Randomized Controlled Trial

Comparative Effectiveness and Safety of Percutaneous Balloon Compression Versus Conventional Radiofrequency Thermocoagulation for Classic Trigeminal Neuralgia: A Randomized Clinical Trial

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Background: Trigeminal neuralgia (TN) is a debilitating facial pain syndrome. Percutaneous balloon compression (PBC) and conventional radiofrequency thermocoagulation (CRF) are widely used for drug-refractory TN, but randomized evidence comparing their efficacy and safety remains limited.

Objectives: To compare the efficacy, safety, and mechanistic correlates of PBC vs CRF in patients with primary TN.

Study Design: Prospective, randomized, single-blind, controlled trial.

Setting: The Pain Medicine Unit, Department of Anesthesiology, at a tertiary care medical institute in the Republic of India.

Methods: Sixty adults with primary TN refractory to ≥ 2 medications were randomized 1:1 to PBC or CRF, stratified by age (< 60 or ≥ 60 years). PBC was performed via the Hartel approach with 0.8 mL contrast inflation and 90-second compression; CRF involved fluoroscopy-guided, electromyography-confirmed lesioning at 65°C and 70°C for 60 seconds. Independent blinded assessors recorded Numeric Rating Scale pain scores at baseline, and at postprocedure days 7, 30, 60, 90, and 180. Secondary outcomes included the Barrow Neurological Institute Pain Intensity Score, Brief Pain Inventory (BPI), Douleur Neuropathique 4 Questionnaire (DN4Q), the Pain Catastrophizing Scale (PCS), and safety measures. Correlations between balloon pressures at the beginning (P1) and end of compression (P2) or nerve division involvement and outcomes were analyzed.

Results: Baseline characteristics were comparable. Both the groups achieved significant pain relief at 6months, but PBC yielded superior outcomes in Numeric Rating Scale scores (mean ± SD) (1.4 ± 0.98 vs 2.35 ± 1.09; $P = 0.002$) and BNI (1.75 ± 0.91 vs 2.28 ± 0.76; $P = 0.01$). Improvement in BPI, DN4Q and PCS were similar. Safety was excellent; transient mild masseter weakness was more common with PBC at day 7 (30% vs 3.3%, $P = 0.005$) but resolved by day 30. Corneal sensation and other cranial nerve functions were preserved. Balloon pressures showed weak, nonsignificant correlations with 6-month outcomes; nerve division involvement had no correlation with the outcome.

Limitations: Single-center design and short 6-month follow-up.

Conclusions: PBC provided superior 6-month pain and functional outcomes compared with CRF, with comparable long-term safety. These results support PBC as the preferred percutaneous intervention for appropriately selected patients with classic TN.

Key words: Conventional radiofrequency thermocoagulation, facial pain, percutaneous balloon compression, tic douloureux, trigeminal neuralgia

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Trigeminal neuralgia (TN) is one of the most debilitating facial pain syndromes, with percutaneous interventions serving as cornerstone therapies for medically refractory cases (1). Despite the widespread use of percutaneous balloon compression (PBC) and conventional radiofrequency (CRF), current evidence suffers from 3 key limitations: 1) a paucity of randomized controlled trials comparing these techniques, 2) a lack of blinded outcome assessments in existing studies, and 3) inconsistent reporting of procedure-specific complications. Our single-blind, randomized clinical trial addresses these gaps by providing the first prospectively collected comparative data with standardized outcome measures and independent blinded evaluators.

The rationale for randomization and blinding is particularly relevant for TN studies, where subjective pain reporting, such as with the Numeric Rating Scale (NRS-11), and functional outcomes, such as the Barrow Neurological Institute Pain Intensity Score (BNI), may be influenced by patient and assessor expectations. Prior nonrandomized comparisons have shown conflicting results, with a 2023 systematic review noting significant selection bias in 78% of published studies (2). Our design mitigates these biases while evaluating both interventions under real-world clinical conditions.

