Euroasia Journal of Mathematics, Engineering, Natural & Medical Sciences
International Indexed and Refereed
ISSN 2667-6702

Sphenopalatine Ganglion Radiofrequency Ablation for the Management of Refractory Chronic Cluster Headache

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Geliş Tarihi / Received: 2.10.2022 *Araştırma Makalesi/Research Article*
Kabul Tarihi / Accepted: 21.11.2022 *DOI: 10.5281/zenodo.7771181*

ABSTRACT

The objective of this study was to evaluate the effectiveness of percutaneous radiofrequency ablation of the sphenopalatine ganglion The outcome of 16 patients with refractory chronic cluster headache who failed pharmacological management was analyzed after a follow-up period of 24 months.

Sixteen patients with refractory chronic cluster headache who experienced temporary pain relief following sphenopalatine ganglion block underwent percutaneous radiofrequency ablation of the sphenopalatine ganglion via the infrazygomatic approach under fluoroscopic guidance. Collected data include duration of the headache and mean attack frequency before and up to 24 months after procedure.

The profile of pain-free survival after undergoing the first SPG-RFA during the follow-up time was calculated according to the Kaplan-Meier method

The average follow-up time was 24 months (range, 18–24 mo). Acute pain relief was accomplished in all patients. Complete pain relief was achieved in 50% of the patients who underwent a single procedure at 24 months The overall pain recurrence rate was 12.5% after 24 months (range, 18–24 mo).

The mean attack frequency improved from 15 attacks/week to 5.5, 6.5, 8.0, 8.8, 8.6, 8. 5, 8.4, at 1-, 3-, 6-, 12-, 18-, 21-, 24- month follow-up visits ($P < .0001$, $P < .0001$, $P < .0001$, $P < .002$, , $P < .003$, $P < .004$, $P < .004$, respectively.

Percutaneous radiofrequency ablation of the sphenopalatine ganglion is minimally invasive, safe and effective procedure with a low complication rate for the treatment of refractory chronic cluster headache in clinical practice.

Keywords: Cluster headache , Radiofrequency ablation, Sphenopalatine ganglion, pain, neuralgia

INTRODUCTION

Cluster headache (CH) is a complex disease characterized by chronic head and neck pain which often accompanied by autonomic features. Headache associated with pain in the maxillary arch and teeth is usually localized to the orbit, supraorbital and /or temporal regions. Autonomic symptoms are lacrimation (tearing), conjunctival injection (redness of the sclera), rhinorrhoea, nasal congestion, hyperhidrosis (excessive sweating) and eyelid oedema and usually occur on the ipsilateral side to the pain.

There are episodic and chronic forms of CH. Episodic CH occurs over periods from 7 days to 1 year separated by pain-free periods lasting at least 1 month. Chronic CH (CCH) occurs over the interval of more than 1 year without remission or with remissions lasting less than 1 month [1] .

Neuroimaging studies have suggested the hypothalamus as attack generator in CHs. CH involves activation of the parasympathetic outflow from the superior salivary nucleus of the facial nerve, predominantly through the sphenopalatine ganglion (SPG) [2] .

Percutaneous radiofrequency ablation of the sphenopalatine ganglion (SPG RFA) was described by Salar et al in 1987 [3] . Although the pathogenesis of CHs has not been completely elucidated, the SPG has traditionally been considered to be involved in the pathophysiology of CHs [4,5]. SPG RFA is a method used to destroy painful nerves with heat [6, 7, 8]. The SPG RFA device uses high frequency (ranges 300-500kHz) to create charged molecular oscillation which generates heat by the friction of ions and radio waves. When the needle tip heats to 80 degrees C for 60 to 90 seconds, it produces the local tissue damage and loss of myelinated fibers. This temperature reliably produces an 8-10 mm affected area [8].

We were interested to examine the effect of percutaneous SPG RFA in patients with refractory chronic cluster headache (CCHr) who failed pharmacological management.

METHODS

After the institutional research review board's approval, the data were collected retrospectively by reviewing patients' diaries, questionnaires, and medical records. Sixteen patients with CCHr operated between 2010 and 2021 were included in this study.

