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Research/Technical Note

Development and Validation of a Chinese Assessment Scale for the Primary Trigeminal Neuralgia Based on the Delphi Method

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Abstract

Objective: To develop and validate an assessment scale for primary trigeminal neuralgia (PTN) that is suitable for Chinese patients' clinical requirements and cultural background. *Methods:* Descriptive study. (1) Construction of pre-scales: A pool of scale entries was prepared based on the common clinical features of PTN, the consensus of domestic experts, clinical diagnosis and treatment guidelines, and the reference of the international scale production process. Based on the Delphi method, 21 experts were invited to participate in two rounds of correspondence and pre-test revisions to develop the pre-scales. (2) Formation and validation of the preliminary version of the scale: A clinical investigation was conducted on 157 patients with PTN in the Pain Department of Shandong Provincial Hospital from March 20, 2024 to January 1, 2025. The entries were screened to form a preliminary version of the scale using the critical ratio method, correlation coefficient method, and discrete trend method. The scientific validity and feasibility of the scale were then assessed through reliability and validity tests, satisfaction measurements, and reflective tests. *Results:* 147 patients with PTN completed the study. The positive coefficient of two rounds of expert correspondence was 100.0%, the authoritative coefficient was 0.927 and 0.957 (>0.900), the Kendall's W coefficient was 0.227 and 0.421, respectively (all P<0.001). The validity and reliability of the scale were positive, with Cronbach's α 0.870 (>0.700), the content validity index 0.935 (>0.900) for S-CVI and 0.810-1.000 (all≥0.780) for I-CVI respectively, the Kaiser-Meyer-Olkin (KMO) value 0.858 (>0.600), and $\chi 2$=1 220.060 (P<0.001) of Bartlett spherical test. The exploratory factor analysis extracted 3 common factors, with a cumulative variance contribution rate of 63.880% (＞50.000%) and factor loadings ranging between 0.533 and 0.905 for each entry. The correlation coefficient (r) between satisfaction and change before and after the treatment was 0.903. The scale demonstrated excellent responsiveness, as evidenced by a standardized response median (SRMed) of 2.71 and an effect size (ES) of 3.17 (both substantially exceeding the established benchmark of >0.80). The final scale consisted of 4 parts: the first part with 6 non-quantitative entries, the second part contained 4 dimensions and 20 quantitative entries, the third part contained 5 entries related to post-treatment evaluation, the fourth part was the overall satisfaction evaluation with 5 entries, and the third and fourth parts were for post-treatment only. *Conclusion:* The primary trigeminal neuralgia assessment scale has good reliability, validity, and applicability.

Keywords

Primary Trigeminal Neuralgia, Pain Measurement, Scale, Chinese Version, Development, Reliability and Validity

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1. Introduction

Trigeminal neuralgia is a neurological disorder characterized by intense and paroxysmal pain in the innervated portion of the trigeminal nerve in the face, which is most commonly triggered by harmless stimuli [1, 2]. The third edition of the International Classification of Headache Disorders (ICHD-3) is categorized as primary trigeminal neuralgia (PTN) and secondary trigeminal neuralgia (STN) [2]. PTN is the most prevalent clinical subtype (accounting for 75% of all cases) [3]. Approximately 35.7% of PTN patients have mild-to-severe depressive symptoms, while over 50% are anxious [4]. These neuropsychiatric manifestations significantly impair quality of life, occupational functioning, and social engagement [5].

Precise clinical evaluation is fundamental for effective treatment, while post-treatment assessment offers a more comprehensive measure of pain management efficacy. Nevertheless, PTN clinical assessment faces persistent multifaceted challenges. Firstly, current evaluations predominantly rely on unidimensional or generic scales: the visual analogue scale (VAS) and numerical rating scale (NRS) to evaluate pain intensity [6], the Douleur Neuropathique 4 (DN4) and Leeds Assessment of Neuropathic Pain Symptoms and Signs Scale (LANSS) to evaluate the characteristics of pain [6, 7], the Medical Outcomes Study 36-item short form health survey (SF-36) [8], the Hospital Anxiety and Depression Scale (HADS) [9], and the Pittsburgh Sleep Quality Index (PSQI) [10] to evaluate the quality of life, psychology, and sleep of patients, respectively. However, these assessment tools inadequately capture the multidimensional impact of pain on patients; simultaneously, the operational complexity associated with multi-scale integration significantly compromises assessment efficiency. Secondly, existing scales are not specifically designed for PTN, exhibiting inadequate sensitivity in identifying its characteristic symptoms—such as paroxysmal electric-shock-like pain in trigeminal nerve distribution areas and pain triggered by touch. Concurrently, they omit systematic evaluation of PTN-associated comorbidities (e.g., anxiety, depression, sleep disorders). Thirdly, most scales were developed within Western cultural contexts. Cultural disparities and divergent healthcare systems introduce measurement bias when applied in China, undermining reliability and accuracy [11]. Finally, current assessments universally lack systematic appraisal of post-treatment outcomes (e.g., treatment complications, patient-reported satisfaction), preventing objective quantification of therapeutic benefit.

Consequently, standardized indices for evaluating pain management efficacy are lacking, particularly for PTN-specific assessment. To address this gap, our research team aims to develop an evidence-based, multidimensional PTN assessment instrument integrating cultural adaptation and treatment response evaluation. This tool will be constructed through systematic analysis of PTN clinical evidence and existing assessment scales, ultimately providing a standardized framework to enable precision assessment and individualized therapeutic strategies.

2. Objects and Methods

2.1. Construction of Pre-scales

2.1.1. Initial Scale Development

Our research team systematically queried PubMed, Scopus, Web of Science, Wanfang, and CNKI databases from inception through December 31, 2023. The keywords searched included trigeminal neuralgia, primary trigeminal neuralgia, pain measurement, scale, efficacy assessment, quality of life/life quality, and others. Through systematic evidence synthesis, we integrated internationally established neuropathic pain diagnostic/therapeutic scales [6] with clinical practice guidelines (Chinese Expert Consensus on Trigeminal Neuralgia Management [12], Chinese Neuropathic Pain Diagnosis and Treatment Guidelines (2024) [13], Expert Consensus on Integrated Chinese-Western Medicine Non-surgical Management of Primary Trigeminal Neuralgia [14]) and experiential insights, clinical manifestations of PTN were systematically categorized using this evidence framework. Extracted validated items from international scales (e.g., VAS, SF-36), incorporated China-specific clinical indicators from consensus guidelines. Finally, generated >50 candidate items encompassing: core symptomatology and clinical signs, mood/sleep comorbidities, and functional impact domains. Furthermore, an expert consultation was conducted with five pain medicine specialists. Through iterative refinement of the item pool incorporating expert feedback, the preliminary scale draft was developed.

2.1.2. Delphi Expert Consultation

The Delphi method was implemented following established medical research standards, which recommend panel sizes of 15-20 experts [15]. Our study enrolled 21 specialists across multiple consultation rounds, with 4-8 weeks inter-round intervals. Experts evaluated items across four domains: clinical significance, linguistic coherence, dimensional rationality, and content validity. Quantitative analysis of expert ratings informed final item selection. Expert inclusion required: (1) Bachelor's degree or higher in clinical medicine, associate senior above professional title; (2) abundant clinical experience or management experience in primary trigeminal neuralgia, experience ≥5 years; and (3) volunteer to participate in this study.

The expert questionnair, adapted from the initial scale draft, comprised four sections: (a) expert demographics, (b) item significance ratings (assessed via a 5-point Likert scale [15],

where 1 = 'very unimportant' and 5 = 'very important'), (c) item evaluation criteria, and (d) a self-assessment of familiarity with the research domain. The questionnaire was sent by e-mail, and the experts were reminded to return the e-mail within 7 days. Upon questionnaire retrieval, the general information of the experts was compiled. Key metrics—mean item importance, coefficient of variation (Cv), Kendall's W concordance coefficient, and expert authority coefficients (Cr)—were computed to assess opinion consistency and reliability. Items failing predefined thresholds (mean importance <3.50 or Cv >0.25) were excluded. The research team then revised the entries through group discussion and voting based on expert feedback, incorporating only suggestions achieving ≥70% approval; this finalized the subsequent questionnaire round. The process concluded when all items met the consensus criteria (mean importance ≥3.50 and coefficient of variation ≤0.25).

