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Efficacy of medical treatment of post-traumatic trigeminal neuralgia (PTTN) a variant of trigeminal neuralgia at tertiary care centre, Bihar: A prospective case – control study.

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Abstract:
Background: *The term neuropathic pain is used for many types of neuropathies diseases such as diabetic neuropathy; herpetic neuropathy etc. Post-traumatic trigeminal neuralgia (PTTN) term is used by author to denote neuropathies occurring due to trauma during dental surgery strictly. This is one of very few studies which have emphasized the role of combination therapy of medicine in the treatment of PTTN.* ***Aim and objectives:*** *To enhance the efficacy of first line of drug i; e carbamazepine CR (control release) and vitamins B-complex (neurobion forte) for treatment of post-traumatic trigeminal neuralgia by adding supportive medicines such an amitryptyline and ranitidine. Secondly, to observe the changes in the blood cells count after medicinal therapy, If at all occur or not and finally to record the improvement in the comorbidity/ quality of life and cure rate followed by the treatment.* ***Material and methods****: The study design was prospective case-control study. The patients of PTTN were included from the dental opd patients, IGIMS, Patna, Bihar, India. The total numbers of patients were taken from the patients reported within one year time of beginning of study. The numbers of subjects were seventy. The patients were divided into two groups, 1. Case group with thirty five subjects and in control group with thirty five subjects were included based on clinical history. Each patient was called for monthly follow up for their improvement in the sign and symptoms especially for pain and gastritis were recorded.* ***Results:*** *The data collected was analyzed by Epi Info/CDC software and the results were presented in the form of tables and graphs. There were effective and complete cure of pain in many cases of patients. Most importantly from the seven months onwards almost all the patients recovered from PTTN pain and gastritis.* ***Conclusions:*** *The pain and comorbidity reduction were more effective in case group than control group. The addition of amitryptyline drug in combination drug therapy effectively reduces the pain to the level of complete cure without medical complication.*

Key words: *Post-traumatic trigeminal neuralgia (PTTN), neuralgic pain, carbamazepine CR, amitryptyline, ranitidine, gastritis, traumatic dental surgery.*

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I. Introduction:

The correct clinical diagnosis is the most important factor for correct treatment. The through history taking is the essential tool for diagnosis for trigeminal neuralgia.[1, 2, 3]. In one of the review study authors have coined the terms as per his discretion "PPTTN" i.e. peripheral painful traumatic trigeminal neuralgia[2].The PTTN could be also called as atypical odontalgia, dental causalgia, and phantom tooth pain after endodontic failure or extraction[3, 4.]Thepost-traumatic trigeminal neuralgia (PTTN) is a variant of trigeminal neuralgia occurs due to traumatic extraction of molar teeth, especially with the extraction of molars teeth in the lower jaw[3,5,6,7,8].The poor dental awareness among the people of Bihar, especially who hails from the low-socio-economic status fall in the trap of quack for their dental treatment due to costly treatment procedure results in PTTN pain .The international association for the study of pain (IASP) defines the trigeminal neuralgia as sudden, recurrent, intense pain along one or more branches of the fifth cranial nerve[7, 8, 9, 10].In beginning it would be correct to mention here that initially as well as in present time no research data and details of the study about the PTTN are available, very scant literature is available[11]. The study details and data mentioned here is the about the trigeminal neuralgia that included both classical and symptomatic trigeminal neuralgia. There are very few