The inclusion criteria comprised the following: (1) the diagnosis of CH is confirmed according to the diagnostic criteria of the International Classification of Headache Disorders third edition [9] ; (2) the patient's age is between 18 and 75 years.

The exclusion criteria included the following: (1) abnormalities in blood measurements, liver and kidney function, blood glucose, coagulation, electrocardiography or chest radiography; (2) prior anticoagulant or antiplatelet therapy; (3) previous mental illness; (4) previous history of narcotic drug abuse; and (5) current pregnancy or breast feeding.

Sixteen patients with CCHr, who experienced temporary pain relief following SPG block, underwent percutaneous RFA via the infrazygomatic approach under fluoroscopic guidance. The needle can be advanced either anterior to the mandible or through the coronoid notch.

The anesthesia was administered at a level that gave comfort to both the patient and surgeon during the electrical test stimulation and lesioning procedure. Because of the vagal reflex, atropine was used for bradycardia. Nitroglycerine dermal patches were applied to patients who were predisposed to cardiac ischemia and acute hypertension.

The patient is placed supine to view the pterygopalatine fossa. A standard C-arm fluoroscopic image intensifier (Toshiba - Surginix SXT-2000A) with image-storing capacity, which provides sufficient picture quality for the clinical procedure was used.

A 22-gauge, 10 cm, curved radiofrequency needle with a 5 mm active tip is inserted coaxially with lateral fluoroscopic guidance and is advanced either anterior to the mandible or through the coronoid notch, and superiorly and medially toward the pterygopalatine fossa (Fig 1). The curve is downward to avoid lesioning the maxillary nerve, which is located at the roof of the pterygopalatine fossa. An AP view is intermittently obtained to check the depth of the needle and avoid any breach of the nasal wall (Fig 2). If the needle tip accidentally advanced through the pterygopalatine foramen into the nasal cavity (Fig 3), it should be withdrawn and directed caudal and medially. The needle tip should terminate immediately lateral to the ipsilateral nasal wall.

Sensory stimulation is obtained with 50 Hz with a 1 millisecond pulse duration at at < 0. 5 V.

If the positon is correct, the parestthesia occurs on the endonasal level. If the maxillary nerve was stimulated, paresthesia occurs on the cheek, upper teeth, or upper lip. The needle should be repositioned caudal and medially. If major or minor palatine nerves were stimulated, the paresthesia occurs on the hard palate. The needle should be moved posterior, medial, and superiorly.

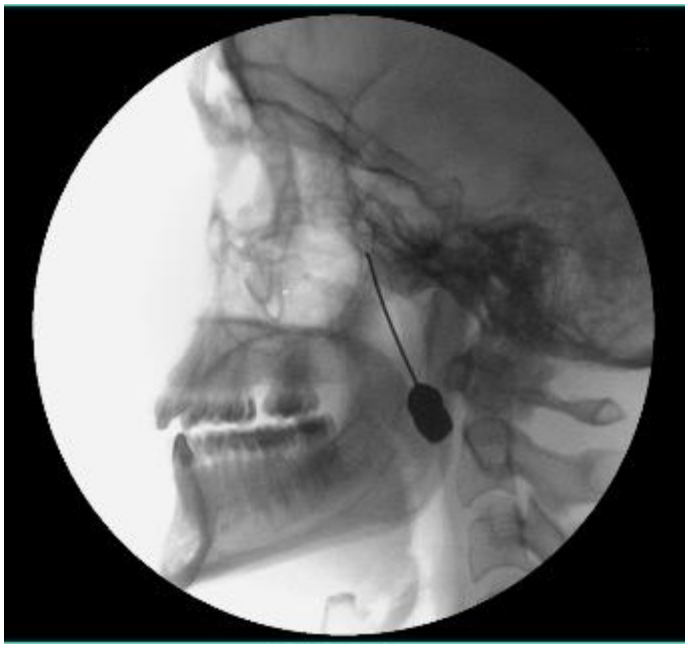


Figure 1. Lateral view of the infrazygomatic approach showing the tip of the needle in the pterygopalatine fossa.