Our study's primary objective was to compare the analgesic effectiveness of PBC vs CRF at 6 months postprocedure as measured by the NRS-11. The secondary objectives were to assess and compare changes in the BNI score, Brief Pain Inventory (BPI) and Pain Catastrophizing Scale (PCS) at 6 months, and to evaluate masseter weakness (graded 0–3), corneal sensation using qualitative esthesiometry, and other cranial nerve deficits. In addition, our study aimed to analyze the correlation between intraprocedural balloon pressures (P1/P2) and clinical outcomes, and to examine the effect of nerve division involvement on treatment response.

We hypothesized that PBC would yield significantly better NRS-11 scores than CRF at the f 6 months postprocedure.

Method

After obtaining Institutional Review Board approval no. (IEC No.: 58/19), the proposed study was listed with the Clinical Trial Registry of India (2020/02/023397). This prospective, randomized, single-blind, clinical trial was conducted at the Pain Medicine Unit of the Department of Anaesthesiology at a tertiary care medical institute in northern India for 18 months. During this study, all procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2013. Written informed consent was obtained from all patients with particular attention to the risks of sensory deficits and alternative treatment options.

The sample size was calculated to detect a clinically significant difference in the mean reduction of NRS-11 scores between the PBC and CRF groups. Based on prior data (1), the expected difference in mean NRS-11 reduction between groups was 1.0, with a pooled standard deviation (σ) of 0.98. To ensure robust power while accounting for potential variability, we assumed a conservative mean difference (Cohen d) of 0.8.Considering an α of 0.05 and an 80% power, 19 patients were needed in each group.

Eligible patients who consented to participate were enrolled consecutively and were randomized in a 1:1 allocation ratio to receive either PBC or CRF. Randomization was performed using a computer-generated block randomization sequence with blocks of size 4, ensuring equal numbers of patients in each group within every block. To control for potential confounding due to age, randomization was stratified based on 2 predefined age categories (< 60 years and ≥ 60 years). Separate randomization lists were prepared for each stratum to maintain balanced allocation across treatment arms within each age group. Outcome assessors were blinded to treatment allocation throughout the 180-day follow-up period.

We enrolled 60 adult patients (30 per group) meeting these criteria:

a. Inclusion: a diagnosis of primary trigeminal neuralgia (ICHD-3 criteria) (3), refractory to ≥ 2 medications.
b. Exclusion: trigeminal neuropathy ICHD-3 (13.1.2), which includes patients with trigeminal neuropathy due to herpes zoster, posttraumatic TN or other disorders; secondary TN causes; previous destructive procedures; or bleeding disorders.

Randomization was done using a computer-generated random number table. Treating physicians were necessarily unblinded, but the assessor who conducted all outcome assessments and the statisticians analysing the coded data were blinded about the group allocation.

The Diagnostic criteria for classic trigeminal neuralgia used were as follows (ICHD-3); (13.1.1.1.1 & 13.1.1.3.1):

A. At least 3 attacks of severe unilateral, recurrent, paroxysmal, electric shock-like, shooting, stabbing or sharp facial pain attacks occurring in one or more divisions of the trigeminal nerve, lasting from a fraction of a second to 2 minutes
B. Pain attacks are precipitated by innocuous stimuli to the affected side of the face
C. No clinically evident neurological deficit.

Interventions

All patients underwent a preprocedure evaluation, including routine complete blood count and coagulation profile. Procedures were conducted in an operation theatre under fluoroscopic guidance; CRF was performed under local anesthesia with monitored anesthesia care while PBC was performed under general anaesthesia with endotracheal intubation. All patients were premedicated with oral alprazolam (0.5 mg) the night before the procedure.

The American Society of Anesthesiologists guideline for patient monitoring was used for all patients with continuous noninvasive blood pressure monitoring, peripheral oxygen saturation, and electrocardiogram monitoring. An intravenous drip of Lactated Ringer solution was administered via a wide-bore, 18G needle to each patient.

A 10-cm, 22G RF cannula with a 0.5 cm active tip and a pain management RF machine (Avanos Ince, USA) was used in patients undergoing RFA. In RFA, in order to treat the maxillary branch, the needle was aimed at the middle of the foramen; to treat the mandibular branch the needle was aimed at the lateral part of the foramen ovale; to treat the ophthalmic branch, the needle was aimed at the medial part of the foramen ovale. The needle insertion depth was assessed with a lateral fluoroscopic C-arm image of the skull with the petroclival junction as the reference. After placing the RF cannula in a suitable position, sensory stimulation was performed for concordant pain and paraesthesia (Fig. 1). Once concordant sensory stimulation was achieved at less than 0.6 V, one lesion of RF ablation at 65°C and another at 70°C for 60 seconds were made after administering 0.5 mL of 1% lidocaine (4).