studies dedicated to study about the various characters of neuropathic pain (PTTN and PPTTN) such as etiology, pain nature and mechanism, pharmacotherapy, psychological reasons , terminology and classification etcetc[2,5,9,10,11].The term "Tic Douloreux" was used by Nicolas Andre in 1756.In 1773, John Fother gave a full and accurate description of TN. It is also known as prosopalgia, suicide disease or Fothergill disease.[2, 3, 19.] The disease is rare and thus data recorded are scant. The less number of PTTN cases are diagnosed in India as well world wise. The reasons could be many due to, diagnosis may be not correct, diagnosis criteria are not well universalized, the term PTTN as newer entity is not well recognized and standardized, well framed drug doses and combination therapy are not universally applied etc. [5,10,19]. The condition occurs more often in the middle aged and is twice as common in females as in males. In most of the patients the pain is strictly unilateral; multiple sclerosis patients constitute the majority of the 2% patients with bilateral disease. Trigeminal neuralgia is twice as common on the right side. Most commonly patients present with pain maximum either in maxillary or mandibular divisions with more predilection for mandible. The criteria of patient selection will be done on the basis of International headache society (I.H.S) has published criteria for the diagnosis of classical and symptomatic trigeminal neuralgia) and the Kaufmanns classification on trigeminal neuralgia[2, 3, 10, 19.] In author own study the prevalence rate of PTTN was 2.11%. Most of the cases reported were in the age groups of 40-59 years and 20-39 years with more of female predilection[5, 20].The pain felt by the patients in this condition is of the dreaded and intolerable. This brings about severe morbidly, cripples life and productivity and in severe cases patient go for suicide. The patho-physiology neuropathic pain are not clearly understood but these are the probable reasons for pain mechanism as radiation exposure, infective reasons, exposure to neurotoxins, axonal injury leads to pain, ephaptic transmission, central sprouting, phonotypical change in primary afferent and dorsal horn neurons, sympathetic nerve activations, changes in segmental inhibitory control, central sensitization etc[18.]The blood picture was monitored every six month while patients were on therapy[22.] In this study no medical complications were reported. Though the literature records the toxic effects of carbamazepine vary, tending to be worse initially and then subside. The adverse reactions reported include vertigo, drowsiness, erythematous morbilliform and urticarial rashes, anorexia, vomiting, diarrhoea, Stevenson Johnson Syndrome etc[22]. The mechanism of action of amitryptyline in the treatment of neuropathic pain remains uncertain, although it is known to inhibit both serotonin and nor-adrenaline reuptake. The adverse events associated with amitryptyline often wane after two or three weeks, when the benefits of the drug become[23.] The newer antidepressants drugs, such as duloxetine, are effective in and since they have fewer side effects than the TCAs, are an alternative. Failure of this second phase is an indication to try combined therapy, duloxetine or amitryptyline may be combined with one of the anticonvulsants such as gabapentin or pregabalin[6, 15, 12, 10].In one of the study also advocates treatment of PTTN with steroids in following dose prednisone 40-60 mg initially then tapered over 7-10 days aiming to reduce early inflammation of nerve injury[13].As per me, steroid should not be used for treatment, but it may be used for early treatment of pain ,when and where the pain persists even after 15 days to 04 months after extraction of teeth, this condition is designated as pre-traumatic trigeminal neuralgia[7, 5,10.] Medicinal therapy is cheap and more acceptable than surgical treatment[5, 10, 23, 24]. This also saves the patients from heavy expenditure for surgery and reduces the psychological stress[24].Thus in this study **aim and objectives of the research are to** 1. To compare and enhance the efficacy of treatment of post- traumatic trigeminal neuralgia (PTTN),by adding amitryptyline drugs to the first line of treatment drugs i.e. carbamazepine CR, vitamin B-complex (neurobion forte) and ranitidine. 2. To observe the changes in the blood cells count, after medicinal therapy, If at all occur or not and 3. To record the improvement in the comorbidity/ quality of life and cure rate followed by the treatment.

II. Material and methods

The study design is prospective case-control study. Study place: The patients of PTTN were included from the dental opd, Dept. of Dentistry, IGIMS, Patna, Bihar, India. The study was conducted after Institutional ethic committee approval from Indira Gandhi institute of medical sciences, Patna, Bihar, India. The study duration was carried out from January 2018 to February 2020. The total numbers of patients were taken from the patients reported within one year of start of study. Sample size: The numbers of subjects were seventy. The patients were divided into two groups, 1. Case group with thirty five subjects and in control group with thirty five subjects were included. The sample size was calculated based on the prevalence of PTTN study done by author and published in the year 2007. The treatment was also done for the same patients. Based on the previous study biostatician advised to induct 70 patients for the study. Subjects and selection methods: In general selection of patient were done on the alternate basis, reporting at the dental out door, IGIMS, Patna, Bihar i; e one subject for case group and next one for control group based on the clinical findings. Each patient was followed up for one year irrespective of reporting date of the patients. The selection of the patients could vary based on clinical history of patient's reports with, if they reports with mild to moderate pain they should be kept preferably in control group. The eight patients with severe and very severe pain were also kept in the control group to check the effectiveness of treatment of control group. Though the improvement after medications in

severe and very severe in control were mild to moderate during first three months of treatment hence amitryptyline was added resulted in rapid improvement in the pain. In deviation of above said number of patients selection of case and control subjects, the forty-four(44) patients were kept in control groups and 26 patients in case group. Mostly severe and very severe pain patient were kept in the case group. Each patient was called for follow up monthly basis for their recording of improvement in the sign and symptoms especially for the pain and gastritis. (See the patient Performa chart for visual/ verbal pain scale (VVPS) chart no.01-A addendum). The improvement of the pain after taking medications was recorded (see chart no. 1–B addendum). The history of gastritis, intensity of the gastritis and their relief after taking medication were taken as per (chart no.01addendum - C, D, &E).

