



# Comparative Analysis of Balloon Compression and Radiofrequency Ablation in Idiopathic Trigeminal Neuralgia: A Retrospective Study with a 24-Month Follow-up

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## Abstract

**Objective:** Trigeminal neuralgia (TN) is a common cause of facial pain, with a prevalence of 40 per million. This paper is a retrospective 24-month follow-up study of 20 patients with idiopathic drug-resistant TN who underwent balloon compression (BC) or radiofrequency ablation (RFA).

**Methods:** When neuralgia affected more than one divisions or it involved ophthalmic division, BC was performed. RFA was performed in neuralgia involving isolated mandibular or maxillary division.

**Results:** At all the time points, numerical rating score (NRS) was lower in the BC group, but the difference was not significant. The proportion of patients developing recurrence of pain was lower in the BC group, but the difference was not significant (p-value 0.63). The proportion of patients requiring a repeat procedure was lower in the BC group, but the difference was not significant. There was no significant correlation among recurrence of pain, age of the patient and number of divisions in which neuralgia was present. In BC, a pear shape of the balloon is desirable, but this shape is not always achievable. Recurrence of pain in the BC group was comparable to that in the available literature, but the recurrence rate in the RFA group was comparatively higher. The complications in BC were higher, but they were transient and improved with time.

**Conclusion:** BC and RFA are effective modalities of treatment for idiopathic TN with comparable results. In TN involving multiple divisions, BC may be more convenient.

**Keywords:** Balloon compression, gasserian ganglion, radiofrequency ablation, trigeminal neuralgia

## Introduction

Trigeminal neuralgia (TN) has a prevalence of 40 per million, and it is one of the most painful conditions (1). It is almost twice as common in females compared with in males. In TN, severe electric-shock-like pain occurs in the distribution of the trigeminal nerve (fifth cranial nerve). Aetiology of TN remains elusive at large with evidence suggestive of pressure on the trigeminal root at the entry zone in the pons (2) causing demyelination, leading to ectopic action potential generation, which leads to neuralgia. In patients with known aetiology, cerebellopontine (CP) angle tumour, multiple sclerosis and aberrant vascular loop causing nerve demyelination are the leading causes.

Among the three divisions, the second is the most commonly affected, while the first is the least affected (1). Over time, the frequency and intensity of neuralgia increases, and responsiveness to medications decreases. TN adversely affects the quality of life of the patients with the effect being more pronounced in the elderly population (3). Cases with idiopathic TN that become drug resistant are suitable for interventions like radiofrequency ablation (RFA) and balloon compression (BC) (4).

Balloon compression was first performed by Mullan and Lichtor in 1983 (5). In BC, a small balloon is percutaneously introduced through a 14G Tuohy Needle. Upon inflation, the balloon compresses the trigeminal ganglion, which induces a controlled injury leading to impaired ability of the nerve to transmit pain signals (6).

Radiofrequency (RF) can be applied to the gasserian ganglion in two ways: thermal RF and the pulsed RF (PRF) mode. Thermal RF causes structural damage to the axon. PRF does not cause structural damage, but it causes microscopic damage to the microfilaments of the C-fibres (sparing the A<sub>delta</sub> fibres) (7). However, a randomised trial demonstrated that PRF did not reduce pain in comparison to conventional RF, which limits the use of PRF in TN (8).

The primary aim of the study was to compare the duration of pain relief in the RFA and BC groups. The secondary aim was to identify any correlation between recurrence of pain and number of divisions of trigeminal nerve having neuralgia and also the recurrence of pain and age of the patient.

## Methods

The data in this study belong to 20 patients with idiopathic drug-resistant TN who underwent RFA or BC for pain management and completed 24-month follow-up.

Patients were diagnosed with TN if they fulfilled the diagnostic criteria laid down by the International Headache Society (9). All patients underwent brain MRI to rule out tumour or multiple sclerosis. Patients were considered for intervention if their pain was resistant to medications or if they did not want to take medication due to some reason (planning pregnancy, excessive sedation, weight gain etc.).

Balloon compression was the modality of choice in cases where TN involved more than one division or where the first division was involved. RFA was used in patients with isolated maxillary or mandibular nerve involvement.

Informed consent was obtained from all patients. RFA was performed under local anaesthesia with monitored anaesthesia care, while BC was performed under general anaesthesia (GA) with mechanical ventilation. All patients were given alprazolam tablet (0.5 mg) at night before the procedure, and they followed standard fasting protocol for GA.