Under fluoroscopy, the Hartel approach was used to perform PBC using a dedicated PBC kit (SYM Matreneu PBC Kit, Shenzhen SYM Medical Tech, China). A 14G access cannula was introduced to the Meckel cave, followed by a specialized blunt guide-wire and 4 Fr PBC balloon catheter inflated with 0.8–1.2 mL radiocontrast medium. After confirming a pear-shape of the inflated balloon, compression was done for 90 seconds. A digital manometer was used to measure the balloon pressure at the beginning (P1) and the end (P2) of the compression duration (Fig. 2).

Outcome Measures

1. Primary: NRS-11 score improvement at postprocedure day 7, 30, 60, 90, and 180.
2. Secondary: BNI, BPI and PCS improvements at postprocedure day180.

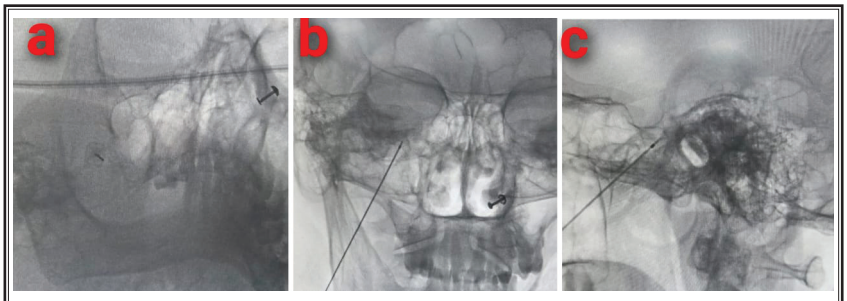


Fig. 1. *Fluoroscopic images of CRF. a) Submento-occipital view- showing the RF cannula in foramen ovale; b) Antero-posterior view- showing the RF cannula reaching the meckel's cave; c) Lateral view- showing the RF cannula for depth perception.*

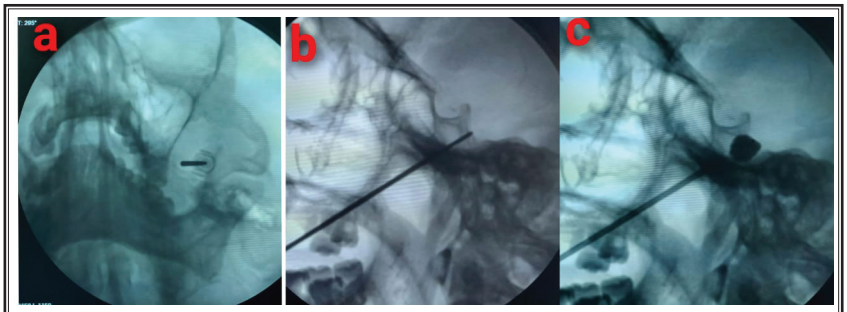


Fig. 2. *Fluoroscopic images of PBC: a) Submento-occipital view- showing the 14G blunt cannula in Forament Ovale; b) Lateral view: showing the blunt guide-wire reaching just up to petro-clival line; c) Lateral view: showing the inflated 'pear-shaped' balloon in meckel's cave.*

3. Safety outcomes: masseter weakness (graded 0–3); corneal reflex (qualitative esthesiometry); and third and sixth cranial nerve deficits.

Grading of Masseter weakness: Grade 0: No weakness – normal masseter strength. Grade 1: Mild weakness – slight reduction in bite force, not functionally limiting. Grade 2: Moderate weakness – noticeable reduction in bite force, some difficulty in chewing. Grade3: Severe weakness – marked reduction or inability to bite/clench, significant functional impairment.

Grading of facial hypoesthesia: mild: up to 25% decrease in facial sensation; moderate: 25%–50% decrease in facial sensation; severe: > 50% reduction in facial sensation.

