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Effectiveness of oral carbamazepine in improving quality of life of trigeminal neuralgia patients by using brief pain inventory facial questionnaire (BPI-Facial). A Randomised Clinical trial

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Abstract

Background: Trigeminal neuralgia (TN) is a debilitating unilateral, stabbing facial painful, condition originating from the trigeminal nerve. It is presented as burning, electric shock, or Tingling. Pain in the trigeminal neuralgia significantly affects both the sensory as well as the motor activities of the body, thus affects the quality of life. Carbamazepine remains the gold standard drug in terms of efficacy for treatment for trigeminal neuralgia. The study aimed to evaluate the efficacy of tablet Carbamazepine in improving quality of life by using BPI Facial questionnaire.

Materials and Methods: A total of 20 patients with a mean age of 50.80 years included in the study were randomly selected from the outpatients having complaints of facial pain. All the patients were given a Brief pain inventory Questionnaire before and after the intervention by the tablet carbamazepine (400mg) divided into two doses. After 1-month patients were again given BPI Facial questionnaire to evaluate the effectiveness of tablet carbamazepine on quality of life. The collected data were then subjected to statistical analysis.

Results: The treatment of trigeminal neuralgia with tablet carbamazepine showed significant improvement in pain. Also, the interference of pain on the general activities and orofacial activities decreased significantly as seen by the Brief pain inventory facial questionnaire. Hence it improved the quality of life of trigeminal neuralgia patients.

Conclusion: The study thus suggested that carbamazepine can be an effective first or second-line drug treatment of trigeminal neuralgia.

Keywords: Carbamazepine, BPI Facial, Trigeminal neuralgia, Quality of life

Introduction

The trigeminal neuralgia (TN) is defined as a "unilateral disorder abrupt in onset and termination, associated with brief electric shock-like pains, and often limited to the distribution of one or more divisions of the trigeminal nerve. Diagnosis is made primarily by clinical history and anamnesis [1]. Pain in the trigeminal neuralgia is very sharp abrupt, throbbing and tingling. This long-term intense pain often affects daily activities, induces negative emotions, such as depression and anxiety as well as deterioration of sleep quality thus disturbing the well-being of patients which affects the patient's quality of life.[2,3,4,5] Thus, understanding and management of patients with chronic orofacial pain is probably the biggest challenge faced by professionals because of both physical and psychosocial symptoms. Hence recognizing the psychological components of pain is critical to conduct an effective treatment and important for understanding the health outcomes and disease impact on quality of life (QL)[1,6-10] When the pain severity and frequency of attacks increases with time, chronic preventive treatment is required. Carbamazepine is usually the first line and gold standard drug for controlling pain in classic or idiopathic TN. It acts by inhibiting voltage-gated sodium channels that reduce the excitability of neural membranes and also potentiate gamma-aminobutyric acid (GABA) receptors. The optimum dose for newly diagnosed cases of TN is 100–200 mg twice daily. The typical total maintenance dose is 300–800 mg/ day, which should be given in two to three divided doses. A maximum total dose of 1200 mg/day could be given [11-13] Despite TN being a very debilitating disease, there are not many papers in the literature that specifically assess the QL of patients with trigeminal neuralgia after treatment modalities. Thus we aimed to evaluate the improvement in quality of life with carbamazepine by using BPI facial questionnaire. It is the ideal facial pain scale that effectively evaluates various domains of pain in an effective short time frame. It is a very sample well-validated and most commonly used questionnaire for the evaluation of chronic pain.it consists of 18 items on a 1 point (0-10) scale in which four items denote pain intensity, seven items represent interference of pain on general life activities, and seven focuses on interference with orofacial activities.[14] Thus, the study aimed to evaluate the efficacy of carbamazepine in improving quality of life by using the (BPI) facial pain scale

Materials and Methods

This study was conducted on patients who were randomly selected from the patients who reported to the Department of oral health science center Pgimer Chandigarh with the chief complaint of orofacial pain. Before undertaking the study, ethical clearance was obtained from the institutional ethical committee and informed consent was taken from all patients. It was an open-labeled randomized clinical trial conducted from March 2019 to Dec 2020. The patients were included according to diagnostic criteria made by the international headache society.[11]

1. Paroxysmal attacks of pain lasting from a fraction of a second to two minutes that affect one or more divisions of the trigeminal nerve
2. Pain has at least one of the following characteristics: Intense, sharp, superficial, or stabbing which can be precipitated from trigger areas or by trigger factors
3. Attacks are similar in individual patients
4. No neurological deficit is clinically evident.
5. Not attributed to another disorder.

