between the groups was for QOL (mood) at 1-month ($P = 0.03$) and 2-month ($P = 0.03$) follow-up.

Intragroup comparison: On analysis of both the groups individually during follow-up, group B showed an earlier fall in pain scores and QOL scores.

Pain Intensity and Pain Relief (Figure 2)

- Worst pain: In group A and group B, statistically significant ($P = 0.06$ and $P = 0.0001$) fall of BPI worst pain scores could be observed at fourth visit (2 months) compared with the baseline. However, at 3 months, pain scores increased and were statistically comparable.
- Minimum pain: In group A and group B, statistically significant fall in minimum pain scores ($P = 0.04$ and $P = 0.02$) occurred at 3 months compared with the baseline.
- Average pain: Maximum fall in average pain scores occurred at 3-month follow-up ($P = 0.03$) and at 2-month follow-up ($P = 0.008$) in group A and group B, respectively. By 3 months, the pain relief was comparable between the two groups.
- Pain right now: Statistically significant fall in pain right now scores occurred maximally at 3-month follow-up in groups A and B ($P = 0.001$, $P = 0.0001$).
- Pain relief: The difference between fall in pain from baseline in group A and B was nonsignificant.

QOL (Figure 3). Group B showed statistically significant improvement from baseline in measure of QOL (mood) 1 month ($P = 0.002$) and (relationship) 2 months ($P = 0.01$) unlike Group A, where these values failed to achieve statistical significance. A statistically significant improvement from baseline was observed at 2 months (fourth visit) for BPI measurement of QOL (general activity, sleep, and emotion) in both groups A and B. However, improvement in BPI measure of QOL (walking ability) in groups A and B was statistically nonsignificant. Values of other indicators showed no significant difference among both the groups.

Safety

In both the groups, no statistically significant hemodynamic alterations were seen. We did not find any arrhythmia during or after giving the block. The mean heart rate before the block was 93.86 ± 7.61 beats per min, systolic blood pressure of 127.86 ± 8.23, and a diastolic of 80.00 ± 3.72 (Figure 4). The average saturation remained 99% throughout the procedure, and there was no episode of desaturation. Of the 90 blocks given, frank blood was aspirated only at one occasion. There are reports of simultaneous block of 10th and 11th cranial nerves [23]. In this study, hoarseness of voice was seen on four occasions and difficulty in swallowing on two occasions. These symptoms resolved after an observation period of 3–4 hours. None of the patient reported shoulder weakness or symptoms of 11th nerve block.