Statistical Analysis

Continuous variables were expressed as mean (SD) and compared using independent or paired t tests, while categorical variables were presented as frequencies/percentages and analyzed with χ^2 or Fisher exact tests. Correlations between balloon pressures (P1, P2), nerve division involvement, and clinical outcomes were assessed using the Pearson correlation. A 2-tailed $P < 0.05$ was considered statistically significant. Analyses were performed using SPSS16 software (SPSS, Inc.) (Fig. 3).

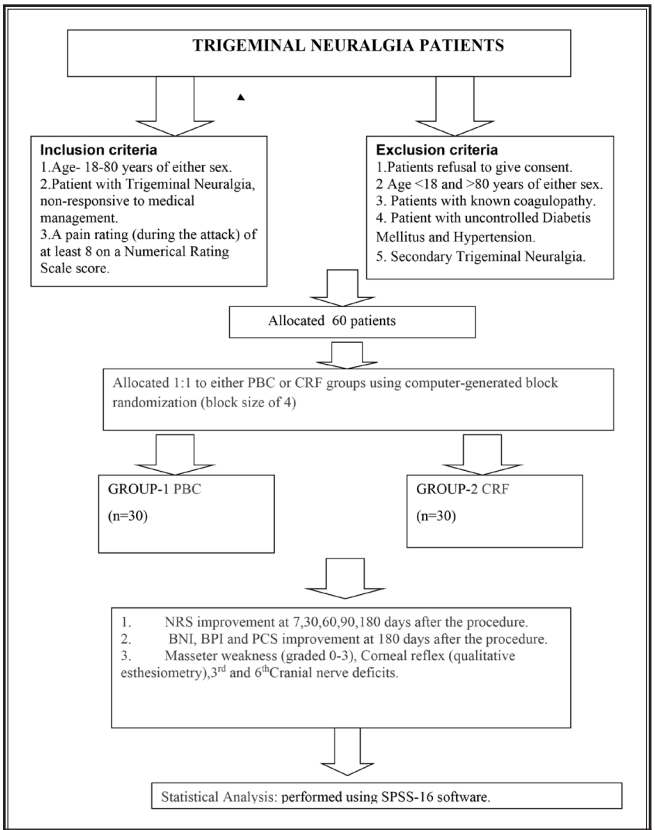


Fig. 3. *CONSORT flow chart.*

Results

Our study assessed 60 patients with TN (30 per treatment group) with comparable baseline characteristics (Table 1). The groups were well-matched for all baseline characteristics.

Serial outcome measurements demonstrated superior efficacy for PBC at multiple endpoints. The PBC group showed significantly greater improvement in NRS-11 pain scores at postprocedure days 7, 30, and 180. Similarly, Brief Pain Inventory scores showed greater improvement at postprocedure day 60 and beyond (Table 2). Repeated measures analysis of variance confirmed these findings (Table 3), revealing significant time×group interactions for both BNI scores ($F[3.2,185.6]=3.8$; $P = 0.009$) and NRS-11 scores ($F[2.8,162.4]=4.1$; $P = 0.008$). Between-group effects significantly favored PBC for BNI scores ($F[1,58]=6.7$; $P = 0.012$) and NRS-11 scores ($F[1,58]=4.9$, $P = 0.031$). Both groups showed substantial improvement in BPI and PCS scores from baseline to postprocedure day 180 ($P < 0.001$ for all within-group comparisons), though no between-group differences reached significance at the postprocedure day 180 endpoint (Table 3).

Preprocedure, all patients had been on a regimen of carbamazepine—800 mg–1600 mg/d. At postprocedure day 180, 69% patients in the CRF group and 57% in the PBC group required some medication (regardless of the dose). This difference in proportion of patients requiring medications (12%) was not statistically significant ($P = 0.33$).

On the day of the procedure 2 patients in the PBC Group had moderate hypoesthesia, while 4 each in the PBC Group and the CRF Group had mild hypoesthesia. No patient in either group had any residual sensory loss on the ipsilateral side at postprocedure day 180. Corneal sensation remained intact in 97%–100% of patients across both groups, with only one transient cases of reduced sensation in the PBC Group (resolved by postprocedure day 180). There were no third/sixth cranial nerve deficits observed after either of the procedures.