2.1.3. Pre-scale Development

To evaluate scale readability and feasibility, we recruited 30 PTN patients [13] from the Pain Department of Shandong Provincial Hospital (20 March - 30 May 2024) using convenience sampling for pilot testing. Inclusion criteria: (1) Age ≥18 years; (2) Voluntary participation with informed consent; (3) Absence of psychiatric disorders or cognitive impairments affecting symptom reporting. Exclusion criteria: (1) Communication barriers precluding scale completion; (2) Declined participation; (3) Ambiguous diagnosis or mixed-pain conditions; (4) Incomplete medical documentation.

We conducted semi-structured interviews [16] to assess scale feasibility, focusing on patients' disease experiences and item comprehension. Participants responded to open-ended probes including: "Describe your primary physical/psychological symptoms since disease onset", "How has this condition impacted your daily life?", "What concerns have arisen since symptom development?", "What do you believe this specific item/question is asking?", "Which response option seems problematic and why?". Interviews (≈20 min each) explored item clarity, interpretational challenges, and operational feasibility. All research team members attended interviews and held discussions post-interview. Problematic items were refined based on pilot results, resulting in the preliminary scale (Table A1).

2.2. Formation and Validation of the Provisional Version of the Scale

2.2.1. Data Collection

The pre-scale comprised four domains (41 items total): patient disease characteristics (7 items), pain assessment (24 items), post-treatment assessment (5 entries), and overall satisfaction evaluation (5 entries), of which the pain assessment part was a quantifiable entry. Only the post-treatment and satisfaction domains were administered exclusively post-intervention. To ensure scale robustness, the 24-item pain subscale underwent statistical validation. Per the standard requiring 5–10 participants per scale item [17], we determined a minimum sample size of 120 for scale testing. Two clinically experienced pain physicians collected data via dual modalities: electronic questionnaires (Questionnaire Star®) and paper-based forms.

We enrolled 157 PTN patients from the Pain Department of Shandong Provincial Hospital (March 20, 2024 - January 1, 2025). Following comprehensive history-taking and physical examination, all participants completed the pre-treatment scale. Post-treatment follow-up assessments were conducted at 1 month using a hybrid approach, primarily in-person during outpatient visits, supplemented by telephone interviews when necessary. Ten patients were lost to follow-up, yielding 147 complete datasets that underwent dual-entry verification before database inclusion.

2.2.2. Pain Assessment

(i). Item Analysis

We employed three methods to analyze the 24-item pain assessment subscale [17]: (1) The critical ratio (CR) method [11], where participants were ranked by total score and extreme groups (top/bottom 27%) [11] were compared via independent t-tests, excluding items with non-significant differences ($P > 0.05$) or CR ($|t|$) < 3; (2) The correlation coefficient method [11], assessing item-total correlations and excluding items with coefficients <0.3 or non-significant associations ($P > 0.05$); and (3) The discrete trend method (coefficient of variation) [11], which calculated item standard deviations (SD) and excluded items with SD < 0.7. Item analysis was performed using data collected at the pre-treatment assessment to ensure adequate variability in symptom severity for evaluating item discrimination.

(ii). Reliability and Validity Tests

Comprehensive validation of the 24-item pain subscale was conducted to establish reliability and validity. Internal consistency reliability was assessed using Cronbach's α and McDonald's ω coefficients [18]. Item-level analysis applied dual exclusion criteria: 1) corrected item-total correlation (CITC) < 0.3; 2) significant increase in Cronbach's α upon item deletion [18, 19]. Validity assessment encompassed content and structural validity [18].

Content validity was assessed using item-level (I-CVI) and scale-level content validity indices (S-CVI) based on expert evaluations with a 4-point relevance scale (1="irrelevant" to 4="very relevant"), with acceptable thresholds set at I-CVI ≥0.780 and S-CVI ≥0.900 [19]. Structural validity was evaluated through exploratory factor analysis after confirming data suitability (KMO ≥0.600; Bartlett's sphericity $P<0.05$), where principal component analysis with Varimax rotation extracted factors that met two criteria: 1) factor loadings >0.50, 2) eigenvalues >1.0 [18], and explained at least

50.0% of the variance in total (cumulative variance ≥50.0%) [11, 17]. The ID-Pain Screening Questionnaire [6], a validated neuropathic pain assessment tool rated as medium-quality with a strong recommendation according to Chinese guidelines, served as the external benchmark.

2.2.3. Overall Satisfaction Evaluation

Satisfaction evaluation was conducted exclusively post-treatment, where Pearson correlation analysis assessed criterion validity between patients' satisfaction scores and therapeutic improvement metrics derived from Part 2: Improvement Index (ΔScore = pre-treatment score - post-treatment score) and Improvement Rate ([ΔScore/pre-treatment score] ×100%) [17]. A strong validity association was confirmed when $|r| > 0.70$ ($P<0.001$), indicating satisfaction ratings significantly reflected clinical improvement outcomes [17].

2.2.4. Post-treatment Complication Analysis

Spearman's rank correlation analysis evaluated associations between complication severity (Part III total score) and both satisfaction scores and improvement rates. Correlation strength was interpreted as: weak ($|r| = 0.3$-0.5), moderate ($|r| = 0.5$-0.7), or strong ($|r| \geq 0.7$) [11], with statistical significance set at $P<0.05$.

2.2.5. Reactivity Evaluation

Reactivity evaluation employed the Wilcoxon signed-rank test to evaluate pre-post treatment differences. This was complemented by three quantitative metrics: change rate (CR), effect size (ES), and standardized response median (SRMed). Excellent responsiveness was confirmed when both ES >0.80 and SRMed >0.80.

2.3. Statistical Methods

Statistical analyses were performed using SPSS 26.0 (IBM Corp.) with Microsoft Excel for data management. Continuous variables are presented as mean ± SD for normally distributed data or medians with interquartile range (IQR) for non-normal distributions. Categorical variables are expressed as frequencies (percentages) [11]. For the Delphi study, expert engagement was quantified through effective response rate and authority coefficient (Cr), while opinion consistency was assessed using coefficient of variation (Cv) and Kendall's W. Scale validation included: item analysis, reliability testing (Cronbach's α/ω), validity assessment (content/construct/criterion), satisfaction correlation and responsiveness evaluation. Statistical significance was defined as $P < 0.05$ throughout.

3. Result

3.1. Delphi Expert Consultation

The Delphi method was employed, engaging a panel of 21 experts. These experts possessed substantial clinical experience, averaging 25.8 ± 7.6 years. Their qualifications included PhDs (33.3%, n=7), Master's degrees (42.9%, n=9), and Bachelor's degrees (23.8%, n=5). Professional titles were Associate Senior (47.6%, n=10) and Senior (52.4%, n=11). Both consultation rounds achieved a 100.0% response rate (21/21), demonstrating high expert engagement.

The certainty assessment (Ca) for the two rounds of expert consultation was 0.967 and 0.962, respectively, while the certainty of source (Cs) was 0.886 and 0.952. The credibility coefficient (Cr) was 0.927 and 0.957 (both >0.900), indicating a high level of expert authority, as shown in Table 1. Opinion consistency improved significantly across rounds. In Round 1, coefficients of variation (Cv) ranged from 0 to 0.257, with Kendall's W = 0.227. Based on predefined item screening criteria, 27 quantitative items advanced to Round 2. In Round 2, Cv values were lower (0 to 0.223, all <0.250), and Kendall's W increased to 0.421 (Table 1), indicating strong consensus. Consequently, the process concluded after two rounds. Expert-rated item importance was high in both rounds (Round 1: mean 4.20 ± 0.46, range 3.33-5.00; Round 2: mean 4.43 ± 0.20, range 4.10-4.90), indicating a high level of consensus on item importance. The final pre-test scale comprised 41 items organized into 4 sections: General Patient Information (7 items), Pain Assessment (24 items), Post-Treatment Assessment (5 items), and Overall Satisfaction Rating (5 items).