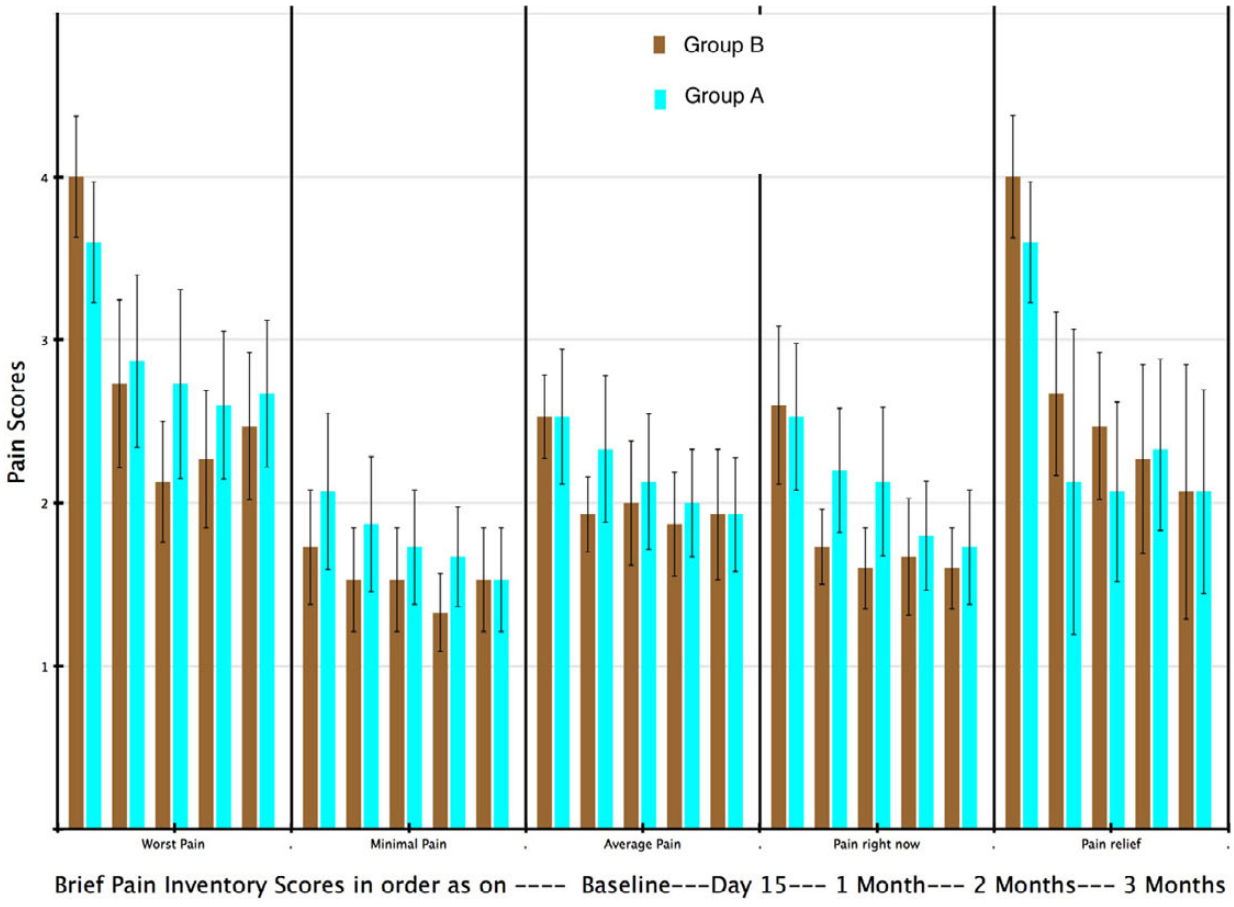

Figure 2 Mean changes in BPI pain intensity and pain relief from baseline to follow-up in both the patient groups. BPI = Brief Pain Inventory Questionnaire.

Discussion

The number of patients with GPN is on the rise and has become a commonly seen facial neuralgia in the pain clinics. The present study was designed to compare the two most commonly used nonsurgical treatments, that is, pharmacological intervention and standard medical therapy combined with nerve block.

Evidence-based medicine (IASP guidelines for neuralgia) recommends that pharmacological agents can be used in combination with each other or as a single agent in treating neuralgia. Hence, we chose combination of gabapentin (first line), tramadol (second line), and vitamin B12 (third line) as standard medical therapy [24,25]. However, increasing doses of gabapentin often also adds more to its sedative effect than only to its analgesic effect; this can become bothersome for many patients thus we used it in combination with tramadol and methylcobalamine avoiding use of higher doses of gabapentin alone. Glossopharyngeal nerve block can be used for both evaluation of atypical facial pain [19,23] and treatment of GPN. We chose extraoral approach as it is less cumbersome and more comfortable to patient than intraoral approach. These findings indicate that extraoral approach for glossopharyngeal nerve block is relatively safe.

The extraoral approach for glossopharyngeal nerve block targets to locate the styloid process and inject the drug solution just posterior to it. However, even when the styloid process is enlarged, it may not be always be possible to locate it, due to its small width. To overcome this problem, we also tried to give fluoroscopy-guided block. However, locating the styloid process using a low resolution fluoroscopy had a limited success even in tangential view. We could locate the styloid process only in 5 of the 15 patents. The block regimen chosen was to limit the total dose of local steroid being injected.