III. Procedure Methodology

After written informed consent was obtained and well-designed questionnaire and modified pain scale, modified pain improvement scale, gastritis questionnaire and their improvement in sign –symptoms were recorded. The complete blood count (CBC) and random fasting sugar (FBS) were recorded to all patients six monthly. This is to rule adverse effects of carbamazepine and FBS for to rule out extraction due to diabetic complications. The dosage and frequency of dosage was decided by patient's severity of pain and clinician judgement as per guidelines. Each patient had undergone for CBC and RBS on the start of treatment, 06 months after follow up and at the end of the treatment follow up i.e. on 12 months. These tests were done at our institute. There was no adverse drug reaction(ADR) reported at ADR monitoring center at Dept. of Pharmacology, IGIMS, Patna, Bihar, India. The OPG was done to record the site of the extracted teeth with bony defects and also to rule out any pathology of the jaw. The X-ray orthopentmogram (OPG) were done at our institute.

The Inclusion criteria are as follows: 1.The patients had given the history of extraction between past 6 months to five yrs. retrospectively. 2. The new patient of PTTN reported to the dental opd with complains of PTTN pain 3. The main medicines amitryptyline was not used by the patients previously for the treatment of trigeminal neuralgia. 4. The patients included in this study were reported with the history of pain persisted after six months of extraction. 5. Paroxysmal attacks of pain (electric/pricking/burning type in nature) lasting from a fraction of a second to two minutes, affecting one or more divisions of the trigeminal nerve.6. Trigger zone should be present with facial muscles spasm, twitching and or tightness etc. 7. Neuralgic pain criteria based on the classification on A.F Kaufmann and M. Patel: Centre for cranial nerve disorders, Winnipeg, Manitoba, Canada. (2001) and International headache society for selection of patients were also followed.

The exclusions criteria are as follows1. Patient doesn't want to participate in the study.2. Patient reported with the known history of classical trigeminal neuralgia. 3. Patient doesn't give sign and symptoms criteria as laid down by A. F Kaufman criteria and international headache society.4. The subjects below twenty years of age were not included. 5. The pain persist/ensues in the subjects before six months of extraction were not included.6. Patients with severely ill and atypical features suggesting symptomatic trigeminal neuralgia or an alternative diagnosis are not included for study, egs cluster headache, paroxysmal hemicranias etc.7. Patient reported with known history of hypersensitivity with drugs.

Statistical analysis: Data was analyzed and evaluated by Epi Info/CDC software. Biostatician summarized the demographic and clinical characteristics s of the participants using frequencies and percentages as appropriate. He reports the proportions of the participants with a diagnosis of PTTN as case and control groups.

IV. Results

The data was retrieved from the dental opd record note book. Data was analyzed and evaluated by Epi Info/CDC software. The following important tables and graphs were included in the study. The table no.01 and graph no.01indicated there were 44 patients in the control group and 26 patients in the case group. The control group was receiving medicine carbamazepine CR, ranitidine and neurobion forte. The case group was receiving carbamazepine CR, amitryptyline, ranitidine, neurobion forte. Table no.02 indicates 20 patients were male with 13 receiving control group medication and 07 were receiving case group of medications subsequently there were 50 female patients out of whom 31 were receiving control group of medication and 19 receiving case group of medication. Table no.03 and graph no.02 indicates the duration of history of teeth extraction that spreads from the 06 months to 10 yrs. The history of extraction between 06 months to 24 months was reported in the 44 patients out of 70. Table no.04 and graph no.03 indicates that intensity of pain reported by PTTN patients into following numbers as mild 07, moderate pain 35, with severe pain 20 and very severe pain 08. Table no.05 indicates the history of gastritis pain presented by all patients. Table no.06 indicates report of the X-ray OPG-Pan where bone defects were seen in the vicinity of extracted teeth in all patients. Table no.07 indicates the fasting blood sugar were normal in all patients. Table no.08 indicates the complete blood count (CBC) were normal at the time of inclusion of patients and during 06 and 12 months of follow up after medication given .