Patients with odontogenic pain and temporomandibular

disorders, those who were unable to come for periodic follow-up, and those having previous drug history for the same pain or older cases, medically compromised and pregnant or lactating mothers were excluded from the study. A total of 20 patients of age 18-65 years were included in the study. After the inclusion of patients in the given trial, All the patients were given a brief pain inventory facial questionnaire (BPI Facial) in Hindi or English language before the treatment intervention to determine the baseline data. After pre-op evaluation, all the patients have given tablet carbamazepine 200mg twice daily for one month. After one month, all the patients were instructed to fill the (BPI Facial) again to evaluate the effectiveness of this treatment modality on quality of life.

Statistical analysis

Descriptive and inferential statistical analysis was carried out in the present study. The results were analyzed by using SPSS version 18 (IBM Corporation, SPSS Inc., Chicago, IL, USA). Results on continuous measurements were presented on Mean ± SD (Min-Max) and results on categorical measurements were presented in Frequency (Percentage). The normality of the data was assessed using the Shapiro-Wilk test. Inferential statistics like paired t-test were used to check the difference over the period.

P-value less than 0.05 were considered to be significant.

Results

A total of 20 patients with a mean age of 50 .80 years were evaluated by BPI Facial questionnaire to see the effectiveness of the tablet carbamazepine for treating trigeminal neuralgia. Significant mean differences were seen in all the domains of pain from baseline to 1 month after intervention by tablet carbamazepine ($p<0.05$). Maximum differences were seen in the domains of pain interfering with the orofacial activities. Also, significant differences in mean were seen both in the pain severity and pain interference scores (interference with general activities and with orofacial activities) $p<0.05$ as depicted in Tables 2 and 3.

Discussion

Trigeminal neuralgia is one of the most common causes of facial pain seen in dental and neurologic practices. The first-line therapy for TN is carbamazepine which inhibits the voltage-gated sodium channels and thus decreases the excitability of neural membranes. Common adverse effects seen are sedation, dizziness, nausea, vomiting, ataxia, increase in the level of hepatic enzymes, blood dyscrasias (leucopenia, aplastic anemia), and hyponatremia. Thus the routine complete blood count tests, serum sodium, and liver function tests within several weeks after starting therapy are advisable to detect any complications quickly[11,15-16] Pain is inherently difficult to measure because of its subjective nature and the strong influence of social context, emotion, and other non-physiological variables. Yet its accurate evaluation is of the utmost importance in determining the efficacy of interventions for pain syndromes, many of which are highly resource-intensive. Efforts have been made in the chronic pain literature to delineate the optimal methods of measuring pain and interpreting the clinical significance of outcome data in pain studies. The multi-institutional Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) has defined 6 core domains to be considered in treatment trials of chronic pain: (1) pain intensity, (2) physical functioning, (3) emotional functioning, (4) participant ratings of improvement and satisfaction with treatment, (5) symptoms and adverse events, and (6)participant adherence to treatment regimens[17]. According to

previous articles patients with orofacial pain seem to have a handicap in quality of life. The same was found in the present study, where TN patients showed a significant handicap in their quality of life. Thus we aim to see the effective efficacy of tablet carbamazepine in increasing the quality of life by BPI Facial questionnaire. There is a lack in the literature similar to the present one, using the modified BPI facial for patients with orofacial pain[1]. It is a simple, short, straightforward, and carefully validated, instrument that is composed of 11 items on a 1-point scale (0-10). Four questions center on pain intensity, and the remaining 7 questions deal with the interference of pain with general activities of daily; life (ADL). 7 items focusing on the interference of pain with orofacial activities[17].