This study found that patients in both the groups had significantly lower pain intensities, improved pain relief, and reduced pain interference with QOL, which was specially evident on fourth visit (2 months) after the initiation of treatment regimen. Both were safe and well tolerated. The study advocates rational polypharmacy approach (oral and block) in difficult to treat painful conditions.

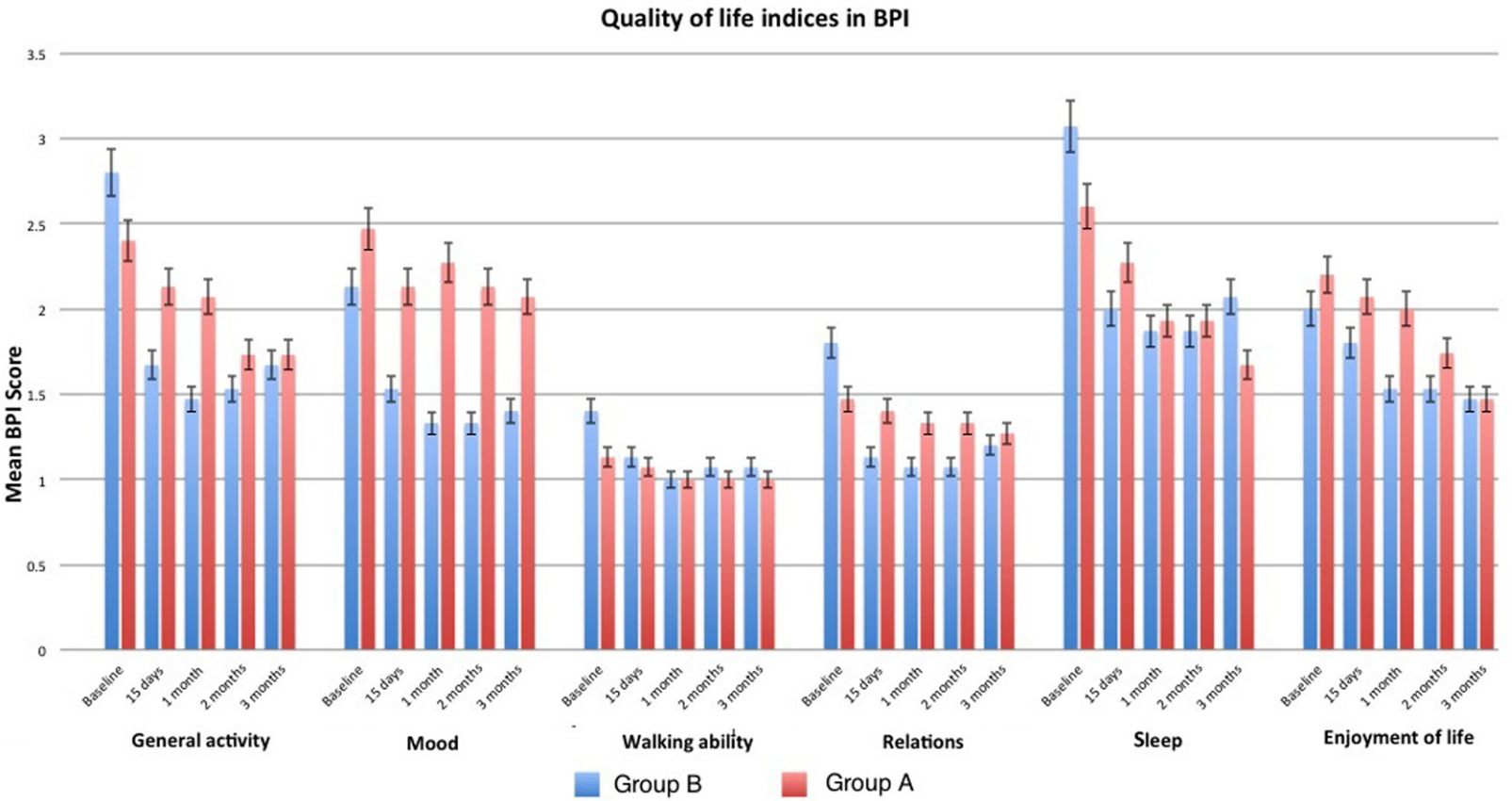

Figure 3 Mean changes in BPI pain interference with activities of daily living (ADL) score from baseline to 3 months in group B represented by Bar while in group A represented by error bar. Brief Pain Inventory Questionnaire.