Graph no.04indicates that at each month follow up of the patients in both groups during first month 04 patients get complete relief in control group and 09 in case groups. In each successive month case group were cured more than control group. Most of the patients in both the groups got complete relief from pain after 7 months.

Table no.01 Pain criteria medication prescribed to case and control group

Medication prescribed			*Tab Tegretol CR. ¶Tab neurobion forte. †Tab histac(control)	Tab Tegretol CR, Tab neurobion forte, Tab histac, #TabAmitryptyline(case)	Total no. of patients
Pain criteria	1.00	Count	44	26	70
		% of Total	62.9%	37.1%	100.0%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

Table no.02 Medication prescribed with sex distribution

		Medication prescribed	Tab Tegretol CR. Tab neurobion forte. Tab histac (control group)	Tab Tegretol CR, Tab neurobion forte, Tab histac, TabAmitryptyline (case group)	Total no. of patients
Sex	male	Count	13	7	20
		% of Total	18.6%	10.0%	28.6%
	female	Count	31	19	50
		% of Total	44.3%	27.1%	71.4%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

Table no.03 History of distributions of extraction in month in case and control group of patients

Medication prescribed			Tab Tegretol CR. Tab neurobion forte. Tab histac	Tab Tegretol CR, Tab neurobion forte, Tab histac, TabAmitryptyline	Total no. of patients
Extraction history in month	6.00	Count	9	2	11
		% of Total	12.9%	2.9%	15.7%
	7.00	Count	1	2	3
		% of Total	1.4%	2.9%	4.3%
	8.00	Count	3	3	6
		% of Total	4.3%	4.3%	8.6%
	9.00	Count	1	1	2
		% of Total	1.4%	1.4%	2.9%
	10.00	Count	2	0	2
		% of Total	2.9%	.0%	2.9%
	12.00	Count	12	6	18
		% of Total	17.1%	8.6%	25.7%
	24.00	Count	11	5	16
		% of Total	15.7%	7.1%	22.9%
	29.00	Count	0	1	1
		% of Total	.0%	1.4%	1.4%
	36.00	Count	1	2	3
		% of Total	1.4%	2.9%	4.3%
	48.00	Count	2	2	4
		% of Total	2.9%	2.9%	5.7%
	60.00	Count	1	2	3
		% of Total	1.4%	2.9%	4.3%
	120.00	Count	1	0	1
		% of Total	1.4%	.0%	1.4%
Total		Count	44	26	70

		% of Total	62.9%	37.1%	100.0%

Table no.04 Report by patients for initial pain intensity and Medication prescribed

			Tab Tegretol CR. Tab neurobion forte. Tab histac(control group)	Tab Tegretol CR, Tab neurobion forte, Tab histac, Tab Amitryptyline(case group)	Total no. of patients
Report_of_pain initially by patients and pain intensity	Mild pain	Count	7	0	7
		% of Total	10.0%	.0%	10.0%
	Moderate pain	Count	29	6	35
		% of Total	41.4%	8.6%	50.0%
	Severe pain	Count	3	17	20
		% of Total	4.3%	24.3%	28.6%
	Very severe pain	Count	5	3	8
		% of Total	7.1%	4.3%	11.4%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

Table no. 05 History of Gastritis given by patients of PTTN

Medication prescribed			Tab Tegretol CR. Tab neurobion forte. Tab histac	Tab Tegretol CR, Tab neurobion forte, Tab histac, TabAmitryptyline	Total no. of patients
Gastritis present	yes	Count	44	26	70
		% of Total	62.9%	37.1%	100.0%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