This study provides quantitative data using a reliable and validated outcome tool in the measurement of pain in patients with TN before and after intervention by tablet carbamazepine. Patients self-rated their improvement in this study, and the change scores are based on the patient's perception of clinical relevance. This study investigated 3 domains of pain: pain intensity, interference with general ADL, and interference with face-specific ADL." In our study, we found both the pain severity scores as well pain interference on the general activities of life and orofacial activities significantly improve 1 month as compared to baseline data ($p<0.05$). Maximum improvement was seen in the domain of pain interfering with the orofacial activities, this could be because improvement in pain relief after intervention directly increases the activities of the orofacial region, thus increasing the quality of life. Thus, although it is the severity of pain that leaves a lasting impression on practitioners who see TN patients in the office, it is the effect of that pain on an individuals ADL that they want to be cured. This supports the concept that pain is multidimensional and cannot be simply measured on intensity alone. A study conducted by Campbell et al. (1966) reveals that the efficacy of carbamazepine is approximately 80% initially and with time higher doses may be needed to maintain efficacy[18]. Khalid et al. also advocate the use of tablet carbamazepine as a first-line drug for treatment for trigeminal neuralgia.[19] Sukhmeet et al. also used BPI facial to see the quality of life in trigeminal neuralgia patients.[14] H. ISAAC et al also advocated the use of BPI facial to assess the improvement of quality of life in trigeminal neuralgia.[17]

In conclusion, it has been seen that the tablet carbamazepine decreases both the pain severity scores as well as decreases the interference of pain on general activities of life and orofacial activities. This study has practical value in determining the comparative effectiveness of tablet carbamazepine for trigeminal neuralgia. Future studies with increased sample size are needed to see the effectiveness of tablet carbamazepine in improving the quality of life of TN and facial pain patients.

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Legend Tables

Table 1: Patient characteristics

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	20	36.0	65.0	50.800	9.7851

Gender	Frequency	Percent	Valid Percent
F	14	70.0	70.0
M	6	30.0	30.0
Total	20	100.0	100.0
Pain side	Frequency	Percent	Valid percent
Left	6	30.0	30.0
Right	14	70.0	70.0
Total	20	100.0	100.0

Table 2: Comparison of BPI Facial scores at baseline and one month after drug intervention (Paired T-tests)

Domain	Baseline Mean±sd	After one month Mean±sd	Mean difference	Test value	Pvalue
Worst pain	8.20±1.28	4.30±1.03	3.90	14.96	.000
Least pain	4.10±1.88	2.70±1.59	1.40	4.38	.000
Average pain	5.85±1.34	3.90±1.11	1.95	5.32	.000
Pain right now	6.00±1.83	2.25±1.68	3.75	6.79	.000
General activity	5.00±2.31	2.60±.099	2.40	5.72	.000
Mood	7.90±1.51	3.20±1.60	4.70	8.65	.000
Walking	2.75±1.61	2.30±1.21	0.45	1.83	.083
Normal work	5.85±1.92	2.30±1.72	2.50	4.898	.000
Relation	6.00±1.83	2.25±1.68	3.75	6.79	.000
Sleep	3.30±1.03	2.40±0.68	0.90	3.59	.002
Enjoyment	5.70±1.86	2.40±1.14	3.30	7.09	.000
Eating meal	5.00±2.31	2.60±0.99	2.40	5.72	.000
Touching	5.85±1.34	3.90±1.11	1.95	5.32	.000
Brushing	7.20±1.36	2.70±1.21	4.50	10.12	.000

Smiling	7.20±1.05	2.55±2.08	4.65	10.79	.000
Talking	7.20±1.28	2.20±0.95	5.00	13.51	.000
Opening mouth	7.35±1.38	1.95±0.75	5.40	13.96	.000
Eating hard food	6.90±1.29	2.35±1.30	4.55	9.404	0.00

Table 3: Comparison of pain severity and pain interferances scores at different time intervals (Paired T-tests)

BPI SCORES	Baseline Mean±SD	After one month Mean±SD	Mean Difference	Test value	P-value
Pain severity score	5.93±0.88	4.12±0.72	1.81	9.44	.000
Pain interference score on general activities	5.21±1.12	2.63±0.52	2.57	10.03	.000
Pain interference score facial	7.21±1.04	3.77±0.49	3.44	16.02	.000