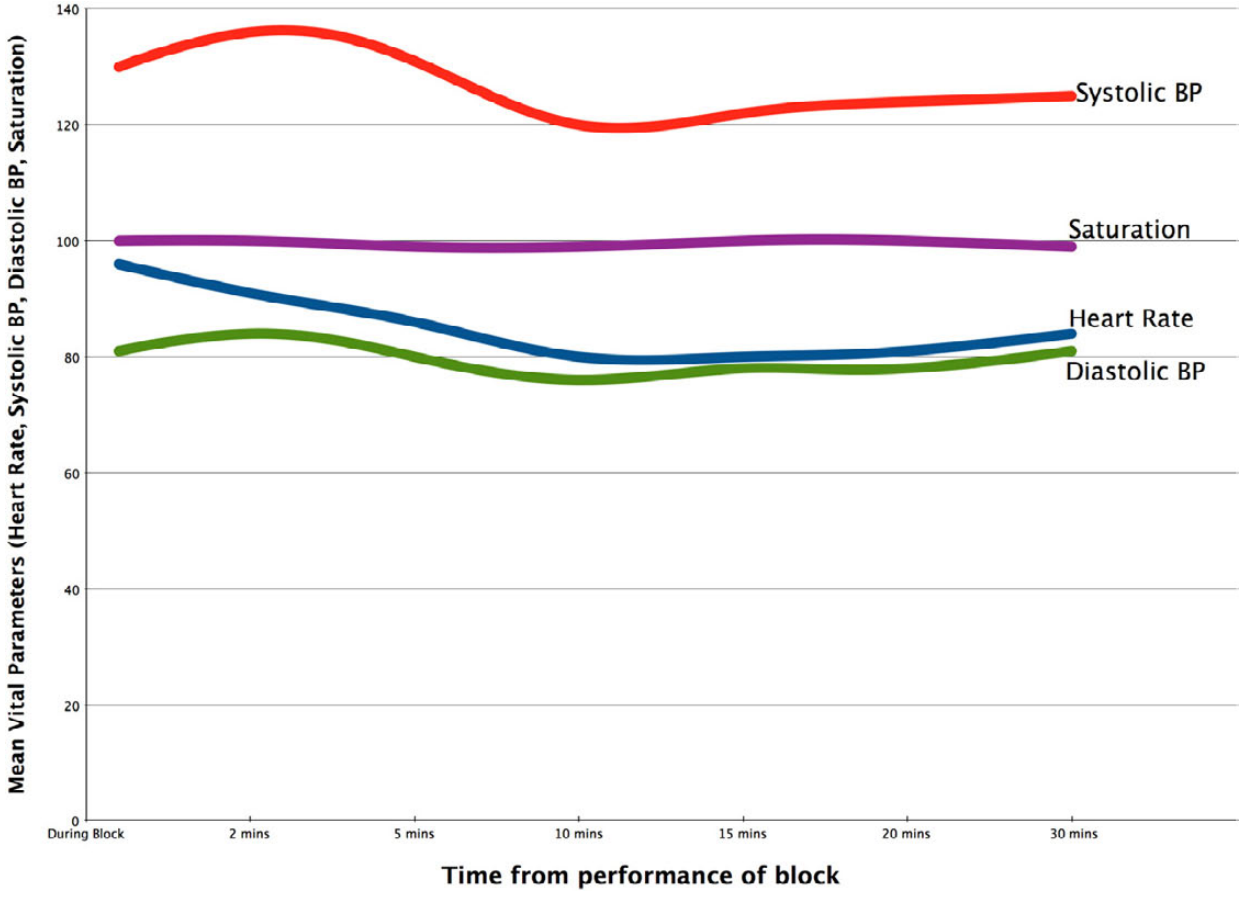

Figure 4 Mean hemodynamic parameters (pulse, systolic blood pressure [BP], diastolic BP, saturation) at different time intervals after administration of glossopharyngeal nerve block.

The mean age of patients in this study is 39.23 ± 8.2 years. The common age group affected by GPN as defined by previous studies is higher than that found in this study. In the previous literature the mean age group commonly affected is around 50 years [26]. The change in age-related demography is probably because of awareness of patients for such disease and availability of better diagnostic modalities. Previous studies have reported male-to-female ratio as 1:2 [16] in GPN, whereas our study had equal incidence of either sex (1:1). This is in agreement with the epidemiological review by Katusic et al. [26–28]. In our study the commonest cause of GPN was found to be Eagle's syndrome (90%) and the remaining (10%) were idiopathic, which is consistent with previous literature.

One of the commonest symptoms in GPN is earache [28]; this is in agreement with the present study as 28 of the 30 patients (93%) reported pain in the ear. The second most common and consistent site involved in the present study was angle of mandible, which was seen in 19 of 30 patients (63%).

Medical therapy alone and medical therapy with glossopharyngeal nerve block both proved clinically beneficial to the patients. On comparing the mean NPS scores in both the groups, a clear reduction in mean values was seen in both the groups and it can be interpreted that both the modalities were effective clinically in treating GPN. However, both of them were statistically similar by the end of 90 days.

