
ORIGINAL ARTICLE

Patient Burden of Trigeminal Neuralgia: Results from a Cross-Sectional Survey of Health State Impairment and Treatment Patterns in Six European Countries

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■ **Abstract:** Trigeminal neuralgia (TN) is an uncommon neuropathic condition associated with excruciating facial pain. It is important to determine the effect of TN pain on patient functioning and to characterize relevant pharmacologic treatment patterns and health resource utilization in general practice. Eighty-two patients with TN were identified in a general practice setting during an observational survey of broad neuropathic pain syndromes in six European countries. Patients answered a questionnaire that included pain severity and interference items from the modified Short Form Brief Pain Inventory (mBPI-SF), the EuroQol Survey of functioning and well-being (EQ-5D), and questions related to current treatment, health status, and resource utilization. Physicians provided information on medications prescribed for TN pain and pain-related comorbidities (anxiety, depression, and sleep disturbance). The mean patient age was 62.7 ± 15.8 years, 46% were ≥ 65 years, and 66% of patients had TN >1 year of duration. The mean Pain Severity Index was 4.2 (range 0–10), reflecting moderate pain despite 94%

of patients taking prescription medications for their TN pain. Prescription medications included carbamazepine (mean daily dose 534.1 ± 269.8 mg), the recommended first-line pharmacologic therapy for TN. Pain severity was significantly associated with reduced EQ-5D health state valuation ($P < 0.001$) and greater pain interference (mBPI-SF) ($P < 0.001$). These findings demonstrate that TN pain presents a substantial patient burden expressed as interference with daily functioning and reduced health status associated with pain severity. This burden may result from both suboptimal management strategies and the frequent resistance of this neuropathic condition to treatment, and suggests a need for more effective pain management strategies. ■

Key Words: trigeminal neuralgia, neuropathic pain, burden of illness, quality of life, health status

INTRODUCTION

Trigeminal neuralgia (TN) is a neuropathic pain condition affecting the facial area that has been defined by the International Association for the Study of Pain as “a sudden, usually unilateral, severe, brief, stabbing, recurrent pain in the distribution of one or more branches of the fifth cranial nerve.”¹ The epidemiology of TN has been poorly characterized. The best available epidemiologic data are from a U.S. study of TN in the population of Rochester, Minnesota, during a 40-year

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period.² The reported annual incidence adjusted for gender and age was 4.7/100,000, with a female : male ratio of 1.7:1, and an incidence that increased with age, and peaked at 70 years. This incidence is somewhat lower than the gender- and age-adjusted rate of 8/100,000 reported in a community-based study in the U.K.³ Adequate data detailing the prevalence of TN in the general population are not available; the U.K. study reported a lifetime prevalence of 0.7/1000.³

Although not a common disorder, the pain associated with TN can be of excruciating severity. This pain is often triggered by non-noxious stimuli or normal activities, such as talking, chewing, swallowing, and brushing teeth, and is considered intractable or difficult to treat. Anticonvulsive drugs, especially carbamazepine, have been shown to be effective in treating TN⁴ and are recommended as first-line therapy. While pharmacologic treatment may be followed by invasive surgical procedures in cases of intractable pain, these procedures are associated with variable success rates and side-effect risks.^{5,6} To help with management strategies at least in the U.K., guidelines have been made available for general practitioners for the treatment of TN.⁷

The recognized impact of neuropathic pain on patient functioning and quality of life^{8,9} suggests that patients with TN may experience a significant disease burden related to this condition. However, few studies have evaluated this burden, especially in the primary care setting, the usual locus of neuropathic pain management.¹⁰

This lack of information suggests a need to better understand pharmacologic treatment patterns and characterize the patient burden of TN. The purpose of the present analysis was to evaluate pain and its impact on patient functioning in patients with TN and to characterize associated treatment patterns in patients recruited from primary care settings in six European countries.

METHODS

The study sample consisted of 82 patients with TN identified during a larger observational, cross-sectional study of broad neuropathic pain syndromes.¹¹ Sampling was limited to general practitioners and nonpain specialists. Patients were recruited from community-based practices in France, Germany, Italy, the Netherlands, Spain, and the U.K. We assessed patient-reported functional health and well-being, pain experience, medication use, and health resource utilization associated with TN pain (eg, physician visits, telephone consultations).