An intravenous cannula, three-lead electrocardiogram, pulse oximeter and blood pressure monitoring were applied to all the patients. A single dose of ceftriaxone (1 g) was intravenously given 15 min prior to the procedure. The procedure was performed in supine position.

Both the procedures were performed under fluoroscopy guidance. A suboccipito-mental (SOM) view of the skull was taken to identify both the coronoid processes. Once the SOM view was obtained, the C-arm was progressively rotated to an ipsilateral oblique position to see the foramen ovale (FO). An RF cannula (10 cm, 23G with 0.5 cm active tip) was used in patients undergoing RFA, while a Tuohy Needle (14G) was used in patients undergoing BC. At all times, an attempt was made to keep the cannula tip in the anterolateral part of FO (to avoid injury to the carotid artery).

In RFA, depth of needle insertion was assessed in the lateral C-arm image of the skull with the petroclival junction (PCJ) as the reference. For targeting the third division, the cannula tip was kept approximately 5 mm proximal to PCJ. If the second division was targeted, cannula tip was kept at PCJ. After placing the RF cannula in a suitable position, sensory stimulation was performed for concordant pain and paraesthesia. Once concordant sensory stimulation was achieved at less than 0.6 V, the RF ablation was commenced after administering 0.5 mL of 1% lidocaine. The first lesion was made at 65°C for 60 s, and then corneal reflexes were checked. If the corneal reflex was intact, the second lesion was performed at 70°C for 60 s.

In BC, the tip of the Tuohy Needle was docked in the Meckel's cave just above FO. After satisfactory placement of the Tuohy Needle, a 4Fr Fogarty catheter was passed through the needle, and the balloon was inflated with diluted ionic radio contrast under continuous fluoroscopy. A pear shape of the Fogarty balloon was desirable. Once the desired shape of the balloon was achieved, compression was performed for 90 s.

Follow-up was performed at 6, 12 and 24 months after the procedure. For this study, an increase in numerical rating score (NRS) to  $\geq 6$  was considered as recurrence of pain. Repeat procedure was performed if the patient had unbearable pain (NRS 10). For patients who developed recurrence and needed to undergo repeat procedure a maximum NRS, i.e. 10, was noted in the subsequent follow-up data and used for statistical analysis.

## Statistical analysis

Statistical analysis was performed using the non-parametric Mann-Whitney U test for comparing NRS between the groups. Chi-square test was used to compare the proportion of patients developing recurrence or requiring a repeat procedure. Logistic regression was applied to study the relation between TN involving more than one dermatome and recurrence of pain. A p-value of  $<0.05$  was considered significant.

**Results**

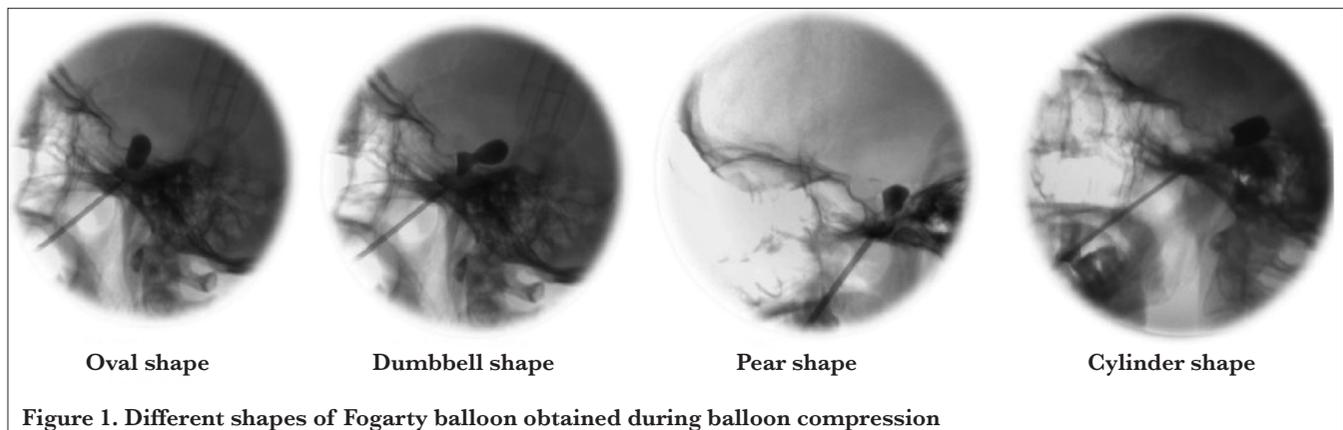
Baseline characteristics like age, pain duration and pain intensity were comparable in both the groups (p-value 0.22, 0.06 and 0.24, respectively). NRS at 6, 12 and 24 months after the procedure was lower in the BC group, but the difference was not significant (p-value 0.88, 0.52 and 0.25, respectively) (Table 1).