Table 1. *Results of Expert Authority and Coordination Levels in Two Consultation Rounds.*

Round	Ca	Cs	Cr	Cv	Kendall's *W*
1	0.967	0.886	0.927	0～0.257	0.227
2	0.962	0.952	0.957	0～0.223	0.421

Note: Cr = (Ca + Cs)/2

3.2. Patient Characteristics

The study enrolled 157 PTN patients. After excluding 10 lost to follow-up, 147 patients comprised the final cohort. The median age was 64 years (IQR: 57-71; range: 31-89), with 80 females (54.4%) and 67 males (45.6%). Disease duration varied widely, most commonly 1-3 years (20.4%), followed by 3-5 years (18.4%) and 5-10 years (18.4%). Right-sided pain predominated (64.6%). The most frequently involved trigeminal nerve branches were V2 (32.7%), V3 (28.6%), and V2+V3 (22.4%). Most patients reported <10 pain episodes/day (87.1%), episodes lasting <1 minute (67.3%), and electric shock-like pain quality (83.0%). Accompanying symptoms included facial muscle spasm/twitching (8.2%), conjunctival congestion/tearing (13.6%), and salivation (14.3%). A majority (78.9%) had prior first-line medication exposure (carbamazepine/oxcarbazepine), with generally low rates of adequate pain relief. Forty-five patients (30.6%) underwent previous interventions: percutaneous trigeminal ganglion radiofrequency thermocoagulation (n=21), Meckel's cave balloon compression (n=9), microvascular decompression (n=10), and Meckel's cave glycerol injection (n=5). Detailed demographics are presented in Table A3. Patient Demographic and Clinical Characteristics.

Primary interventions included percutaneous trigeminal ganglion radiofrequency thermocoagulation (64.6%, n=95) and Meckel's cave balloon compression (29.9%, n=44), while peripheral nerve radiofrequency was infrequent (2.7%, n=4). Among the 143 patients undergoing surgical intervention, 126 (88.1%) achieved complete pain resolution with medication discontinuation at 3-month follow-up. Follow-up data are summarized in Table A4. Follow-up Outcomes of 147 Patients with Primary Trigeminal Neuralgia.

Patient Demographic and Clinical Characteristics.

Table content remains unchanged but moved to appendix(Table A3)

Follow-up Outcomes of 147 Patients with Primary Trigeminal Neuralgia.

Table content remains unchanged but moved to appendix(Table A4)

3.3. Pain Assessment

3.3.1. Item Analysis

Critical Ratio Method flagged Q2, Q8, Q23, and Q24 for non-significant differences ($P > 0.05$), while Q2, Q5, Q8, Q20, Q22, Q23, and Q24 warranted exclusion due to low discrimination ($|t| < 3$). Pearson's Correlation Analysis showed Q2, Q8, Q20, Q21, Q22, Q23, and Q24 had insufficient scale correlation ($r < 0.3$), with Q8/Q23/Q24 additionally exhibiting non-significant relationships ($P > 0.05$) [11]. The Dispersion Trend Method confirmed adequate discriminative power (SD > 0.700 for all items) with no items requiring elimination. Based on the convergent evidence from critical ratio and correlation analyses, items Q2, Q5, Q8, Q20, Q21, Q22, Q23, and Q24 were excluded from the final scale (detailed in Table A5. Item Analysis of the Preliminary Chinese PTN Assessment Scale).

Table 2. *Reliability Analysis of the Preliminary Chinese PTN Assessment Scale (n=147).*

(Detailed item-level data moved to appendix; only summary retained in main text)

Item-Number	Item Content	Cronbach's α	McDonald's ω
Q1	How severe was your most intense facial pain? recently?		
Q2	How would you rate your mildest facial pain recently?		
Q3	How would you rate your average facial pain recently?		
Q4	Does your pain worsen with weather/environmental changes?		
Q5	Does your pain worsen with fatigue/emotional stress?		
Q6	Does voluntary facial movement (speaking, chewing, expressions) trigger your pain?	0.870	0.871
Q7	Does light touch/stretching of facial areas (gums, lips, ala nasi, cheeks, periorbital regions) trigger pain?		
Q8	(Physician's examination) When comparing light touch on affected vs. unaffected facial skin, do you experience reduced sensation in the pain area? If yes, select the degree		
Q9	Do you feel anxious, tense, or restless due to facial pain recently?		
Q10	Do you feel depressed, discouraged, or helpless due to facial pain recently?		
Q11	Do you feel fatigued or lacking energy due to facial pain recently?		

Item-Number	Item Content	Cronbach's α	McDonald's ω
Q12	Does facial pain cause difficulty concentrating (e.g., when using phones/watching TV)?		
Q13	Does facial pain make you feel worthless, like a failure, or that you've let down yourself/family?		
Q14	Have you ever felt unable to cope, had thoughts of dying, or self-harm due to facial pain?		
Q15	Does facial pain affect your sleep quality?		
Q16	Do you wake up from sleep due to facial pain?		
Q17	Does pain affect daily activities (washing, eating, speaking, smiling)?		
Q18	Do negative emotions from pain (depression, helplessness, anxiety) affect your work/life (job, socializing, chores)?		
Q19	Does pain affect your social interactions with family/friends/colleagues?		
Q20	Is facial pain accompanied by facial/masticatory muscle spasms/twitching?		
Q21	Is facial pain accompanied by conjunctival congestion and/or tearing?		
Q22	Is facial pain accompanied by salivation?		
Q23	What is your recent pain attack frequency?		
Q24	What is your recent pain attack duration?		

Note: [a]$P<0.05$

3.3.2. Reliability and Validity Analysis

(i). Reliability Analysis

Reliability analysis demonstrated strong internal consistency (Cronbach's α = 0.870; McDonald's ω = 0.871, both >0.70, Table 2. Reliability Analysis of the Preliminary Chinese PTN Assessment Scale). However, Q4 showed poor corrected item-total correlation (CITC <0.3), warranting exclusion.

(ii). Validity Analysis

(a) Content Validity

All items achieved excellent content validity (I-CVI range: 0.810–1.000; all >0.780), with strong scale-level validity (S-CVI = 0.935 >0.900).

(b) Structural Validity

Exploratory factor analysis of the 15 retained items demonstrated appropriate sampling adequacy (KMO=0.858) and significant sphericity (χ^2=1,220.060, P<0.001). Principal component analysis with varimax rotation extracted three factors (eigenvalues >1; cumulative variance explained: 63.880%, Table A6. Factor Analysis Total Variance Explained by the Preliminary Chinese PTN Assessment Scale), with subsequent scree plot (Figure 1. Scree Plot) analysis confirming this factor retention. Following removal of items Q9 and Q10 due to significant cross-loadings (>0.5 on multiple factors), the final factor structure revealed three distinct dimensions: Factor 1 ("Mood & Sleep", 6 items) reflecting pain's psychological impact, Factor 2 ("Quality of Life", 5 items) assessing daily function and pain triggers, and Factor 3 ("Pain Experience", 2 items) quantifying pain intensity (Table 3. Factor Loadings of Items in the Preliminary Chinese PTN Assessment Scale).

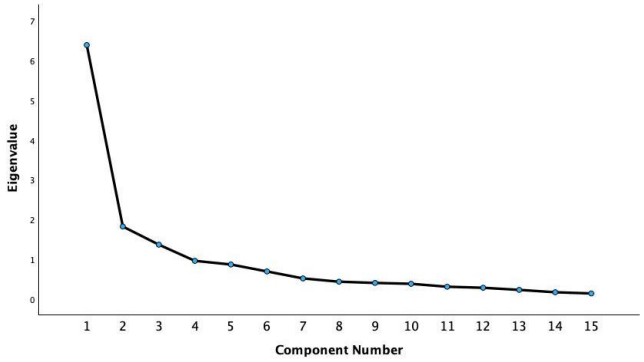


Figure 1. *Scree Plot.*

Note: Component with eigenvalues above the inflection point (typically >1.0) should be retained. However, substantially higher eigenvalues in Factors 1-3 and plateau after Factor 4 support retaining three common factors.

(iii). Criterion Validity

The provisional scale demonstrated moderate criterion validity, evidenced by a Pearson correlation of r = 0.59 (P < 0.05) with ID-Pain total scores.

Factor Analysis Total Variance Explained by the Prelimi-

nary Chinese PTN Assessment Scale.