Masseter weakness initially showed a significant difference at postprocedure day 7 ($P = 0.005$); only mild cases were observed which were higher in the PBC Group (9/30 vs 1/30). At postprocedure day 30,

Table 1. *Baseline demographic and clinical characteristics of patients undergoing percutaneous balloon compression (PBC) vs conventional radiofrequency thermocoagulation (CRF) for trigeminal neuralgia.*

S. no	Parameter	PBC (mean+/-SD)	CRF (mean+/-SD)	*P* Value
1.	Age	61.03+/-12.5	60.24+/-12.7	0.81
2.	Gender (M:W)	14:16	17:13	0.47
3.	Duration of pain(months)	79.4+/-86.7	80.4+/-83.0	.051
4.	BNI score	4.5+/-0.5	4.5+/-0.50	0.54
5.	NRS-11 score	9.2+/-0.46	9.1+/-0.62	0.71
6.	BPI	8.1+/-0.84	8.0+/-0.83	0.87
7.	Pain Catastrophising Scale score	43.8+/-3.9	43.7+/-3.8	0.91
8.	Normal MRI: vascular loop	18:12	21:9	0.59
9.	Right : left	16:14	19:11	0.60
10.	Single: multidivisional	11:19	17:13	0.19
11.	Previous procedure(Y/N)	8:22	6:24	0.76

BNI (Barrow Neurological Institute) score, BPI (Brief Pain Inventory), NRS-Numeric Rating Scale.

Table 2. *Comparative outcomes of percutaneous balloon compression (PBC) vs conventional radiofrequency thermocoagulation (CRF).*

Parameter	Time-point	PBC Group (mean+/-SD)	CRF Group (mean+/-SD)	*P* Value
NRS Pain	Baseline	9.2 ± 0.46	9.1 ± 0.62	0.51
	D7	2.37 ± 1.04	3.2 ± 1.76	0.04*
	D30	1.9 ± 1.03	2.55 ± 1.40	0.03*
	D60	1.67 ± 1.42	2.0 ± 1.6	0.41
	D90	1.33 ± 0.84	1.75 ± 1.8	0.21
	D180	1.4 ± 0.98	2.35 ± 1.09	0.002*
BNI	Baseline	4.5 ± 0.5	4.5 ± 0.50	0.99
	D7	2.44 ± 0.73	2.79 ± 0.77	0.08
	D30	2.37 ± 0.62	2.62 ± 0.56	0.12
	D60	2.1 ± 0.64	2.58 ± 0.62	0.006*
	D90	1.9 ± 0.75	2.34 ± 0.76	0.02*
	D180	1.75 ± 0.91	2.28 ± 0.76	0.01*
BPI	Baseline	8.1+/-0.84	8.0+/-0.83	0.87
	D180	2.13+/-0.87	2.3+/-0.86	0.45
Pain Catastrophizing	Baseline	43.8+/-3.9	43.7+/-3.8	0.9
	D180	14.1+/-5.8	15.8+/-5.8	0.12

BNI (Barrow Neurological Institute) score, BPI (Brief Pain Inventory), NRS-Numeric Rating Scale.
*P value < 0.05

nearly all patients in both groups returned to normal strength (PBC Group: 28/30, CRF Group: 29/30, (P = 1.0). No third or sixth cranial nerve palsies occurred.

Initial balloon pressure (P1) at the time of achieving an adequate pear-shaped balloon image averaged 181 kPa ± 66.7 kPa, while the end pressure (P2) was 138 kPa ± 57.4 kPa. Correlation analysis revealed a weak positive association between both pressure measures and NRS-11 score reduction at 6 months, with coefficients of r = 0.19 for P1 and r = 0.20 for P2. The correlation analysis yielded a coefficient of r = 0.03, indicating an extremely weak and statistically nonsignificant relationship between the number of affected nerve divisions and the degree of pain reduction.

Discussion

Our study provides strong evidence that at 6 months follow-up, PBC is superior to CRF for primary treating TN.

PBC produced significant greater improvements in pain intensity and functional outcomes at postprocedure month 6 as measured by NRS-11 and BNI scores, while maintaining an excellent safety profile.