In the RFA group, one patient had a recurrence of pain at 12-month follow-up, while six patients reported a recurrence of pain at 24 months. In the BC group, no patient had a recurrence at 12 months, while three patients had a recurrence at 24 months. The proportion of patients developing recurrence of pain was comparable in the two groups (p-value 0.17). During the 24-month follow-up, four patients in the RFA group and three patients in the BC group needed to undergo a repeat procedure. The proportion of patients requir-

**Table 1. Tabulated follow-up data of the cohort**

Serial	Age in years	NRS baseline	Division involved	Pain Duration in years	Treatment Group	NRS at 6 months	NRs at 12 months	NRS at 24 months
1	32	8	3	3	RFA	2	2	7
2	44	9	3	8	RFA	1	3	10
3	56	8	2	7	RFA	1	2	2
4	76	7	1,2	15	BC	0	1	3
5	45	10	3	5	RFA	3	5	10
6	86	8	1,2,3	25	BC	1	3	3
7	38	9	3	6	RFA	3	3	3
8	53	10	2	6	BC	3	5	10
9	51	7	1	3	BC	0	0	3
10	66	9	1,2,3	9	BC	3	3	3
11	51	10	3	4	RFA	2	6	10
12	56	8	2	3	RFA	1	3	4
13	45	8	2,3	5	BC	2	2	3
14	55	9	1,2,3	18	BC	3	3	3
15	69	10	2	4	RFA	3	4	10
16	51	8	3	3	RFA	2	3	4
17	65	9	1,2,3	12	BC	4	5	10
18	72	8	2,3	10	BC	2	4	10
19	56	10	3	5	RFA	3	4	4
20	44	9	2,3	2	BC	3	3	3
p	0.12	0.24		0.06		0.88	0.52	0.25

p<0.05 is significant. NRS refers to numerical rating score, RFA refers to radiofre-quency ablation, BC refers to balloon compression. NRS: numerical rating score; RFA: radiofrequency ablation; BC: balloon compression



**Figure 1. Different shapes of Fogarty balloon obtained during balloon compression**

ing repeat procedure was also comparable in the two groups (p-value 0.63).

In the BC group, the balloon was pear-shaped in seven patients (Figure 1c), while in three patients, the balloon was not pear-shaped (Figure 1a, 1b, 1d). Recurrence of pain occurred in patients in whom the balloon was not pear-shaped, and later, these patients had to undergo a repeat procedure.

There was a statistically non-significant negative correlation between TN involving more than one division and recurrence of pain with an odds ratio (OR) of 0.19 (p-value 0.17). There was a statistically non-significant positive correlation between age and recurrence of symptoms (OR 1.01, p-value 0.71).

## Discussion

Firstly, in this retrospective cohort study, the pain relief over the follow-up period was comparable in the two groups. Secondly, the recurrence of pain and need for repeat intervention (although less in the BC group) were statistically compared between the groups. Thirdly, the BC group patients had a higher incidence of complications like loss or reduction of corneal sensations, lateral rectus palsy, headache in the post-operative period, but these complications were transient in nature and without any significant morbidity during the follow-up period. Fourthly, there was no relation between the TN involving multiple divisions and recurrence of pain. There was a non-significant correlation between age and recurrence of pain.

All the patients received good pain relief that correlates with observations of Omeis et al. (10) who reported immediate pain relief in 80% of the patients. In patients undergoing BC, 19% and 32% recurrence rates have been demonstrated over a period of 5 and 20 years, respectively (11). The recurrence rate in our patients was comparatively higher with three out of ten patients developing recurrence by the end of just 2 years.