Table content remains unchanged but moved to appendix (Table A6).

Table 3. *Factor Loadings of Items in the Preliminary Chinese PTN Assessment Scale.*

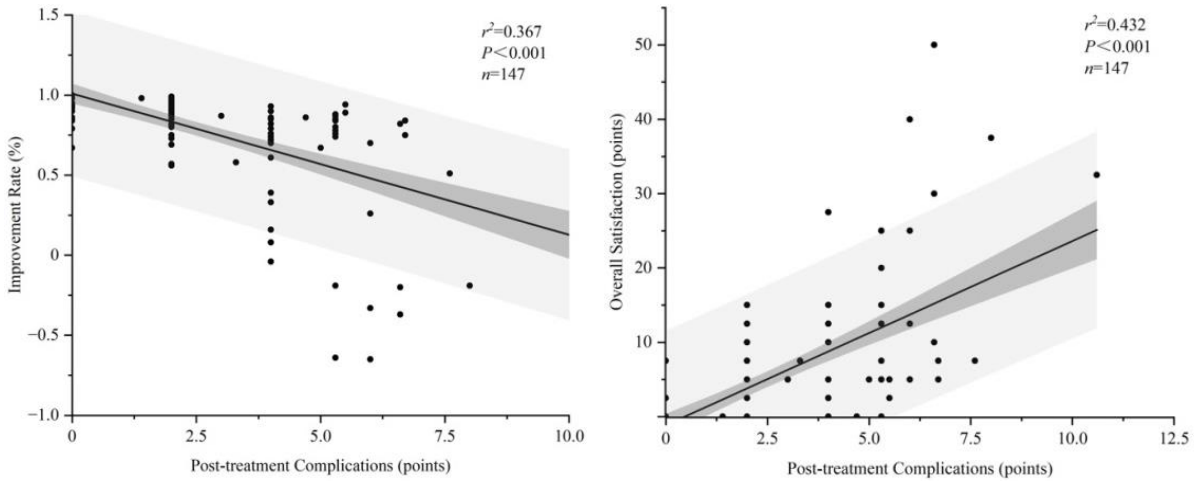
Item	Factor		
	1	2	3
Q12	0.805		
Q13	0.759		
Q11	0.674		
Q15	0.673		
Q14	0.649		
Q16	0.642		
Q9	0.533	0.501	
Q10	0.542	0.653	
Q17		0.850	
Q7		0.762	
Q6		0.656	
Q19		0.595	
Q18		0.585	
Q1			0.905
Q3			0.890

3.3.3. Final Scale Restructuring

Building upon the tentative 3-dimensional, 13-item factor analysis structure, the research group incorporated six clinically significant PTN features previously excluded during preliminary scaling (Q8, Q20-Q24), justified by their value in assessing core disease characteristics (e.g., attack frequency, duration, pain quality, and concomitant symptoms; see Discussion). While these items were statistically excluded initially, their clinical relevance for capturing essential PTN features (e.g., attack patterns, autonomic symptoms) warranted retention. However, their methodological implications necessitate further validation in multicenter studies. Simultaneously, Part 1's qualitative pain descriptors (e.g., electric shock-like, pins and needles) were transformed into a composite quantitative item. The restructured Part 2 consequently organized 20 items into four dimensions: Pain Experience (5 items: original 2 + Q23 + Q24 + composite pain-type item), Concomitant Symptoms (4 items: Q8 + Q20 + Q21 + Q22), Mood & Sleep (6 items; unchanged), and Quality of Life (5 items; unchanged).

3.4. Overall Satisfaction Evaluation

Treatment satisfaction was assessed using 5 items in 147 patients. Satisfaction scores showed a strong correlation (r = 0.903) with a clinical improvement index derived from 6 key items (Q1, Q3, Q15-Q18). This association remained significant despite substantial symptom reduction from baseline (35.8 ± 9.3) to post-treatment levels (median: 0, IQR: 0-2), confirming satisfaction was closely linked to therapeutic efficacy.



2A 2B

Figure 2. *Results of Correlation Analysis between Post-Treatment Complications and Improvement Rates/Overall Satisfaction.*

Note: Figure 2A analyzes complication-improvement rate correlations; Figure 2B examines complication-satisfaction relationships using inverse-scored metrics (lower satisfaction scores denote higher satisfaction).

3.5. Post-Treatment Complication Analysis

Complication severity demonstrated a strong negative correlation with symptom improvement rate ($r = -0.712$, $p < 0.001$) and a significant positive correlation with satisfaction scores ($r = 0.716$, $p < 0.001$). Given the inverse scoring of satisfaction (lower scores = higher satisfaction), these results indicate that greater complication severity corresponds to both reduced clinical improvement and diminished patient satisfaction (Figure 2. Results of Correlation Analysis between Post-Treatment Complications and Improvement Rates/Overall Satisfaction).

3.6. Reactivity Evaluation

The scale demonstrated excellent responsiveness, featuring rapid completion (mean: 5 minutes) and significant treatment effects confirmed by the Wilcoxon signed-rank test ($P < 0.001$, Table 4. Responsiveness Test Results of the Preliminary Chinese PTN Assessment Scale). Robust responsiveness indices substantially exceeded established benchmarks—Standardized Response Median (SRMed = 2.71 > 0.80), Effect Size (ES = 3.17 > 0.80), and Change Rate (CR = 94%)—collectively verifying its sensibility to detect clinically meaningful post-treatment changes.

Table 4. *Responsiveness Test Results of the Preliminary Chinese PTN Assessment Scale.*

Scale	Pre-Treatment (Points)	Pre-Post Change (Points)	*Z-value*	*P-value*	CR	ES	SRMed
Preliminary Version Scale	81.67 (66.49, 90.16)	76.84 (59.33, 87.67)	10.518	<0.001	0.94	3.17	2.71

Note: CR, Change Rate; ES, Effect Size; SRMed, Standardized Response Median

4. Discussion

Trigeminal neuralgia (TN) causes multidimensional impairment across physical, psychological, and social domains due to its characteristic pain [5]. Although current treatments—including pharmacotherapy and percutaneous interventions such as trigeminal ganglion radiofrequency thermocoagulation—demonstrate efficacy [3, 20], systematic assessment instruments remain essential for comprehensive management. Multidimensional indices facilitate rapid pain assessment, personalized treatment planning, and accurate efficacy monitoring, thereby enhancing clinical utility for both diagnosis and ongoing treatment evaluation. However, commonly used scales in China are predominantly translated instruments lacking localization validation; their limited dimensionality or generic design inadequately capture TN-specific manifestations (e.g., pain characteristics, trigger points, autonomic symptoms). Consequently, this study developed an assessment tool comprises four sections: Part 1 includes 6 qualitative items addressing disease course, pain laterality, and patient self-evaluation of prior treatment efficacy; Part 2 provides a comprehensive quantitative assessment of pain across 4 dimensions—pain experience, accompanying symptoms, mood and sleep, and quality of life—through 20 items, enabling rapid and accurate evaluation of pain severity in PTN patients; Parts 3 and 4 are exclusively used for post-treatment evaluation, with Part 3 containing 5 post-treatment assessment items and Part 4 serving as an overall satisfaction evaluation requiring patients to rate 5 aspects: pain relief, mood and sleep improvement, quality-of-life enhancement, and overall treatment efficacy. Parts 3 and 4 assist clinicians in holistically understanding post-treatment patient status to optimize clinical decision-making.

The development of the scale strictly followed a scientific process. Item design was thoroughly integrated with the cultural background and habits of Chinese patients. The initial scale was formed through literature review, the group discussions, two rounds of Delphi expert consultations [21, 22], and preliminary testing. Twenty-one clinical experts from eastern and central China, all with ≥10 years of experience, participated in the consultations. Both rounds achieved a 100% response rate. The authority coefficients (Cr) were 0.927 and 0.957, respectively. Kendall's W coefficient significantly increased in the second round (0.421 vs. 0.227), while the coefficient of variation (Cv) decreased (0.257 to 0.223), indicating a strong and stable expert consensus.