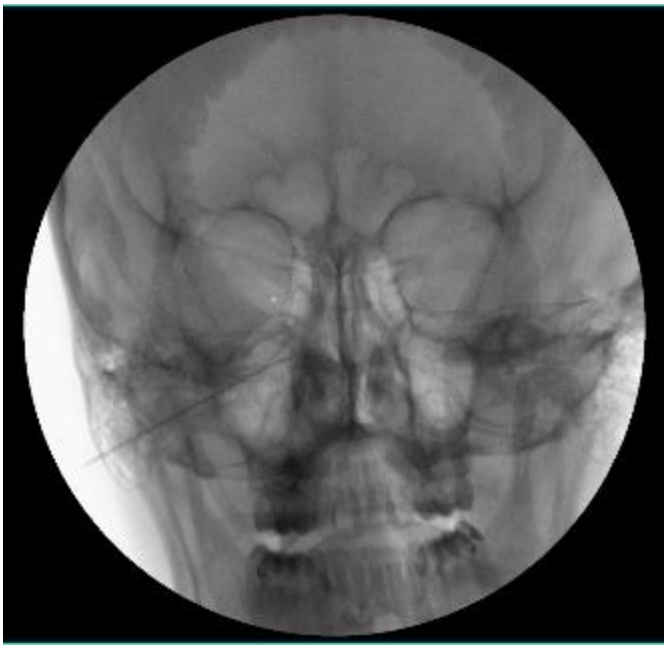


Figure 2. Anteroposterior view showing needle tip terminating immediately lateral to ipsilateral nasal wall.

Once stimulation is achieved and prior to lesioning, 0.2-0.4 mL of contrast agent is injected under real-time fluoroscopy to rule out intranasal or intravascular spread (Fig 4). After stimulation and proper positioning are confirmed, 0.4 mL of lidocaine 2% is injected, and two radiofrequency lesions are carried out at 80°C for 90 seconds. After lesioning, 0.4 mL of bupivacaine 0.5% and 5 mg of triamcinolone are injected with the aim to prevent postprocedure neuritis.

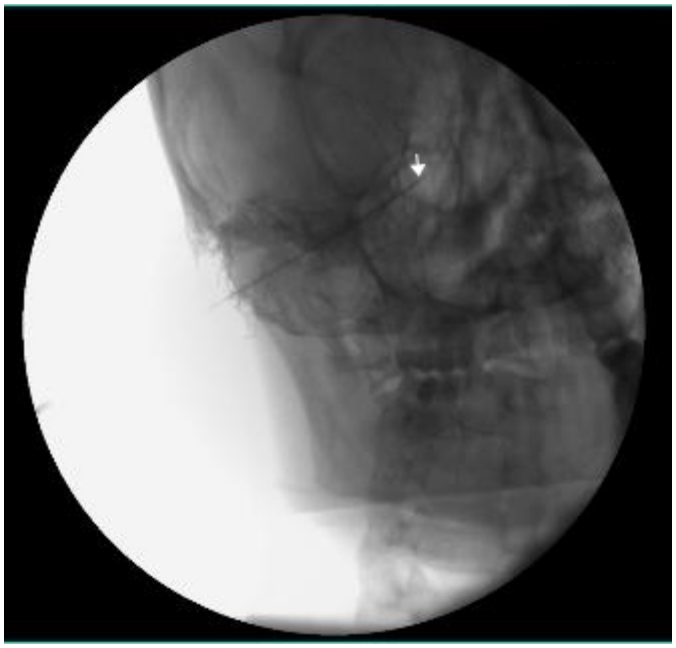


Figure 3. Anteroposterior views showing the needle tip penetrating the pterygo palatine foramen and entering the nasal cavity (white arrow).