Our observations regarding the shape of the balloon in BC and pain relief are similar to those of Park et al. (12). Results were better when the balloon was pear-shaped when inflated with no recurrence of pain in 24-month follow-up. Three patients had a recurrence of pain in the BC group: two of them had a cylindrical-shaped balloon, while one had oval-shaped.

Although the pear shape of the inflated balloon is desirable, this is not achievable in all cases for some unknown reasons. Dumbbell shape of the balloon is also associated with long-lasting results. An oval shape may appear due to the large size of the cave, adhesion in ganglion, inadequate inflation of the balloon or a wrongly positioned catheter tip (12).

A cylindrical shape balloon may be due to the intradural placement of the catheter with minimal compression on the ganglion (13).

In the BC group, five patients had a 50%-70% reduction of sensation in the ipsilateral face (three in the all the three divisions, one patient each in the maxillary and mandibular divisions). Complete loss of corneal sensation was noticed in one patient, while two patients developed reduced corneal sensation. One patient developed exposure keratopathy that was successfully managed conservatively. The same patients also developed transient lateral rectus palsy and diplopia on ipsilateral lateral gaze that were successfully managed with the help of taping of eyelid and physiotherapy and could be discharged home after 10 days. Similar to the observation of Lopez et al. (14), two patients developed masseter weakness, which recovered after two weeks of physiotherapy. All patients undergoing BC had a moderate-to-severe ipsilateral temporal headache that got relieved over the next 3-4 days with NSAIDs. The facial hypoesthesia showed improvement over subsequent follow-up visits.

In this study, patients with isolated maxillary or mandibular nerve involvement were treated with RFA (seven mandibular nerve and three maxillary nerve involvement). Patients with ophthalmic division involvement were not treated with RFA in view of high chances of corneal anaesthesia and its related complications. In all patients undergoing RFA, a satisfactory concordant motor and sensory stimulation was achieved. All of them had a satisfactory pain relief in the immediate post-operative period. Kanpolat et al. (15) had reported a recurrence rate of 15%-20% in the initial 12 months and 50% by the end of 5 years. Our rate of recurrence in the RFA group was similar at 12 months but was considerably higher (70%) at 24-month follow-up in comparison to 17.4% as reported by Kanpolat et al. (15).

Corneal reflex was maintained in all patients; transient lateral rectus weakness was noticed in one patient that recovered in 2 weeks. One patient developed transient masseter weakness that recovered in 3 weeks. All patients had mild loss of sensation in the treated dermatome. The less frequent complications of RFA documented in the literature include diminished corneal sensation, masseter weakness, dysaesthesia, anaesthesia dolorosa, transient paralysis of cranial nerves III and VI, aseptic meningitis and carotico-cavernous fistula (15).

This study identified that the results of BC and RFA are statistically similar at the end of 24-month follow-up, although the results appear to be clinically better in the BC group (in view of the lesser pain score and lesser recurrence rates). In view of the author, BC is easier to perform than RFA because there is no need for isolated localisation of the nerve division.

BC is more comfortable for the patient as it is performed under GA, while RFA is performed in an awake patient. BC can be helpful in management of TN with multidivisional involvement. RFA may not be appropriate in cases with multidivisional involvement as nerve localisation becomes difficult and may require multiple procedures to ablate one division at a time.

Complication rates in BC were comparatively higher, but most of them were transient in nature except an ipsilateral decrease in facial sensation.

Since TN is an uncommon problem, it becomes difficult to gather data of a large cohort. The authors have tried to study key aspects of the two most common percutaneous procedures. To the best of our knowledge, there is no study that compares the two modalities. The main limitation of this study is the small number of patients and a relatively short follow-up period. Although in this study, the two modalities appear to be comparable, studies of a larger scale and longer follow-up are needed to make the scenario clearer.

Although the initial trends suggest a possible association between balloon shape and longer duration of pain relief, a larger study is needed to give a more definitive answer. The association between serious complications like corneal anaesthesia, masseter weakness and lateral rectus paralysis with any particular balloon shape needs to be established.

## Conclusion

In patients with drug-resistant idiopathic TN, BC and RFA are effective treatment modalities with comparable results. BC may be more convenient in patients with neuralgia in multiple divisions, but the associated complications have to be kept in mind.

**Informed Consent:** Written informed consent was obtained from all patients who participated in this study.

**Peer-review:** Externally peer-reviewed.

**Conflict of Interest:** The author have no conflicts of interest to declare.

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