Item analysis and reliability testing constitute fundamental methodological components in scale development [11]. Item analysis—assessing item discrimination and item-total homogeneity—requires administration during clinically active disease phases to preserve discriminant validity. Post-treatment symptom improvement reduces score variability, compromising item discrimination. As the post-treatment assessment and satisfaction modules measure therapeutic effects rather than core disease characteristics, they were excluded from validation. These parts underwent independent verification through reactivity evaluation and

correlation analysis. The retained 16-item scale demonstrated excellent internal consistency (Cronbach's α=0.870; McDonald's ω=0.871). Content validity was robust (I-CVI=0.810-1.000; S-CVI/UA=0.935), while exploratory factor analysis extracted three factors explaining 63.88% cumulative variance. A significant correlation with the ID-Pain scale ($r = 0.59$, $P < .001$) further supports its validity.

A significant correlation was observed between post-treatment satisfaction and clinical improvement ($r = 0.903$, $P < 0.001$), indicating that the scale effectively captures patient-reported treatment efficacy. Complications were negatively correlated with the improvement rate ($\rho = -0.712$) and positively correlated with satisfaction (reverse-scored; $\rho = 0.716$), this reflects complications' detrimental impact on treatment, confirming this domain's predictive value for efficacy evaluation. Regarding reactivity evaluation—defined as sensitivity to clinically meaningful changes [23]—significant pre-post treatment differences ($P<0.001$) with robust effect sizes (SRMed=2.71; ES=3.17, both >0.80) establish the scale's capacity to detect subtle transitions, validating its utility for monitoring.

With the transition in medical models from the unidimensional "biomedical model" to the multidimensional "biopsychosocial model", the significance of Patient-Reported Outcomes (PRO) has gained growing recognition in health status assessment and clinical efficacy evaluation [23]. Compared to internationally established unidimensional pain assessment tools (e.g., VAS, NRS) or generic scales (e.g., PSQI, HADS, SF-36), this study innovatively developed a multidimensional assessment scale specifically designed for PTN characteristics. Grounded in the biopsychosocial model framework and integrating PRO principles with PTN's typical clinical features, the scale comprises the biological domain, psychological domain, and social domain. Its biological domain focused on pain experience (intensity and characteristics) and accompanying symptoms; the psychological dimension evaluates the impact of anxiety, depressive mood, and sleep disturbances on quality of life and prognosis [24]; while the social domain assesses pain's comprehensive effects on daily living activities (e.g., hygiene, eating, speaking) and social participation (e.g., work, social engagement). In addition, this scale incorporates two key dimensions—post-treatment assessment (monitoring common adverse effects like dizziness, nausea, drowsiness, and sensory disturbances) and overall satisfaction (evaluating treatment experience across pain level, mood/sleep, quality of life, and overall efficacy)—using a combined PRO and objective quantitative approach to comprehensively assess PTN patients from subjective/objective perspectives and enable quantitative treatment comparisons. Statistical analysis initially excluded 6 items (pain episode frequency/duration, sensory loss, and symptoms accompanying attacks: muscle spasms/twitching, conjunctival congestion/tearing, and salivation); however, recognizing their clinical value, further analysis revealed an 82.6% concomitant symptom positivity rate in patients with ≥1-year duration and significant associations between specific symptoms and trigeminal nerve branch involvement (conjunctival congestion/tearing with V_1 -70%, muscle spasms/twitching with V_2 -91.6%, salivation with V_3 -76.2%). These findings support the classification of the aforementioned symptoms as exploratory auxiliary localization indicators; however, their methodological transparency requires further refinement. To strengthen the robustness of the conclusions, it is recommended that future studies include sensitivity analyses (comparing model reliability and validity with versus without these indicators) and explicitly state that these indicators necessitate validation through multicenter clinical trials. Similarly, despite statistical exclusion, "attack frequency" and "duration" were retained as essential hallmarks of PTN's episodic pain [5, 24]. Pain type descriptors (e.g., electric shock, pins and needles) [24], crucial for differential diagnosis and severity assessment, were modified into a composite quantitative item (evaluating five pain types). It must be emphasized that the retention of these indicators may have implications for the psychometric properties of the scale. Therefore, their validity and reliability must be further verified through external datasets and nationwide multicenter clinical trials. The final scale comprises four sections, four dimensions, and 36 items, scored 0–300 (higher scores indicate worse pain, function, and outcomes), applicable pre-/post-treatment. Designed for clarity to Chinese PTN patients, it integrates disease-specific clinical characteristics to holistically assess the condition and treatment response.

In summary, this study developed a culturally adapted and multidimensional assessment scale for PTN (Trigeminal Neuralgia) in Chinese patients through a rigorous Delphi process and validation procedures. The scale demonstrates good psychometric properties and integrates patient-reported outcomes (PRO) within a biopsychosocial framework, comprising four complementary dimensions that enable rapid and comprehensive evaluation, thereby facilitating the development of individualized treatment strategies. For example, high scores in the emotion and sleep dimension may indicate the need for adjunctive psychotropic medications or behavioral interventions, while persistent accompanying symptoms may suggest involvement of specific trigeminal nerve branches, providing a basis for further imaging examination or interventional therapy.

However, this study has certain limitations. The validation phase relied solely on convenience sampling from a single hospital, which limits the representativeness of the sample and the generalizability of the results. Variations in patient characteristics across different regions and healthcare settings may affect the applicability of the scale. It should be noted, however, that the criterion validity correlation with the ID-Pain scale ($r = 0.59$), while statistically significant and reflecting a large effect size, did not reach a strong correlation threshold (e.g., $r > 0.70$). This moderate correlation may reflect differences in construct emphasis or cultural adaptation between the scales, and suggests the need for further validation against additional external criteria in future studies.

Therefore, future research should further validate the reliability, validity, and cross-cultural applicability of the scale through multicenter, large-sample clinical trials. Sensitivity analysis is also recommended to assess the impact of auxiliary indicators on the robustness of the model. Despite these limitations, this study provides a culturally adapted, psychometrically sound multidimensional assessment tool for Chinese patients with PTN, offering strong support for comprehensive clinical evaluation and treatment decision-making.

5. Conclusion

This study successfully developed and validated a multidimensional assessment scale for primary trigeminal neuralgia (PTN), tailored to the Chinese cultural and clinical context through a rigorous Delphi method. The scale demonstrates strong reliability (Cronbach's α = 0.870), validity (S-CVI = 0.935, cumulative variance explained = 63.88%), and responsiveness (SRMed = 2.71, ES = 3.17). Its four-dimensional structure—encompassing pain experience, concomitant symptoms, mood and sleep, and quality of life, along with post-treatment evaluation modules—provides a comprehensive tool that aligns with the biopsychosocial model. By integrating culturally adapted patient-reported outcomes and objective metrics, the scale supports individualized treatment planning and enhances clinical efficacy assessment. Further multicenter validation is recommended to confirm its generalizability across diverse populations and settings.

Abbreviations

PTN	Primary Trigeminal Neuralgia
STN	Secondary Trigeminal Neuralgia
ICHD-3	The International Classification of Headache Disorders, 3rd edition
VAS	Visual Analogue Scale
NRS	Numerical Rating Scale
DN-4	Douleur Neuropathique 4
LANSS	Leeds Assessment of Neuropathic Pain Symptoms and Signs Scale
SF-36	Medical Outcomes Study 36-item Short form Health Survey
HADS	Hospital Anxiety and Depression Scale
PSQI	Pittsburgh Sleep Quality Index
IQR	Interquartile Range
CR	Critical Ratio
CV	Coefficient of Variation
Ca	Certainty Assessment
Cs	Certainty of Source
Cr	Credibility Coefficient
CR	Change Rate
SD	Standard Deviation
CITC	Corrected Item-Total Correlation
I-CVI	Item-level Content Validity Index
S-CVI	Scale-level Content Validity Index
KMO	Kaiser-Meyer-Olkin
SRMed	Standardized Response Median
ES	Effect Size
PRO	Patient-Reported Outcomes
ADRs	Adverse Drug Reactions
ADL	Activities of Daily Living
CNS	Central Nervous System
GI	Gastrointestinal

Author Contributions

Zhao Jinfeng: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Software, Validation, Visualization, Writing – original draft

Wang Yuxuan: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Software, Validation, Visualization, Writing – original draft, Writing – review & editing

Sun Tao: Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing

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Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Appendix

Table A1. *Chinese Version of Primary Trigeminal Neuralgia Therapeutic Efficacy Assessment Scale (Preliminary Questionnaire).*

Name: Gender: Age: Hospital ID: Contact:

To accurately evaluate and effectively treat your condition, please provide truthful responses to the following questions. Mark "√" in the box that best reflects your actual situation.