Table no.06 X-ray OPG report seen and reported bony defect observed

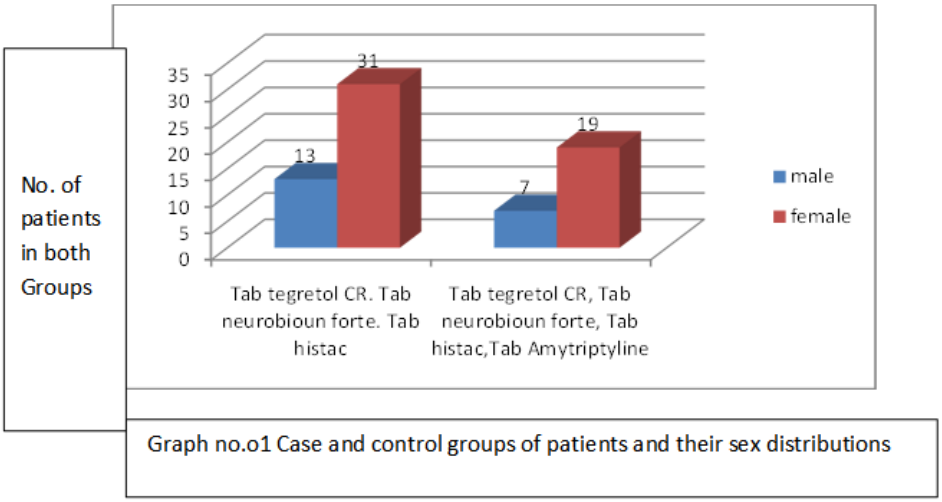
Medication prescribed		Tab Tegretol CR. Tab neurobion forte. Tab histac	Tab Tegretol CR, Tab neurobion forte, Tab histac, TabAmitryptyline	
X-ray OPG (bony defect observed in all patients)	Count	44	26	70
	% of Total	62.9%	37.1%	100.0%
Total	Count	44	26	70
	% of Total	62.9%	37.1%	100.0%

Table no.07 Fasting Blood sugarreports of all patients during initial visit, six month and at the end of 12 months follow up.

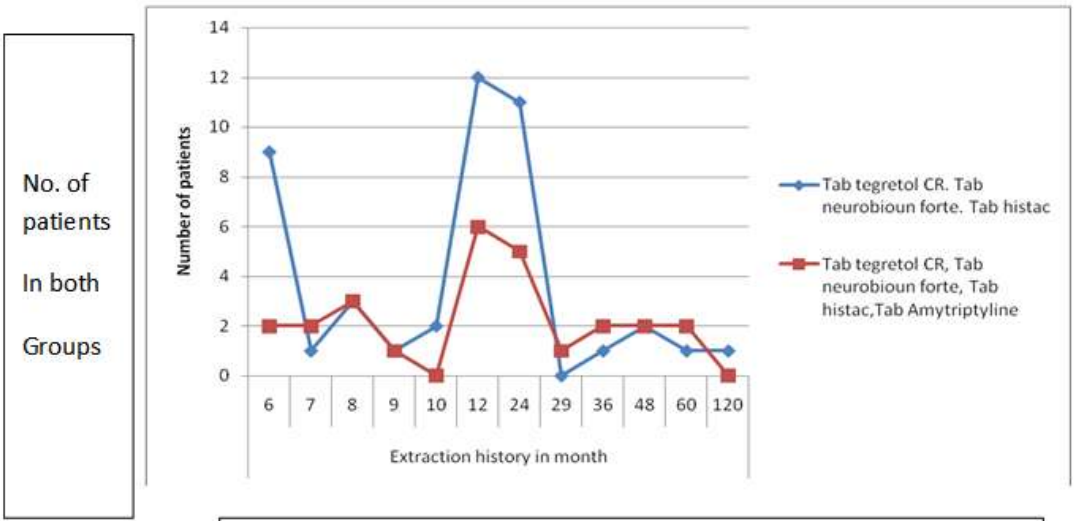
			Tab Tegretol CR. Tab neurobion forte. Tab histac	Tab Tegretol CR, Tab neurobion forte, Tab histac, TabAmitryptyline	
Blood sugar	Normal	Count	44	26	70
		% of Total	62.9%	37.1%	100.0%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

Table no.08 Complete_blood_Count of all patients of all patients during initial visit, six month & at end of 12 months follow up

Medication prescribed			*Tab Tegretol CR. ¶Tab neurobion forte. Tab histac	Tab Tegretol CR, Tab neurobion forte, Tab histac, †TabAmitryptyline	Tab Tegretol CR. Tab neurobion forte. Tab histac
CBC/(Complete blood Count)	Normal	Count	44	26	70
		% of Total	62.9%	37.1%	100.0%
Total		Count	44	26	70
		% of Total	62.9%	37.1%	100.0%