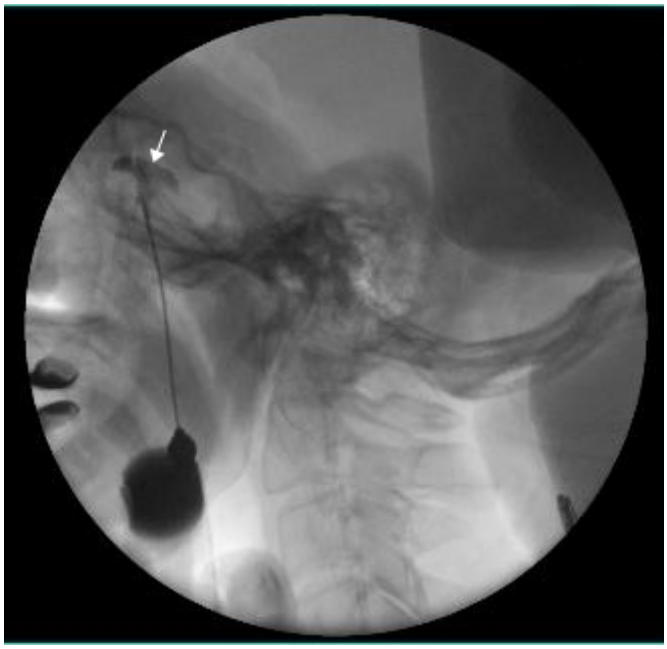


Figure 4. Lateral view showing the spread of the contrast material in the pterygopalatine fossa (white arrow).

The patients were typically discharged on the day of surgery. Overnight hospitalization was recommended in patients with poor medical status to observe pain alleviation and vital functions after the procedure was completed. All medications previously provided for pain control were discontinued after the patient had undergone SPG RFA.

The data were matched with the data acquired from a questionnaire that provided information about the degree and duration of pain relief, the need for further therapy, the presence of surgical sequelae, and a subjective assessment of the patients' overall degree of improvement that is, complete pain relief, partial satisfactory pain relief, partial unsatisfactory pain relief, no change, and

worse. Partial satisfactory pain relief meant that recurrent pain was less severe than preoperatively; that pain could be controlled with medication; and that there was no need for a subsequent SPG RFA procedure. Complete pain relief meant that the patient took no medication and experienced no pain; only data for patients in the latter category are shown in the results. The profile of pain-free survival after undergoing the first SPG-RFA during the follow-up time was calculated according to the Kaplan-Meier method (Table 1).

Collected data include demographic variables, onset and duration of the headache, mean attack frequency (MAF), baseline, 1, 3, 6, 12, 18, 21, 24 months after procedure. Headache pattern, medications use, and adverse events were recorded.

Statistical analysis performed using paired t-test comparing each time to baseline, and P < .5% (Bonferroni-corrected) is considered significant.

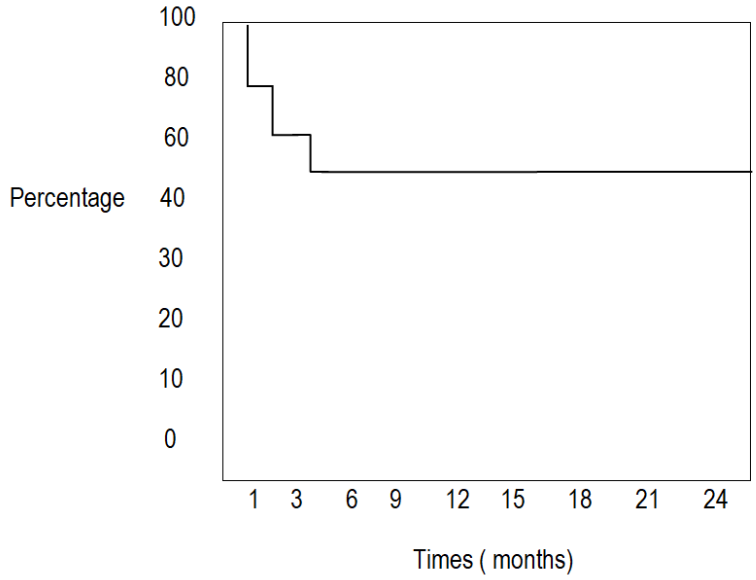
RESULTS

During a 24 –month period, 16 patients were included in the study. The average follow-up time was 24 months (range, 18–24 mo). There were 8 men and 8 women. The average of men was 42(±4) years and the average of women was 35 (±5) years. The average age of the entire group was 40 ±5 years.

Acute pain relief was experienced by 16 patients (100%) after SPG RFA was performed, and this finding was accepted as the initial success rate of SPG RFA. Early (6 mo) pain recurrence was observed in 1 patient (6.25%), whereas late (6 mo) recurrence was reported in association with 1 patient (6.25%). The overall pain recurrence rate was 12.5% during an average follow-up period of 24 months (range, 18–24 mo).