I. Patient Demographic Data

1. Affected Side:

□Left □Right

2. Branch Involvement:

□V1 □V2 □V3 □V1+V2

□V2+V3 □V1+V2+V3

3. Pain Characteristics:

□Electric shock-like □Tearing-like □Stabbing-like

□Needle-prick-like □Burning-like

4. Attack Frequency:

□< 10 times/day □10-50 times/day □≥ 50 times/day

5. Attack Duration:

□< 1 min □1-10 min □≥ 10 min

6. Disease Course:

□<6 months □ ≥6 months, <1 year

□≥1 year, <3 years □ ≥3 years, <5 years

□≥5 years, <10 years □ ≥10 years, <20 years

□≥20 years

7. Remission Period:

□< 1 week □ ≥1 week, <1 month

□≥1 months, <6 months □ ≥6 months, <1 year

□ 1-5 years □ 5-10 years

□ > 10 years

8. Current Analgesic Use (Check pain relief rate and specify medications):

(No relief) 0 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% (Complete relief)

(1) First-line:

□Carbamazepine □Oxcarbazepine

(2) Second-line:

□ Pregabalin □ Gabapentin

□ Baclofen □ Lamotrigine

(3) Others:

□ Ibuprofen □ Tramadol □ Diclofenac sodium

□ Paracetamol/Dihydrocodeine □ Duloxetine

□ Venlafaxine □ Oxycodone □ Other (_____)

9. Prior Non-pharmacological Interventions (Check pain relief rate and specify procedure):

(No relief) 0 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% (Complete relief)

□ Percutaneous Radiofrequency Thermocoagulation of Trigeminal Ganglion

□ Meckel's Cave Balloon Compression

□ Meckel's Cave Glycerol Rhizotomy

□ Nerve Block Therapy

□ Microvascular Decompression

□ Gamma Knife Radiosurgery

□ Other (_____)

To ensure accurate assessment and effective treatment of your condition, please answer the following questions truthfully based on your experiences over the past week. Mark "√" next to the option that best reflects your actual situation. 0 = No pain; 1-3 = Mild pain; 4-6 = Moderate pain; 7-9 = Severe pain; 10 = Excruciating pain

II. Pain Assessment (Total 22 items, 220 points)

(I) Symptoms and Signs

1. How severe was your most intense facial pain?

(No pain) 0 1 2 3 4 5 6 7 8 9 10 (Unbearable pain)

2. How would you rate your mildest facial pain recently?

(No pain) 0 1 2 3 4 5 6 7 8 9 10 (Unbearable pain)

3. How would you rate your average facial pain recently?

(No pain) 0 1 2 3 4 5 6 7 8 9 10 (Unbearable pain)

4. Does your pain worsen with weather/environmental changes?

0- No (0 pt) 1- Yes (10 pt)

5. Does your pain worsen with fatigue/emotional stress?

0- No (0 pt) 1- Yes (10 pt)

6. Does voluntary facial movement (speaking, chewing, expressions) trigger your pain?

0-Never (0 pt)

1-Occasionally mild (2.5 pt)

2-Moderately in 50% cases (5 pt)

3-Severely in most cases (7.5 pt)

4-Very severe in nearly all attacks (10 pt)

7. Does light touch/stretching of facial areas (gums, lips, ala nasi, cheeks, periorbital regions) trigger pain?

15. Does facial pain cause difficulty concentrating (e.g., when using phones/watching TV)?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

16. Do you feel anxious, tense, or restless due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

17. Do you feel depressed, discouraged, or helpless due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

18. Does facial pain affect your sleep quality?

0-No effect (0 pt)

0-Never (0 pt)

1-Occasionally mild (2.5 pt)

2-Moderately in 50% cases (5 pt)

3-Severely in most cases (7.5 pt)

4-Very severe in nearly all attacks (10 pt)

8. (Physician's examination) When comparing light touch on affected vs. unaffected facial skin, do you experience reduced sensation in the pain area? If yes, select the degree.

0 1 2 3 4 5 6 7 8 9 10

(II) Accompanying symptoms

9. Is facial pain accompanied by facial/masticatory muscle spasms/twitching?

0- No (0 pt) 1- Yes (10 pt)

10. Is facial pain accompanied by conjunctival congestion and/or tearing?

0- No (0 pt) 1- Yes (10 pt)

11. Is facial pain accompanied by salivation?

0- No (0 pt) 1- Yes (10 pt)

12. Have you ever felt unable to cope, had thoughts of dying, or self-harm due to facial pain?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

13. Does facial pain make you feel worthless, like a failure, or that you've let down yourself/family?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

14. Do you feel fatigued or lacking energy due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

1-Occasional disturbance (2.5 pt)

2-< 6 hrs sleep/night (5 pt)

3-< 4 hrs sleep/night (7.5 pt)

4-< 2 hrs sleep/night (10 pt)

19. Do you wake up from sleep due to facial pain?

0-Never (0 pt)

1-Rarely (2.5 pt)

2-≥1 time/month (5 pt)

3-≥1 time/week (7.5 pt)

4-Almost nightly (10 pt)

20. Does pain affect daily activities (washing, eating, speaking, smiling)?

0- No impact (0 pt)

1- Minimal impact (manageable without intervention) (2.5 pt)

2- Moderate impact (disruptive but daily activities sustainable) (5 pt)

3- Severe impact (requires cessation of activities) (7.5 pt)

4- Complete disability (unable to perform any routine tasks) (10 pt)

21. Do negative emotions from pain (depression, helplessness, anxiety) affect your work/life (job, socializing, chores)?

0- No impact (0 pt)

1- Minimal impact (manageable without intervention) (2.5 pt)

2- Moderate impact (disruptive but daily activities sustainable) (5 pt)

3- Severe impact (requires cessation of activities) (7.5 pt)

4- Complete disability (unable to perform any routine tasks) (10 pt)

22. Does pain affect your social interactions with family/friends/colleagues?

0- No impairment (0 pt)

1- Minimal impact (noticeable but ignorable) (2.5 pt)

2- Moderate impact (disruptive yet sustainable with effort) (5 pt)

3- Severe impact (requires social withdrawal) (7.5 pt)

4- Complete social disability (functionally isolated) (10 pt)

To ensure precise evaluation and effective treatment of your condition, please provide truthful and accurate responses to the following questions. Mark "✓" next to the option that best corresponds to your actual situation.

III. Post-treatment Evaluation (Total 5 items, 50 points)

1. Adverse drug reactions (ADRs) from first-line therapy? (Cumulative scoring)

0- No ADRs or resolved spontaneously (0 pt)

1- CNS reactions (dizziness, headache, ataxia, somnolence, fatigue, diplopia) (3.33 pt)

2- GI disturbances (nausea, vomiting) (3.33 pt)

3- Cutaneous hypersensitivity (3.33 pt)

2. Surgical complications? (Cumulative scoring)

IV. Overall Satisfaction Assessment (Total 5 items, 50 points)

1. Overall treatment satisfaction?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

2. Pain intensity improvement?

0- Very satisfied (0 pt)

0- No complications or transient (0 pt)
1- Hypoesthesia (2 pt)
2- Non-specific complaints (2 pt)
3- Dysesthesia (2 pt)
4- Keratitis (2 pt)
5- Anesthesia dolorosa (2 pt)

3. Impact of ADRs/complications on daily living?
0- No impact (0 pt)
1- Minimal impact (2.5 pt)
2- Mild impact (5 pt)
3- Severe impact (7.5 pt)
4- Complete disability (10 pt)

4. Does sleep disturbance occur due to treatment-related adverse effects or complications?
0-No effect (0 pt)
1-Occasional disturbance (2.5 pt)
2-< 6 hrs sleep/night (5 pt)
3-< 4 hrs sleep/night (7.5 pt)
4-< 2 hrs sleep/night (10 pt)