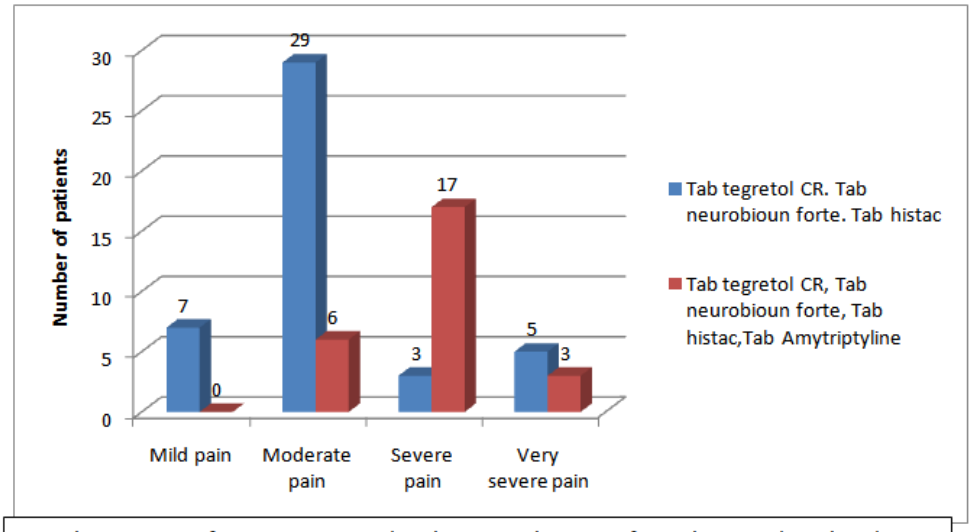


Graph no.o1 Case and control groups of patients and their sex distributions



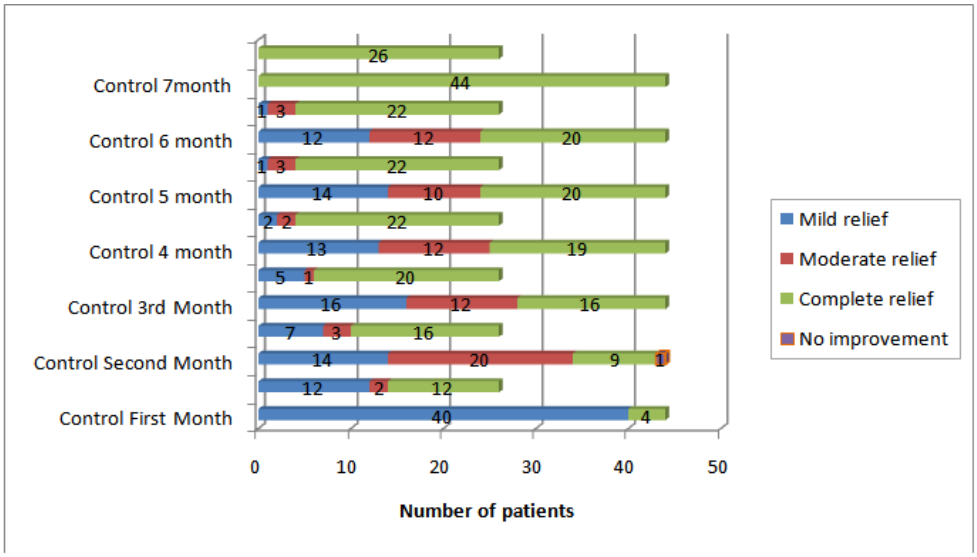
Graph no.2 Extraction history in months in both groups

No. of Patients in both Groups



Graph no.03 No. of patients reported with pain at the time of initial visit in dental opd

Monthly report of relief of pain in both Groups



Graphs no.04 intensity of relief after medication given in both groups

V. Discussions:

The treatment of post-traumatic trigeminal neuralgia (PTTN) is challenging. It is well documented terminology and one of the variant of trigeminal neuralgia[10, 17]. The term PTTN was proposed by the international headache society (IHS) to reflect neuropathic pain of trauma in origin affecting the trigeminal nerve[12]. International Association for the Study (IAPS) of Pain (2011) definition of neuropathic pain is "pain caused by a lesion or disease of the somatosensory system" (Jensen 2011) based on a definition agreed at an earlier consensus meeting, (Treede 2008)[9, 24]. Neuropathic pain is usually divided according to the cause of nerve injury. There may be many causes, but some common causes of neuropathic pain include diabetes (painful diabetic neuropathy, PDN), shingles (post-herpetic neuralgia, PHN), amputation (stump and phantom limb pain), neuropathic pain after surgery or trauma, stroke or spinal cord injury, trigeminal neuralgia (TGN), and human immunodeficiency virus (HIV) infection. The diagnosing criteria are quite variable and not universally classified; in this study Kaufmann's study on cranio-facial pain disorders was considered as diagnostic criteria for research[10, 17]. In this study traumatic dental surgery and other dental procedures may be here considered as reasons for neuropathic pain disorders of PTTN variety. The incidence of injury to either of this nerve by elective dental or oral maxillofacial surgical procedures ranges from 0.6-90%. The most common cause is of injury in order third molar extraction, reconstructive mandibular surgery, mandibular trauma, dental injection, dental implant placement, dental endodontic therapy and consequences of pathology of the oral cavity or