Physicians were screened for their interest in participating in the study, and a feasibility assessment was conducted to determine their ability to identify patients for inclusion. Physician training by teleconference included reviewing (1) the study objectives, (2) physician responsibilities, (3) patient eligibility criteria, and (4) administrative procedures. The clinical case report form provided classical definitions of TN, including references to patient-reported pain descriptors and pain location. The presence of dental pain and trigeminal neuropathy could not be clearly excluded based on the diagnostic criteria used in the general practice setting of this study. Trigeminal neuropathy is a painful condition similar to TN that results from damage to any of the branches of the trigeminal nerve.

The study protocol was approved by local ethics committees. Participating physicians invited patients to participate in the study during routine care visits. Eligible patients were identified by physicians based on the presence of neuropathic facial pain (typically, in the lips, eyes, nose, scalp, forehead, upper jaw, and lower jaw), and on report of symptoms consistent with allodynia (pain in reaction to non-noxious stimuli such as the light touch of a cotton ball) and hyperalgesia (exaggerated pain reaction to mild pain stimuli) and/or the patient's use of specific words taken from the pain descriptor items of the Short Form McGill Pain Questionnaire¹² (eg, burning, shooting, and stabbing) that typically describe neuropathic pain. Symptom duration of ≥ 3 months and up to at least the week prior to the survey was required.

Patients were excluded from the study if they had (1) participated in an investigational drug study within the past 30 days, (2) presented with or had a history of a serious or unstable medical or psychological condition that would compromise participation in the study, or (3) a concomitant illness unrelated to TN (eg, neurological disorder or other pain condition) that would likely confound the assessment of TN. Patients were eligible if they had other chronic pain conditions such as osteoarthritis or migraine headaches, provided that they could distinguish between their neuropathic pain and the other conditions.

Patients who consented completed a questionnaire as described below. Physicians provided clinical information related to duration of disease and prescribed medications for TN and common pain-related comorbid conditions (eg, anxiety, depression, and sleep disturbance).

Patient Questionnaire

The questionnaire, described below, included 11 items from the modified Short Form Brief Pain Inventory (mBPI-SF),¹³⁻¹⁵ the EuroQol (EQ-5D) survey,¹⁶ and additional questions on resource utilization. Validated translations of the mBPI-SF and EQ-5D survey were used, and the remaining questions were translated and reviewed for accuracy by native speakers.

mBPI-SF. Pain severity, assessed using the mBPI-SF, was measured using an 11-point numeric rating scale ranging from 0 (no pain) to 10 (pain as bad as you can imagine). Items included current pain, worst, least, and average pain over the previous 24 hours. The Pain Severity Index was calculated as the average of the four ratings. Pain severity cut-points were 1–3 for mild pain, 4–6 for moderate pain, and 7–10 for severe pain.¹⁷

The remaining items measured pain-related interference over seven health status domains using 11-point numeric rating scales ranging from 0 (does not interfere) to 10 (completely interferes). The mean of these seven ratings measured the patient's overall level of pain interference (Pain Interference Index).

EuroQol Survey (EQ-5D). The EQ-5D assessed overall functioning and well-being with respect to mobility, self-care, usual activities, pain or discomfort, and anxiety or depression.¹⁶ Domains were rated using a 3-point ordinal scale. The resulting profile was used to calculate health state valuations based on precalculated scoring coefficients.¹⁸ In this analysis, we used scoring coefficients generated in the U.K. to assign health state valuations to patients. Health state valuations ranged from –0.59 (worst health state) to 1.00 (best health state).

Additional Questions. Specific questions addressed patients' overall health rating and health resource utilization. Patients rated their current health on a scale of 0–100, where 0 represented “worst possible health” and 100 represented “perfect health”; patients also provided a health rating under the hypothetical scenario of having complete relief of their TN pain.

Physicians provided information about current prescription medications for TN. Patients provided information about the use of nonprescription medications and other therapies (eg, acupuncture, topical lotions, herbs or vitamins, devices such as electroneural stimulation, and exercise). Patients also evaluated the efficacy of prescription medications (extremely effective, very effective, somewhat effective, a little effective, or not

effective), including information on treatment adherence and medication satisfaction. Other questions included the frequency of neuropathic pain-related physician visits and telephone consultations during the past four weeks, and evaluation by pain specialists.