5. Has your emotional state been altered due to treatment-related adverse effects or complications?
0- None (0 pt)
1- Sometimes (2.5 pt)
2- Half the time (5 pt)
3- Mostly (7.5 pt)
4- Nearly daily (10 pt)

Signature: _____ Date: _____

1- Somewhat satisfied (2.5 pt)
2- Neutral (5 pt)
3- Somewhat dissatisfied (7.5 pt)
4- Very dissatisfied (10 pt)

3. Sleep improvement?
0- Very satisfied (0 pt)
1- Somewhat satisfied (2.5 pt)
2- Neutral (5 pt)
3- Somewhat dissatisfied (7.5 pt)
4- Very dissatisfied (10 pt)

4. Activities of daily living (ADL) improvement?
0- Very satisfied (0 pt)
1- Somewhat satisfied (2.5 pt)
2- Neutral (5 pt)
3- Somewhat dissatisfied (7.5 pt)
4- Very dissatisfied (10 pt)

5. Emotional status improvement?
0- Very satisfied (0 pt)
1- Somewhat satisfied (2.5 pt)
2- Neutral (5 pt)
3- Somewhat dissatisfied (7.5 pt)
4- Very dissatisfied (10 pt)

Table A2. *Chinese Version of Primary Trigeminal Neuralgia Therapeutic Efficacy Assessment Scale (Preliminary Edition).*

Name: Gender: Age: Hospital ID: Contact:

To accurately evaluate and effectively treat your condition, please provide truthful responses to the following questions. Mark "√" in the box that best reflects your actual situation.

I. Patient Demographic Data

1. Affected Side:
□Left □Right

2. Branch Involvement:
□V1 □V2 □V3 □V1+V2
□V2+V3 □V1+V2+V3

3. Pain Characteristics:
□Electric shock-like □Tearing-like □Stabbing-like
□Needle-prick-like □Burning-like

4. Attack Frequency:
□< 10 times/day □10-50 times/day □≥ 50 times/day

5. Attack Duration:
□< 1 min □1-10 min □≥ 10 min

6. Disease Course:
□<6 months □ ≥6 months, <1 year

8. Current Analgesic Use (Check pain relief rate and specify medications):
(No relief) 0 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% (Complete relief)
(1) First-line:
□Carbamazepine □Oxcarbazepine
(2) Second-line:
□ Pregabalin □ Gabapentin
□ Baclofen □ Lamotrigine
(3) Others:
□ Ibuprofen □ Tramadol □ Diclofenac sodium
□ Paracetamol/Dihydrocodeine □ Duloxetine
□ Venlafaxine □ Oxycodone □ Other (_____)

9. Prior Non-pharmacological Interventions (Check pain relief rate and specify procedure):
(No relief) 0 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% (Complete relief)

□≥1 year, <3 years □ ≥3 years, <5 years

□≥5 years, <10 years □ ≥10 years, <20 years

□≥20 years

7. Remission Period:

□< 1 week □ ≥1 week, <1 month

□≥1 months, <6 months □ ≥6 months, <1 year

□ 1-5 years □ 5-10 years

□ > 10 years

□ Percutaneous Radiofrequency Thermocoagulation of Trigeminal Ganglion

□ Meckel's Cave Balloon Compression

□ Meckel's Cave Glycerol Rhizotomy

□ Nerve Block Therapy

□ Microvascular Decompression

□ Gamma Knife Radiosurgery

□ Other (_____)

To ensure accurate assessment and effective treatment of your condition, please answer the following questions truthfully based on your experiences over the past week. Mark "√" next to the option that best reflects your actual situation. 0 = No pain; 1-3 = Mild pain; 4-6 = Moderate pain; 7-9 = Severe pain; 10 = Excruciating pain

II. Pain Assessment (Total 17 items, 170 points)

(I). Pain intensity

1. How severe was your most intense facial pain?

(No pain) 0 1 2 3 4 5 6 7 8 9 10 (Unbearable pain)

2. How would you rate your average facial pain recently?

(No pain) 0 1 2 3 4 5 6 7 8 9 10 (Unbearable pain)

(II). Accompanying symptoms

3. (Physician's examination) When comparing light touch on affected vs. unaffected facial skin, do you experience reduced sensation in the pain area? If yes, select the degree.

0 1 2 3 4 5 6 7 8 9 10

4. Is facial pain accompanied by facial/masticatory muscle spasms/twitching?

0- No (0 pt) 1- Yes (10 pt)

5. Is facial pain accompanied by conjunctival congestion and/or tearing?

0- No (0 pt) 1- Yes (10 pt)

6. Is facial pain accompanied by salivation?

0- No (0 pt) 1- Yes (10 pt)

(III). Mood and Sleep

7. Do you feel fatigued or lacking energy due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

8. Does facial pain cause difficulty concentrating (e.g., when using phones/watching TV)?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

9. Do you feel anxious, tense, or restless due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

11. Does facial pain affect your sleep quality?

0-No effect (0 pt)

1-Occasional disturbance (2.5 pt)

2-< 6 hrs sleep/night (5 pt)

3-< 4 hrs sleep/night (7.5 pt)

4-< 2 hrs sleep/night (10 pt)

12. Do you wake up from sleep due to facial pain?

0-Never (0 pt)

1-Rarely (2.5 pt)

2-≥1 time/month (5 pt)

3-≥1 time/week (7.5 pt)

4-Almost nightly (10 pt)

(IV). Quality of Life

13. Does voluntary facial movement (speaking, chewing, expressions) trigger your pain?

0-Never (0 pt)

1-Occasionally mild (2.5 pt)

2-Moderately in 50% cases (5 pt)

3-Severely in most cases (7.5 pt)

4-Very severe in nearly all attacks (10 pt)

14. Does light touch/stretching of facial areas (gums, lips, ala nasi, cheeks, periorbital regions) trigger pain?

0-Never (0 pt)

1-Occasionally mild (2.5 pt)

2-Moderately in 50% cases (5 pt)

3-Severely in most cases (7.5 pt)

4-Very severe in nearly all attacks (10 pt)

15. Does pain affect daily activities (washing, eating, speaking, smiling)?

0 - No impact (0 pt)

1- Minimal impact (manageable without intervention) (2.5 pt)

2- Moderate impact (disruptive but daily activities sustainable) (5 pt)

3- Severe impact (requires cessation of activities) (7.5 pt)

4- Complete disability (unable to perform any routine tasks) (10 pt)

16. Do negative emotions from pain (depression, helplessness, anxiety) affect your work/life (job, socializing, chores)?

0- No impact (0 pt)

1- Minimal impact (manageable without intervention) (2.5 pt)

2- Moderate impact (disruptive but daily activities sustainable) (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

10. Do you feel depressed, discouraged, or helpless due to facial pain recently?

0-Never (0 pt)

1-Sometimes (2.5 pt)

2-Half the time (5 pt)

3-Mostly (7.5 pt)

4-Nearly daily (10 pt)

3- Severe impact (requires cessation of activities) (7.5 pt)

4- Complete disability (unable to perform any routine tasks) (10 pt)

17. Does pain affect your social interactions with family/friends/colleagues?

0- No impairment (0 pt)

1- Minimal impact (noticeable but ignorable) (2.5 pt)

2- Moderate impact (disruptive yet sustainable with effort) (5 pt)

3- Severe impact (requires social withdrawal) (7.5 pt)

4- Complete social disability (functionally isolated) (10 pt)

To ensure precise evaluation and effective treatment of your condition, please provide truthful and accurate responses to the following questions. Mark "✓" next to the option that best corresponds to your actual situation.