Complete pain relief was achieved in 50% of the patients who underwent a single procedure at 24 months (Table 1).

Table 1. Kaplan–Meier curves for pain-free survival following percutaneous radiofrequency ablation of the sphenopalatine ganglion as assessed by patient chart review in patients with CCHr. The curves were calculated over all patients with initial pain relief following treatment (n = 16). Mantel-Cox 7.813, P = 0.005.



The mean attack frequency (MAF) improved from 15 attacks/week to 5.5, 6.5, 8.0, 8.8,

8.6, 8.5, 8.4 at 1-, 3-, 6-, 12-, 18-, 21- ,24- month follow-up visits (P < .0001, P < .0001

P< .0001, P < .002, , P < .003, P < .004,P < .004, respectively.

Twenty five percent of patients (4/16) reported no change or increase in the headache intensity and/or frequency during the first few post-procedure weeks before noticing improvements in their headache pattern. However, 50 % of the patients (8/16) reported change in the headache pattern with return to the episodic form of CH at a mean follow-up period of 24 months. Those patients were eventually able to cut down on their preventive medications, namely indometazine, verapamil and lithium. 25% of the patients (4/16) remained headache free and off medications for the duration of the follow-up (18-24 months).

Regarding adverse events, about 50% of the patients (8/16) reported temporary paresthesias in their upper gums and cheek that lasted for 3-6 weeks with complete resolution.

No mortalities occurred after SPG RFA procedure.

Reflex bradycardia occured during radiofrequency stimulation in %50 of our cases. Atropine was used for bradycardia.

None of the patients developed significant infection, bleeding, hematoma formation, dysesthesia, or numbness of palate, maxilla, or posterior pharynx.

DISCUSSION

CCH accounts for about 10% of patients with cluster headache, and it usually lacks the circadian pattern typical of the episodic cluster. Patients with CCH are often resistant to pharmacological management. Percutaneous SPG RFA is a quick and simple technique that has proven itsefficacy in episodic CH, having been used in a short series of CCHr with variable results. Our results showed that percutaneous SPG RFA is a quick and partially effective method to treat CCHr.

In recent years, there have been a series of reports on the treatment of chronic CH via the pterygopalatine ganglion. One type of pterygopalatine ganglion treatment is SPG RFA, which blocks pain signalling by denaturing pterygopalatine ganglion proteins. The other type is minimally destructive treatment, such as pterygopalatine ganglion pulsed radiofrequency treatment (PRF) and electrical nerve stimulation [1, 8, 12, 13].

Li J et al reported that PRF in patients with CCHr can quickly relieve pain without significant side effects [13]. However, a randomised controlled trial is still necessary to evaluate whether PRF treatment is a viable treatment option for patients with CCHr.

Neurostimulation of the vagal nerve, supraorbital nerve, occipital nerve and sphenopalatine ganglion, transcranial magnetic stimulation and deep brain stimulation have been investigated for the treatment of migraine and/ or CH [10, 11, 14, 15]. Whereas invasive methods of neurostimulation would be reserved for patients with very severe and treatment refractory migraine or CH, noninvasive methods of stimulation might serve as useful adjuncts to more conventional therapies [15]. Jürgens TP et al reported that SPG stimulation is an effective acute therapy in 45% of patients, offering sustained effectiveness over 24 months of observation [16]. However, the potential utility of each type of neurostimulation has yet to be completely defined [15].

The sphenopalatine ganglion (SPG) is located in the pterygopalatine fossa. It is suspended from the maxillary nerve by the pterygopalatine nerves, inferiorly it is connected to the greater and lesser palatine nerves, and posteriorly it is connected to the vidian nerve [4]. Efferent branches of the SPG form the posterior lateral nasal and pharyngeal nerves, as well as the pharyngeal branch of the maxillary nerve. There are also orbital branches reaching the lacrimal gland [4,17]. The medial wall of the pterygopalatine fossa communicates with the nasal cavity via the sphenopalatine foramen, which transmits the sphenopalatine artery, the nasopalatine nerve and the posterior superior nasal nerves [17].