Statistical Analyses

Summary statistics were utilized to describe the study sample: means \pm standard deviations were provided for continuous variables and frequency distributions for categorical variables. One-way analysis of variance models for continuous outcomes and chi-squared tests for categorical outcomes were used to evaluate the association between pain severity (categorized as mild, moderate, or severe)¹⁷ and other outcomes. Statistical significance was evaluated at the 0.05 level, with no adjustments for multiple comparisons given the descriptive nature of the study. All analyses were performed using PC-SAS version 8.0 (SAS Institute, Cary, NC, U.S.A.).

RESULTS

The demographic and clinical characteristics of the 82 patients with TN are presented in Table 1. The mean age was 62.7 ± 15.8 years, and there was an almost even distribution between patients younger than and older than 65 years. Twice as many women as men had TN (67.1% vs. 32.9%), and more than half of the patients (65.9%) had pain due to TN for >1 year. Only 28.8%

Table 1. Characteristics of the Patient Sample

Characteristic*	Value
Age, years	
Mean (SD)	62.7 (15.8)
Age group, n (%)	
18–64 years	44 (53.7)
≥ 65 years	38 (46.3)
Gender, n (%)	
Male	27 (32.9)
Female	55 (67.1)
Employment status, n (%)	
Employed, full-time	15 (18.8)
Employed, part-time	8 (10.0)
Unemployed	2 (2.5)
Disabled	4 (5.0)
Retired	34 (42.5)
Full-time homemaker	16 (20.0)
Other	1 (1.3)
Duration of neuropathic pain, n (%)	
3–6 months	16 (19.5)
7–12 months	12 (14.6)
13–35 months	10 (12.2)
≥ 36 months	44 (53.7)

*N = 82. Some numbers vary due to missing data.

of patients were employed, and while 42.5% were retired, 20.0% reported being full-time homemakers.

Two-thirds (65%) of patients reported moderate (score of 4–7) to severe (score of 7–10) pain as their overall pain within the prior 24 hours as indicated by their Pain Severity Index scores (Figure 1A), and the mean Pain Severity Index score was 4.2 ± 2.4 , indicating an overall moderate level of pain. However, worst pain reported in the previous 24 hours was reported as severe by almost half (48%) of the patients and moderate by 28% of patients (Figure 1B).

Patients reported pain interference on seven mBPI-SF health status domains. Pain severity was significantly associated with greater interference in each of these domains (Figure 2). Walking was the least affected domain, and substantial interference was observed on

all other domains that impact activities of daily living and health status (ie, general activity, mood).

The majority of patients (94%) received at least one prescription medication for their neuropathic pain. Polypharmacy was common (Table 2). More than half of the patients (56%) were prescribed antiepileptic medications, which are recommended for neuropathic pain¹⁹ (Table 2), including carbamazepine (55%) and gabapentin (29%) at mean daily doses of 534.1 ± 269.8 and 1036.4 ± 555.1 mg, respectively. Among patients prescribed carbamazepine and gabapentin, 71% and 64% received these as their first pharmacologic therapy, respectively. Other prescribed medications for TN included standard analgesics (47%), such as anti-inflammatory drugs and opioid agents, antidepressants (26%), and sedative or hypnotic medications (13%).

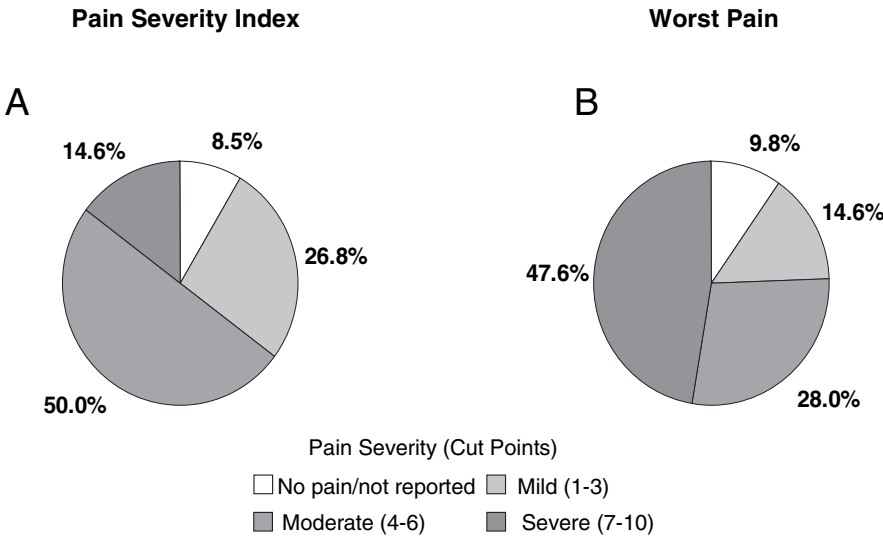


Figure 1. Pain-Reported Pain Intensity.