III. Post-treatment Evaluation (Total 5 items, 50 points)

1. Adverse drug reactions (ADRs) from first-line therapy? (Cumulative scoring)

0- No ADRs or resolved spontaneously (0 pt)

1- CNS reactions (dizziness, headache, ataxia, somnolence, fatigue, diplopia) (3.33 pt)

2- GI disturbances (nausea, vomiting) (3.33 pt)

3- Cutaneous hypersensitivity (3.33 pt)

2. Surgical complications? (Cumulative scoring)

0- No complications or transient (0 pt)

1- Hypoesthesia (2 pt)

2- Non-specific complaints (2 pt)

3- Dysesthesia (2 pt)

4- Keratitis (2 pt)

5- Anesthesia dolorosa (2 pt)

3. Impact of ADRs/complications on daily living?

0- No impact (0 pt)

1- Minimal impact (2.5 pt)

2- Mild impact (5 pt)

3- Severe impact (7.5 pt)

4- Complete disability (10 pt)

4. Does sleep disturbance occur due to treatment-related adverse effects or complications?

0-No effect (0 pt)

1-Occasional disturbance (2.5 pt)

2-< 6 hrs sleep/night (5 pt)

3-< 4 hrs sleep/night (7.5 pt)

4-< 2 hrs sleep/night (10 pt)

5. Has your emotional state been altered due to treatment-related adverse effects or complications?

0- None (0 pt)

1- Sometimes (2.5 pt)

2- Half the time (5 pt)

3- Mostly (7.5 pt)

4- Nearly daily (10 pt)

IV. Overall Satisfaction Assessment

(Total 5 items, 50 points)

1. Overall treatment satisfaction?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

2. Pain intensity improvement?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

3. Sleep improvement?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

4. Activities of daily living (ADL) improvement?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

5. Emotional status improvement?

0- Very satisfied (0 pt)

1- Somewhat satisfied (2.5 pt)

2- Neutral (5 pt)

3- Somewhat dissatisfied (7.5 pt)

4- Very dissatisfied (10 pt)

Signature: _____ Date: _____

Table A3. *Patient Demographic and Clinical Characteristics.*

	Frequency	Percentage (%)
Gender		
Male	67	45.6%
Female	80	54.4%
Age		
≦50	13	8.8%
51-65	64	43.5%
66-80	65	44.2%
>80	5	3.4%
Side		
Left	52	35.4%
Right	95	64.6%
Course		
<6 months	22	15.0%
≥6 months, <1 year	15	10.2%
≥1 year, <3 years	30	20.4%
≥3 years, <5 years	27	18.4%
≥5 years, <10 years	27	18.4%
≥10 years, <20 years	21	14.3%
≥20 years	5	3.4%
Branch Involvement		
V_1	2	1.4%
V_2	48	32.7%
V_3	42	28.6%
V_1+V_2	14	9.5%
V_2+V_3	33	22.4%
$V_1+V_2+V_3$	8	5.4%
Attack Frequency		
<10 times/day	128	87.1%
10 ~ 49 times/day	18	12.2%
≥50 times/day	1	0.7%
Attack Duration		
<1 minute	99	67.3%
1 ~ 10 minutes	25	17.0%
≥10 minutes	23	15.6%
Pain Characteristics		
Electric-shock-like	122	83.0%

	Frequency	Percentage (%)
Knife-stabbing-like	35	23.8%
Tearing-like	14	9.5%
Pricking-like	57	38.8%
Burning-like	10	6.8%
Associated Symptoms		
Hemifacial spasm/twitching	12	8.2%
Conjunctival injection/lacrimation	20	13.6%
Salivation	21	14.3%
Prior Treatments		
First-line medications	116	78.9%
Other medications	16	10.9%
Surgical interventions	45	30.6%
Symptom Relief after First-line Medications		
Major relief	11	7.5%
Moderate relief	39	26.5%
Mild relief	66	44.9
No relief / Not used	31	21.1%
Symptom Relief after Other Medications		
Major relief	1	0.7%
Moderate relief	1	0.7%
Mild relief	14	9.5%
No relief / Not used	131	89.1%
Symptom Relief after Surgical Interventions		
Complete relief	11	7.5%
Major relief	17	11.6%
Moderate relief	8	5.4%
Mild relief	9	6.1%
No relief / Not used	102	69.4%

Table A4. *Follow-up Outcomes of 147 Patients with Primary Trigeminal Neuralgia.*

Treatment Modality	n	Pain-free with medication discontinued [n, (%)]	Sustained analgesia requires decreased dose [n, (%)]	Sustained analgesia maintained at current dose [n, (%)]	Sustained analgesia requires increased dose [n, (%)]
Meckel's balloon compression	44	43 (97.7)	1 (2.3)	0	0
Percutaneous trigeminal ganglion radiofrequency thermocoagulation	95	80 (84.2)	10 (10.5)	3 (3.2)	2 (2.1)
Maxillary/infraorbital nerve radiofrequency thermocoagulation	4	4 (100.0)	0	0	0

Treatment Modality	n	Pain-free with medication discontinued [n, (%)]	Sustained analgesia requires decreased dose [n, (%)]	Sustained analgesia maintained at current dose [n, (%)]	Sustained analgesia requires increased dose [n, (%)]
Pharmacological treatment	4	0	2 (50.0)	1 (25.0)	1 (25.0)

Table A5. *Item Analysis of the Preliminary Chinese PTN Assessment Scale (n=147).*

Item-Number	Item Content	Critical Ratio (*t*)	Item-Total Correlation (*r*)	SD
Q1	How severe was your most intense facial pain? recently?	5.219[a]	0.492[a]	1.520
Q2	How would you rate your mildest facial pain recently?	0.100	0.181[a]	3.266
Q3	How would you rate your average facial pain recently?	5.424[a]	0.513[a]	1.585
Q4	Does your pain worsen with weather/environmental changes?	6.676[a]	0.414[a]	5.016
Q5	Does your pain worsen with fatigue/emotional stress?	2.802[a]	0.371[a]	2.945
Q6	Does voluntary facial movement (speaking, chewing, expressions) trigger your pain?	7.123[a]	0.547[a]	1.856
Q7	Does light touch/stretching of facial areas (gums, lips, ala nasi, cheeks, periorbital regions) trigger pain?	6.334[a]	0.516[a]	2.347
Q8	(Physician's examination) When comparing light touch on affected vs. unaffected facial skin, do you experience reduced sensation in the pain area? If yes, select the degree	0.583	0.087	1.408
Q9	Do you feel anxious, tense, or restless due to facial pain recently?	7.265[a]	0.647[a]	2.268
Q10	Do you feel depressed, discouraged, or helpless due to facial pain recently?	10.642[a]	0.713[a]	2.534
Q11	Do you feel fatigued or lacking energy due to facial pain recently?	10.266[a]	0.729[a]	2.324
Q12	Does facial pain cause difficulty concentrating (e.g., when using phones/watching TV)?	8.081[a]	0.705[a]	2.409
Q13	Does facial pain make you feel worthless, like a failure, or that you've let down yourself/family?	6.407[a]	0.639[a]	1.348
Q14	Have you ever felt unable to cope, had thoughts of dying, or self-harm due to facial pain?	4.122[a]	0.497[a]	1.159
Q15	Does facial pain affect your sleep quality?	9.331[a]	0.695[a]	2.137
Q16	Do you wake up from sleep due to facial pain?	9.287[a]	0.724[a]	3.184
Q17	Does pain affect daily activities (washing, eating, speaking, smiling)?	9.188[a]	0.558[a]	2.390
Q18	Do negative emotions from pain (depression, helplessness, anxiety) affect your work/life (job, socializing, chores)?	7.879[a]	0.660[a]	2.048
Q19	Does pain affect your social interactions with family/friends/colleagues?	8.886[a]	0.604[a]	1.764
Q20	Is facial pain accompanied by facial/masticatory muscle spasms/twitching?	2.267[a]	0.203[a]	1.502
Q21	Is facial pain accompanied by conjunctival congestion and/or tearing?	3.665[a]	0.285[a]	1.847
Q22	Is facial pain accompanied by salivation?	2.855[a]	0.282[a]	1.650
Q23	What is your recent pain attack frequency?	1.050	0.144	2.511
Q24	What is your recent pain attack duration?	1.359	0.133	3.413

Note: [a]$P<0.05$

Table A6. Factor Analysis Total Variance Explained by the Preliminary Chinese PTN Assessment Scale.

Factor	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	Variance (%)	Cumulative (%)	Total	Variance (%)	Cumulative (%)	Total	Variance (%)	Cumulative (%)
1	6.388	42.588	42.588	6.388	42.588	42.588	3.877	25.849	25.849
2	1.825	12.167	54.755	1.825	12.167	54.755	3.701	24.674	50.524
3	1.369	9.125	63.880	1.369	9.125	63.880	2.003	13.356	63.880

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