Follow-up allows assessment of long-term effectiveness of treatment regimen. Even though we could not find any statistically significant difference in terms of pain scores, however, a peculiar trend was noted during follow-up. There was a gradual reduction in pain scores in both the groups. These results point toward an early onset of pain relief in group B compared with group A. Average pain scores were more rapidly reduced in group B (maximal fall at 2 months) in comparison with group A (maximal fall at 3 months), which shows the clinical benefit of block more in the earlier part of the follow-up. Relief since last visit is an indirect indicator of patient satisfaction score and was statistically same in both the groups at 3 months.

Improvement from baseline in BPI measurement of QOL (mood, interpersonal relationship, and emotion) was earlier in group B (1,2, and 1 months, respectively) compared with group A (2, 3, and 2 months, respectively) which would definitely improve patient satisfaction. These effects can be due to various reasons—alternate day block with bupivacaine, which is a long-acting local anesthetic (around 6 hours) led to pain-free intervals by local nerve blockade in the early course of treatment. This caused early decrease in pain scores in these patients. Besides, nerve block has superadded effect to medical therapy, which when administered alone has delayed onset. There is no literature comparing the rate of relief in medical therapy vs the medical therapy with block group. Even though statistically no significant difference was found between the groups but a clinical benefit is clearly evident. By the end of the third month, both the groups had statistically comparable pain relief and QOL scores that shows that both the groups are equal in terms of clinical benefit by 3 months.

Arrhythmias and syncope have been reported to be associated with GPN due to the nerve supplying the carotid sinus [6,30]. In our study, none of the patient had any history of syncope or palpitations. We did not find any arrhythmias on electrocardiographic monitoring during and after glossopharyngeal block. As the area of block is highly vascular with major vessels like carotid artery and jugular vein around, the chance of inadvertent intravascular injection is always there.