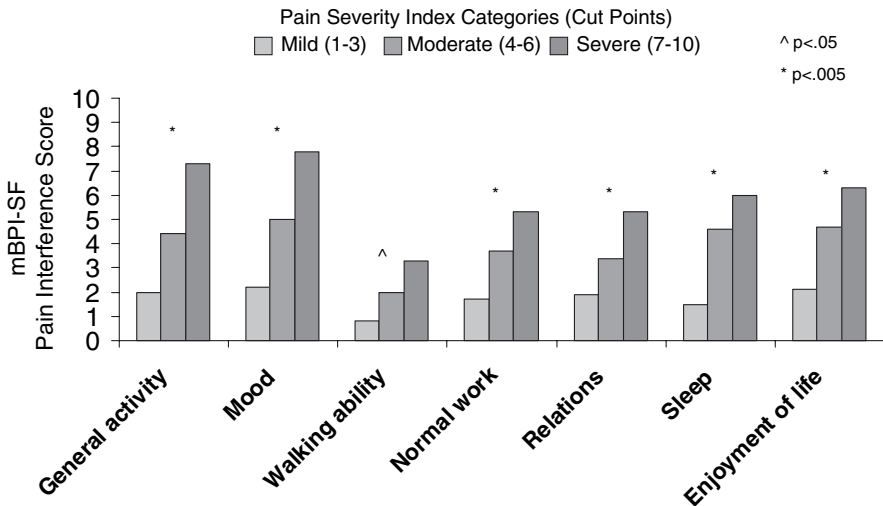


Figure 2. Association Between Pain Severity and Interference on Health Status Domains. mBPI-SF, modified Short Form Brief Pain Inventory.

Table 2. Treatment Patterns

Treatment*	n (%)
<i>Physician-reported prescription medications for TN</i>	
Current prescription medication [†]	77 (93.9)
Antidepressants	20 (26.0)
Amitriptyline	16 (20.8)
Other	4 (5.2)
Sedatives/hypnotics	10 (13.0)
Standard analgesics	36 (46.8)
Opioids and opioid compounds	11 (14.3)
NSAIDs or COX-2 inhibitors	19 (24.7)
Antiepileptic drugs	71 (55.5)
Gabapentin	22 (28.6)
Carbamazepine	42 (54.5)
Duration of prescription medication use	
<3 months	11 (13.9)
3–6 months	15 (19.0)
7–12 months	4 (5.1)
13–35 months	11 (13.9)
≥36 months	38 (48.1)
<i>Physician-reported concomitant prescription medications</i>	
Current concomitant prescription medications ^{††}	30 (32.5)
Prescribed medications for anxiety	8 (26.7)
Prescribed medications for sleep disturbance	14 (46.7)
Prescribed medication for depression	11 (37.7)
<i>Patient-reported other treatments for TN</i>	
Non-prescription medications [†]	25 (30.5)
Aspirin	6 (24.0)
Acetaminophen (paracetamol)	11 (44.0)
Ibuprofen	8 (32.0)
Other	10 (40.0)
Physical treatments	25 (30.5)
Topical lotions/creams	11 (13.4)
Herbs, vitamins, and supplements	14 (17.1)
Devices	8 (9.6)
Exercise	9 (11.0)

*Neither the treatment categories nor the subcategories are mutually exclusive.

[†]Percent of patients utilizing specific agents reflects the proportion of the treatment category.

^{††}Prescribed either antidepressants, sedatives/hypnotics (benzodiazepines, buspirone, or other hypnotics), or analgesics (tramadol, any opioids or opioid compounds, NSAIDs, or COX-2 inhibitors) for concomitant anxiety, depression, or sleep disturbance. COX-2, cyclo-oxygenase 2; NSAIDs, nonsteroidal anti-inflammatory drugs; TN, Trigeminal neuralgia.