The sphenopalatine artery injury may occur with this infrazygomatic approach if the needle is advanced too far medially through the lateral nasal wall or in the the sphenopalatine foramen. Epistaxis may occur after the sphenopalatine artery injury. Intravascular injection and cheek hematoma formation can occur after maxillary artery injury, which lies within the pterygopalatine fossa.

The needle tip accidentally was advanced through the pterygopalatine foramen into the nasal cavity in two of 16 patients (12.5 %) in our study (Fig 3). Epistaxis and infection didn't occur in patients underwent percutaneous SPG RFA in our study. Narouze S et al reported that epistaxis is the most common complication, and infection is always a possibility especially if the nasal mucosa is accidentally penetrated [18].

A standard C-arm fluoroscopic image intensifier with image-storing capacity, which provides sufficient picture quality for the clinical procedure was used. The sphenopalatine artery injury, epistaxis and cheek haematomas didn't occur in our cases. Li J et al reported that the use of-use a CT scanner during the procedure to verify the position of the puncture needle in the pterygopalatine fossa [13]. Li J et al that the orientation and depth of the puncture needle was adjusted according to the CT image until the needle approaches the pterygopalatine ganglion [13]. They reported that surgery-related complications, such as epistaxis and cheek haematomas were successfully avoided [13].

Loomba V et al reported that the use of cone beam computed tomography as a alternative to bi-plane fluoroscopy for image guidance in the management of chronic CHs [19].

Further, reflex bradycardia was reported during radiofrequency lesioning, which could be explained by the rich parasympathetic connections to the SPG [1]. Reflex bradycardia occured during radiofrequency stimulation in %50 of our cases. Atropine was used for bradycardia.

Radiofrequency lesioning of the SPG can result in permanent or, more commonly, temporary hypesthesia or dysesthesia in the palate, maxilla, or posterior pharynx [12]. Dryness of the eye as a result of interruption of the parasympathetic supply is also common; however, it is usually only temporary [12,18]. But this complication didn't occur in our cases.

We followed 16 patients underwent percutaneous SPG RFA for a mean follow-up of 24 months (range, 18-24 months). Four of our patients (25%) experienced complete clinical relief of both pain and parasympathetic symptoms, 8 patients (50%) had the partial and transient relief, and 4 patients (25%) didn't improve. Salgado-Lopez et al. published their results on the safety and efficacy of SPG RFA [6]. They followed 37 patients underwent percutaneous SPG RFA for a mean follow-up of 68 months (range, 15-48 months). Five of their patients (13.5%) experienced complete clinical relief of both pain and parasympathetic symptoms, 21 patients (56.8%) had the partial and transient relief, and 11 patients (29.7%) did not improve. They documented no complications in any of these patients. Samer Narouze et al. published their results on the safety and efficacy of percutaneous SPG RFA [18]. They followed 15 patients underwent percutaneous SPG RFA. 3 patients (20%) reported no change or increase in the headache intensity and/or frequency during the first few post-procedure weeks before noticing improvements in their headache pattern. However, 7 patients (46.7%) reported change in the headache pattern with return to the episodic form of cluster headache at a mean follow-up period of 18 months. Three patients (20%) remained headache free and off medications for the duration of the follow-up (18-24 months). Regarding adverse events, about %50 (7/15) reported temporary paresthesias in the upper gums and cheek.

The our results agree with the findings of Salgado-Lopez et al. and Samer Narouze et al.

Radiofrequency lesioning of the SPG can result in permanent or, more commonly, temporary hypesthesia or dysesthesia in the palate, maxilla, or posterior pharynx and dryness of the eye. Precise needle placement with the use of real-time fluoroscopy and electrical stimulation prior to attempting radiofrequency lesioning may reduce the incidence of adverse events.

Single-centre reports on small groups of patients have shown that SPG RFA treatment in patients with CCHr can quickly relieve pain without significant side effects. However, a randomised controlled trial is still necessary to evaluate whether SPG RFA treatment is a viable treatment option for patients with CCH who are not responding to drug treatment.

CONCLUSION

Percutaneous SPG RFA is minimally invasive, safe and effective procedure with a low complication rate for the treatment of refractory chronic cluster headache in clinical practice.

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