However, as the study sample size was small, further controlled trials involving larger population is warranted. Another limitation of the study was that extraoral nerve block blocks only the sensory component that relies solely upon the landmark technique that might not be reliable in all the patients. Though the use of a group with block alone would have been more logical in bringing out the differences in pain relief compared with medical therapy alone, however, there is no study based on effectiveness of extraoral GPN block and hence this methodology faces ethical concerns in a patient with severe pain. In a scenario where block would have shown to be ineffective, it would have meant patient receiving no treatment for the study purpose. Besides, use of a block-only subgroup would be more relevant when neurolytic blocks are used but not with non-neurolytic blocks, which form an adjuvant to medical therapy to improve outcome in chronic pain patients.

GPN is very incapacitating, and add-on nerve block can avert surgical intervention in patient's refractory to medical treatment. Besides achieving a significant pain relief, one of the goals of treating pain is to achieve relief as rapidly as possible. This factor is even more important in chronic pain syndromes where each day is adding to agony of the patient. Even though the long-term efficacy of block was not statistically evident in the study, however, we would still recommend using the block as an adjuvant to conventional therapy in view of quicker onset of pain relief. The transient and minor adverse effects seen with the block are offset by the fact that analgesia is achieved earlier, which in patient's perspective is an important therapeutic endpoint. If the pain at the start of treatment is mild and not interfering with daily activities than a GPN, block may not be used due to possibility of associated complications that may outweigh the benefits. However, in severe pain, it would help the patient to resume his daily activities earlier thus block in such cases may not be a likely added economic burden but in reality would improve the QOL and thus efficiency of the patient.

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Appendix

Brief Pain Inventory

Date. . . . . Name. . . . . .

Age/Sex. . . . . CR. No. . . . . .

1. Throughout our lives, most of us have had minor aches and pains from time to time. Have you had pain, other than these everyday kinds of pain?
   Yes No

2. Please rate your pain by circling the word that best describes your pain **at its worst** in the past 24 hours.
   No Mild Moderate Severe Most Intense Pain Imaginable

3. Please rate your pain by circling the word that best describes your pain **at its least** in the past 24 hours.
   No Mild Moderate Severe Most Intense Pain Imaginable

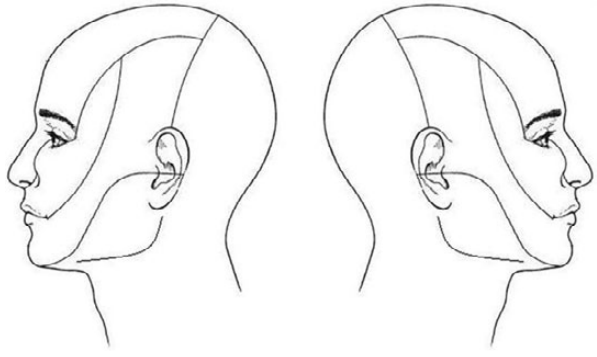
4. Please rate your pain by circling the word that best describes your pain **on average**.
   No Mild Moderate Severe Most Intense Pain Imaginable

5. Please rate your pain by circling the word that best describes your pain **right now**.
   No Mild Moderate Severe Most IntensePain Imaginable

6. What treatments or medications are you receiving for your pain?
   _____
   _____

7. Since last Visit, how much relief have pain treatments or medications provided?
   No relief Some relief Considerable relief Complete relief

8. On the diagram, shade the area where you feel pain. Put an X on the area that hurts the most.



9. Circle the word that describes how pain has interfered with your:

A. General activity				
No Interference	Mildly	Moderately	Severely	Complete Interference
B. Mood				
No Interference	Mildly	Moderately	Severely	Complete Interference
C. Walking ability				
No Interference	Mildly	Moderately	Severely	Complete Interference
D. Relations with other people				
No Interference	Mildly	Moderately	Severely	Complete Interference
E. Sleep				
No Interference	Mildly	Moderately	Severely	Complete Interference
F. Enjoyment of life				
No Interference	Mildly	Moderately	Severely	Complete Interference