Amitriptyline was prescribed to most of the patients (16 out of 20) taking antidepressants. Chronic prescription medication use (>1 year) was reported by the majority (62%) of patients (Table 2), and almost half (48%) reported use ≥3 years. Concomitant use of medications for anxiety, sleep disturbance, and/or depression was reported by one-third (33%) of patients.

Ninety-four percent of patients reported taking their prescription medication for TN “all” or “most of the time.” While compliance was high, only 42% of patients reported their prescription medication as “extremely” or “very effective.”

Patients reported using other medications/treatments for their TN-associated pain (Table 2). These adjunctive therapies included over-the-counter medications (31%), such as paracetamol (acetaminophen) and aspirin, physical treatments (31%), and other therapies (38%).

Pain had a significant impact on health status, including functioning and well-being. Patients reported an overall mean EQ-5D health state valuation of 0.56 ± 0.31 (scale of $-0.59 =$ worst health state to $1.00 =$ best health state) and a mean Pain Interference Score of 3.6 ± 2.4 (scale of $0 =$ no interference to $10 =$ complete interference). A significant association was observed between increasing pain severity and poorer scores on both of these scales (Figure 3).

Patients placed a high value on obtaining pain relief. On a 0–100 scale, patients estimated a 30% increase in their health rating score (improvement from 60.2 ± 20.0 to 78.4 ± 22.7 ; $P < 0.0001$, paired *t*-test) if they could experience complete relief from their TN pain.

TN pain directly impacted medical resource utilization; 78% of patients visited their physician at least once during the past four weeks, and 24% of the patients reported having at least one telephone consultation for pain due to TN. Although no trend was observed between pain severity and the number of physician visits, multiple physician visits were common; 45% of patients visited their physicians two or more times, and of these patients, 25% reported four or more visits. Evaluation by a pain specialist was reported by more than half (53%) of patients.

Pain associated with TN impacted employment in 34% of patients, either through reduction of scheduled work time, disability, or unemployment/early retirement (Table 1). Among the 28% ($n = 23$) of patients working at least part-time, reduction in productivity was reported at least some of the time by 35% of these patients. Additionally, employed patients reported a mean of 3.9 ± 6.9 days missed from work in the prior month due to their pain from TN.

DISCUSSION

This study demonstrates a substantial patient burden resulting from the pain associated with TN and its interference on health status domains. This is consistent with what has been reported in other studies of neuropathic pain conditions, including painful diabetic peripheral neuropathy and postherpetic neuralgia.^{9,11} Patient burden, expressed as impairment of function and reduced quality of life, was significantly associated with TN pain as indicated by poorer health status (lower EQ-5D scores) and greater pain interference with functioning (higher mBPI-SF Pain Interference scores) with increasing neuropathic pain severity. One-third of patients were prescribed medications for depression, anxiety, and sleep disturbance related to TN; conditions consid-