surgery for pathology of the oral cavity [14], [21].The diagnosing of lingual never injury usually noticed in lower third molar extraction, this could be tested by sensory testing using touch and moving two-points discrimination and subjective reporting[8]. In a study follow-up of 1107 dento-alveolar operations in the post-canine region, 24 (2.2%) temporary sensitivity disturbances of the inferior alveolar nerve and 16 (1.4%) of the lingual nerve were found. Permanent disturbances were not present. Complete recovery had occurred by 6 months in all 17 cases. The incidence of developing PTTN pain has been reported to range from 0.45% to 70% of injuries involving the inferior alveolar nerve and lingual nerve[14]. In this study 50 patients were female and 20 patients male (table no.02). The study results reveal that more female are affected this finding are in concordance with previous finding[4,8,] Exact reason for this sex predilection is not unknown but in our perspective it could be due to poor-socio-economic and less care are provided to female's hence they approaches to quack for their treatment. In previous study author noticed that most of the case of PTTN patients in both sex had history of extraction by quack [8.] In previous study of author it was also noticed that the pain were more in the lower arch than in the upper arch[5, 20]. There are 04 categories of pain patients reported in the present study with 07 mild pain patients, moderate 35, severe 20 and with very severe 08 only (graph no.03).this diverse pain categories were noticed , there exact reasons could not be explained for these categories of pain . For above pain conditions it will be correct to discuss about the how the pain transmits after trauma and what are the nature of nerve injury? The studies on this topic are scant and needs discussions. There are three types of nerve injury as per Seddon reported neuropraxia, axonotmesis and neurotmesis. The neuropraxia (nerve bruise) is the mildest type of nerve injury, and the recovery takes days to months, where in axonotmesis heals by wallerian regeneration, which is process of fragmentation of the axon and myelin sheath. It takes 2-4 months to recovery. The last one is neurotmesis it is severest form of nerve injury in which all the nerve layers including axon get destroyed where full recovery is not possible pain may be continuous with neuroma formation[21]. As per my view axonotmesis and neurotmesis type of nerve injury may be reasons PTTN type of pain. So therefore it was prudent to include the inclusion criteria for PTTN patients with persistent of pain after 06 months of dentals surgical trauma[17]. Where in one study they have included the PTTN patient's pain criteria between 3-6 months which logically seems not a good idea as neuralgic pain of neuropraxia and or axonotmesis can subsided after healing within so it could serve as false selection of case[10, 12, 13.] So in this study pain duration a criterion was not less than six months was considered for inclusion criteria. After reviewing many sources of literatures there were very few studies which carried out to treat the PTTN case with unison medicinal treatment protocol[1, 9, 10, 12, 5, 16, 19]. So aim of this study to test the efficacy of medicinal therapy proposed by author. In this study results also shows that majority of patients gave the history of extraction between 6 months to 24 months in which pain was observed (table no.03). Though the exact reason for could not be made out for above finding. This study reveals also that moderate pain and severe pain patients were 45 out of 70 patients in both groups. The severest pain patients were 10 only in both groups (table no.04). The medicine prescribed in both groups and their complete cure rate were more in case group I.e. in first month 12 in comparison to 04 in control group , second month-16 in comparison to 09 , in third month 20 in comparison to 16 in control group and so on . In this study it reflects that case group of medicines combination were more effective than control group in management of severe pain groups of patients. It is observed that mild and moderate pain patients were given control group of medicine and the severe and very severe group of patients were given case group of medicines resulted in more success in treatment(table no.04) .In long run i.e. from 07 months onward both groups' patients were recovered completely (graph no.04). In one study they have compared the medicines (AEDS) effect on classical trigeminal neuralgia and PTTN patients and concluded that medicines are not very effective[1.] In Cochrane review study as per study at least one third of patients with neuropathic pain who took traditional antidepressants (such as amitryptyline) obtained moderate pain relief or better[,9,10,12, 15, 19.] however in a another study of 63 PTTN patients with retrospective study was carried out that reveals some promising effects of medicine therapy in treatment of PTTN patients as advised in this study[12]. In a study, in treatment of idiopathic trigeminal neuralgia in 15 cases were also successful with amytriptyline[7]. So therefore author advices for this type of combination of medicine therapy for PTTN patients are more successful. All the patients were tested for complete blood count and fasting blood sugar at the initial stage, after 06months and after 12 months consequently to rule any adverse effects. The diabetic test was done to rule out compounding factors in the traumatic dental extraction and diabetic neuropathy[1, 1 2]. On long use of carbamazepine drug there is chances of bone marrow suppression that could results in blood count changes and enhances for infection and other medical complications[22]. In this study FBS and CBC were normal to all patients from beginning to last month of test reports (table no. 7 &8) The X-ray OPG-Pan were taken to all patients and report revealed that healed socket were not proper in comparison to the normal healed socket of extracted healthy persons(table no.06). This could be one of the bony markers in the diagnosis PTTN patients. In this regard a new study was proposed for novel diagnostic criteria for diagnosis of PTTN [12, 1 3.] Before this only criterion for diagnosing PTTN was pain as their clinical sign and symptoms. In both groups of patients medicine ranitidine were prescribed, who had complained of gastritis (table no.5). The