Our results show that the superiority of PBC became apparent by postprocedure day 60 and persisted throughout all follow-ups, with patients achieving near-complete pain relief by 6 months. Both techniques were effective in reducing BPI and PCS scores, indicating substantial improvement in quality of life and pain-related psychological distress, though between-group differences were not significant. The postprocedure analgesic requirements also came down in both groups but more so in the PBC Group. These findings highlight PBC's more durable nerve modulation compared to the ablative mechanism of CRF.

Safety outcomes were favorable in both groups. Transient masseter weakness was more frequent post PBC at day 7 but resolved in nearly all patients by day 30; no patient experienced persistent deficits. Corneal sensation and cranial nerve function were preserved in almost all cases. These findings suggest that while PBC is associated with short-term masticatory weakness, it does not compromise long-term functional safety.

Our results align with recent meta-analyses and large retrospective studies, which report comparable short-term outcomes for PBC and CRF, but superior long-term efficacy with PBC, particularly in recurrence-

Table 3. *Longitudinal outcomes of percutaneous balloon compression (PBC) vs conventional radiofrequency thermocoagulation (CRF) for trigeminal neuralgia.*

Parameter	Effect Tested	F-value (df)	*P* value
BNI Scores	Within-subjects (Time)	F(3.2, 185.6)=84.3	< 0.001***
	Between-groups	F(1,58)=6.7	0.012*
	Time×Group Interaction	F(3.2,185.6)=3.8	0.009**
NRS-11 Pain Scores	Within-subjects (Time)	F(2.8,162.4)=312.6	< 0.001***
	Between-groups	F(1,58)=4.9	0.031*
	Time×Group Interaction	F(2.8,162.4)=4.1	0.008**
BPI Scores	Baseline vs D180	t(29)=34.1 (PBC) t(29)=32.8 (CRF)	< 0.001*** (both)
	Between-groups (D180)	t(58)=0.73	0.47
Pain Catastrophizing	Baseline vs D180	t(29)=26.5 (PBC) t(29)=22.4 (CRF)	< 0.001*** (both)
	Between-groups (D180)	t(58)=1.16	0.25

BNI (Barrow Neurological Institute) score, BPI (Brief Pain Inventory), NRS-Numeric Rating Scale.
*P value < 0.05

free survival (5-9). While prior studies noted higher rates of masticatory weakness with PBC, our data show that such weakness was mild and self-limited. Importantly, none of our patients developed persistent hypoesthesia at 6 months, compared to other reports where sensory deficits were predictive of longer-term relief.

We also examined mechanistic correlates. Balloon pressures (P1/P2) showed only weak, nonsignificant correlations with long-term outcomes. This is inconsistent with some earlier studies, who have found a positive correlation of pain relief with balloon pressure; this may be due to the fact that our sample size was conservative and future studies with large sample size may adequately reflect the importance of pressure. Though our findings echoes with previous studies suggesting that balloon morphology-particularly achievement of the characteristic pear shape-and accurate positioning within Meckel's cave may be more important determinants of efficacy (10). Similarly, nerve division involvement had no effect on treatment response, underscoring that PBC may provide uniform efficacy across divisions. Future work incorporating imaging-based predictors, such as foramen ovale dimensions (10), may refine patient selection and procedural optimization.

The strengths of our study include its randomized design, blinded assessment, and standardized protocols, addressing key limitations of prior observational work. However, limitations must be acknowledged: it was a single-center study with a modest sample size and relatively short follow-up. Longer-term outcomes, particularly recurrence rates beyond 12 months–24 months, remain to be determined.

Overall, our trial demonstrates that PBC achieves superior mid-term pain control compared to CRF without compromising safety. These findings support PBC as the preferred percutaneous intervention in appropriately selected patients with classic TN and highlight the need for multicenter studies with extended follow-up to confirm durability and explore mechanistic predictors of outcome.

Conclusion

In this randomized, single-blind trial, PBC showed superior analgesic and functional outcomes compared with CRF thermocoagulation for TN without compromising safety. Pain relief with PBC was greater and more durable, while side effects were transient and mild. Given its favorable risk–benefit profile, PBC should be considered the preferred percutaneous intervention for patients with medically refractory classic TN. Larger multicenter studies with longer follow-up are warranted to validate these findings and optimize procedural parameters.

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