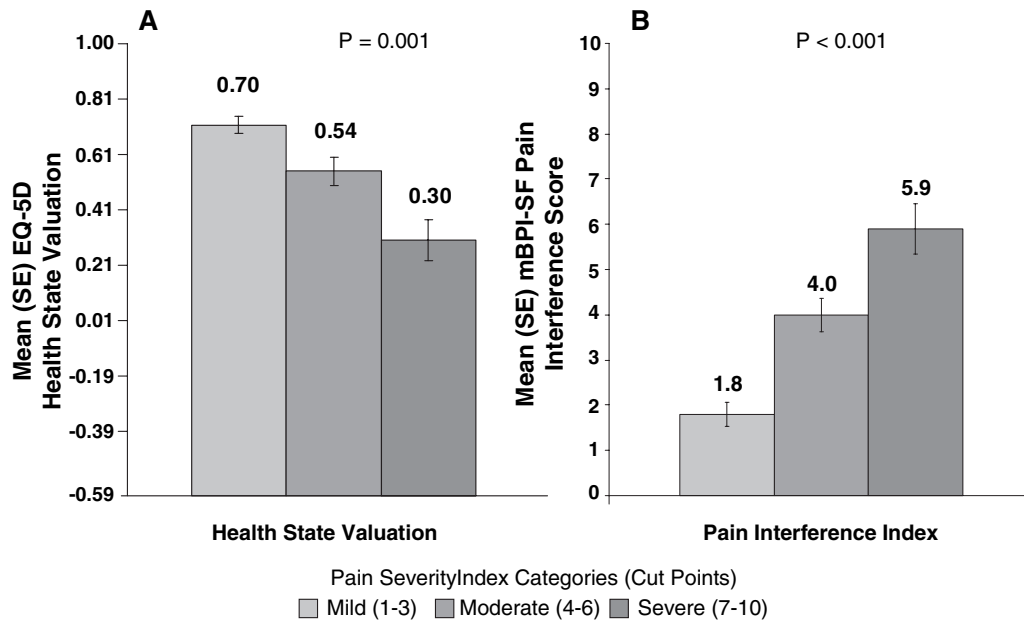


Figure 3. Association Between Pain Severity and (A) Health State Valuation and (B) Pain Interference Index. mBPI-SF, modified Short Form Brief Pain Inventory.

ered comorbid with chronic pain including that associated with neuropathic syndromes.^{8,20}

Despite the widespread use of prescription medications, including the recommended first-line therapy carbamazepine for TN, pain severity levels among patients remained high. While this suggests that the intractable nature of TN significantly contributes to difficulty in treatment, it should be noted that, in at least some patients, suboptimal management may contribute to the perpetuation of neuropathic pain. This in turn would lead patients to seek pain relief through the use of alternate therapies having no evidence of efficacy in neuropathic pain, including over-the-counter analgesics, topicals, and supplements.

Suboptimal pain management may be ascribed to several factors, including the use of agents having no demonstrated efficacy for the treatment of neuropathic pain (eg, nonsteroidal anti-inflammatory drugs or cyclooxygenase [COX]-2 inhibitors) or drugs with efficacy in neuropathic pain conditions other than TN (ie, amitriptyline). Additionally, the mean doses of carbamazepine, the only drug with an indication for the treatment of TN²¹, and gabapentin, which has demonstrated efficacy in treating TN,^{22,23} were at the lower end of the recommended maintenance dose range.^{5,21,24}

Suboptimal pain management, expressed as inadequate pain relief, and significant patient burden, expressed as impaired functioning, have similarly been

reported in the primary care setting in studies of broad neuropathic pain conditions.^{9,11,25} As observed in the current study, these studies also suggest that suboptimal neuropathic pain management contributes to the significant association between pain severity and impairment in other domains of health status, as well as to increased healthcare resource utilization.

This study has several limitations. The small number of patients may have limited our ability to detect potentially significant associations, including employment, which may be important considering the majority of patients (54%) were younger than 65 years. Although the effects of TN on reduced employment productivity were evaluated, no similar data were collected for the 20% of patients who identified themselves as full-time homemakers. This might have been relevant considering that two-thirds of the patients in this study were women, consistent with the predominance of TN in the female population.

Misclassification bias may be considered a limitation as we could not clearly exclude the presence of dental pain or trigeminal neuropathy. The report that 80% of the patients had a duration of “neuropathic pain” longer than six months may argue against the presence of dental pain in the majority of patients. Conversely, TN and trigeminal neuropathy also may fall within the domain of dentists, a population that was not included in this analysis. Although distinguishing between TN

and trigeminal neuropathy may be important from the diagnostic perspective, pharmacologic management is similar and does not impact our observations with regard to pain severity and patient burden. Nevertheless, this uncertainty underscores the challenge regarding diagnosis of TN and the general problem of neuropathic pain management in the clinical setting.

Other limitations include the potential for selection and recall bias; patients were actively seeking medical care, and only some of the chosen physicians agreed to participate (possible selection bias); and some information from the survey was collected by self-report (possible recall bias). Pain is a complex and multidimensional experience, and our focus on pain severity may not have captured the full impact of pain on patient burden. The use of >3 to distinguish between moderate and mild pain severity and interference was consistent with that reported in other studies. This cut-point correlated with resource utilization and patient outcomes in diabetic peripheral neuropathy,^{13,17} and demonstrated agreement with activities of daily living and quality of life in a Herpes zoster-specific adaptation of the Brief Pain Inventory.²⁶

In conclusion, this study demonstrates that pain resulting from TN is associated with a substantial patient burden, which was significantly greater when pain was less controlled. This burden likely resulted from the combination of suboptimal or inappropriate management strategies and the frequent intractability of TN. Regardless of the cause, the persistence of pain in these patients demonstrates a need for improved management strategies in patients presenting with TN. These strategies should include the development of more effective drugs as well as physician education regarding neuropathic pain mechanisms, treatment options, and pain management guidelines.

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