modifying factors of PTTN pain could be stress, in my study gastritis could be one of the modifying factors[22]. There was significant association of gastritis and the PTTN patient's pain.

VI. Conclusions

The pain and comorbidity reduction in both the groups were marked with addition of amitryptyline drug. The most of the patients in both groups were improved completely from pain after use of combination of medicines advocated in the research without any medical complications. The role of gastritis in the PTTN patients is unclear though gastritis sign and symptoms improve in all patients. The role of gastritis in modifying factors in PTTN pain needs further evaluation.

Limitations of the study:

The limitation of this research is that it was not blinded, results in clinician bias. The placebo effect of the study was also not trialed. The psychological-social assessments of the patient were not analyzed. The long term use and effectiveness of medicinal therapy is also not evaluated.

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Chart no.01 (addendum): MONTHLY FOLLW-UP CHART FOR THE PATIENT (sample)

Name: Age/sex Date:
Opd no. Occupation: Postal address:

Telephone no. and email if available:
Income /month or yearly:
Extraction date/year: Done by: Doctor/quack
Prescription of previous treatment available or not:

The severity of pain will be judged by modified visual/verbal pain scale (VVPS)

Pain is categorized into four types with degree of duration of pain/ type/intensity and disability resulting from traumatic trigeminal neuralgia (PTTN)

1. Mild pain: normal life, daily life activities not affected.
2. Moderate pain : causes some concern, pain episode for few seconds for once or twice in a day ,causes some concern, uncomfortable complain of pain preventing, no disability.
3. Severe pain = prevents normal life, pain episode of high intensity more than three in a day but less than five episodes, preventing certain usual activities, mild to moderate disability like difficulty in eating, speaking etc.
4. Very severe pain: adverse effects on normal activities, pain episodes more than five in day of higher intensity, causes important disability like as mentioned above egs depression, thought of suicide, fear of pain attack any time etc

B. Patient scale for improvement in pain followed by treatment will be asked in by "lay man term" in local dialects version of Hindi for better data recording:

1. 0=no improvement (aka dam thik nahi hai)
2. 25= mild improvement (char Anna/thora –mora)
3. 50= moderate improvement (pahle se achha hai, bahut Thik hai lekin pura thik nahi hai)
4. 100= Complete relief, no pain and disability and or normal activities not hampered (AK dam thik ho Gaya)

C. Questionnaire for patient complains of gastric problems:

Q. no. 1 Do you feel stomach burns/pain sensation (Gastritis)?
a) Yes b) no c) don't know d) any other comment

D. Gastritis scale based on complains of stomach pain, frequency/ intensity and duration.

a. No gastritis pain (no anta-acids prescribed)
b. Mild pain (prescribed anta-acids, one/twice mild pain).
c. Moderate pain (tolerable pain, with/two-three episodes in a day (anta-acids prescribed) d. Severe pain (intolerable pain, more than three times in a day anta-acids required)

E. The improvement in the sign and symptoms of gastritis will record as per patient history and presentation.

Does the gastritis improve after taking antacids consumption?
a. No b. yes c. moderate d. don't know e. any other comment

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