



A research on quality of life score (QOLS) of patients with trigeminal neuralgia (TN)

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ABSTRACT

Background: To evaluate the clinic effect of treatment of trigeminal neuralgia (TN).

Methods: The current study aims to develop a multiple-scale characteristics quality of life (QOL) for patients with TN. After interview, the individual questionnaire was acquired, indicating the QOL has a good responsiveness and surveying effects of the dynamic state of health on TN patients.

Conclusion: It is feasible to form multiple-scale characteristics QOL for patients with TN.

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Introduction

Trigeminal neuralgia (TN) is a kind of paroxysmal and intense pain incurred in n. trigeminus dominated regions. Long-term intense pain often results in somnolence, impacts on daily activities [1], negative emotions, such as depression and anxiety as well as sleep quality deteriorating to patients, which may increase the frequency and degree of pain in most cases, and greatly affect the patient's quality of life. In severe cases, it may lead to body systems dysfunction and low immunity which further induce various kinds of complications or even painful disability as well as threats to the patients' life [2–4]. Researches have revealed that after pain relieving, generally patients still have psychological burden and feel dissatisfied to therapeutic effects which affect postoperative QOL of patients [5]. Correspondingly, clinical curative effects evaluation is no longer limited to evaluation of the disease itself, nor only focusing on pain relief rate, efficiency, security, but has transformed to comprehensive and multi-dimensional evaluation on patients, to a joint evaluation mode combining with effectiveness of treatment means, satisfaction degree of patients, psychological mental state as well as social functions. Consequently, the concept of QOL scale has been introduced.

TN is a chronic pain disease mainly presenting in subjective feeling and experience without specificity laboratory index reflect-

ing self-perception of patients. Therefore QOL evaluation is to be performed by applying a series of scales such as WHOQOL-BREF, SF-36, Sickness Impact Profile (SIP) etc. However, there is no unified TN QOLS [6] applied in clinic. For various diseases, the applied QOL scales include different dimensions and aspects. Thus, developing a TN QOLS with clinical research staff, patients, sociologists and professional psychology participated in has important clinical significance.

Consequently, the topic focuses on developing a specific module specific for patients with TN and establishing scale items combining with the general module (QLICD-GM) [7] of QOL scale system of chronic diseases. In addition, establish a specific QOLS applicable to patients with TN through items screening and optimization, as well as reliability and validity evaluation which provides reference for clinical curative effects evaluation of TN.

Methods

Research objects

Source of research objects: selected 298 patients with TN who accepted treatment in Stomatological Hospital of Chengdu Military General Hospital from January 2014 to March 2015.

Inclusion criteria: (1) definitely diagnosed as primary TN; (2) age ≤80-year-old; (3) with good communicative competence and willing to accept scale evaluation; (4) being able to understand contents of scale; (5) no major life events detected recently.

Exclusion criteria: (1) with poor compliance and communicative competence; (3) with serious physical diseases which affect daily

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life, and with hospital medical history within half a year; (4) long-term drug dependence and alcohol dependence history.

Research contents and approaches

Set up research working team: the research adopted structured decision-making method [8], namely to complete the scale by inter-working of topic group and core working group. The core team is composed of the researcher, tutor professor Li Chenjun to be responsible for subject design and concrete implementation; the topic group is composed of QOL research specialists, experts on oral and maxillofacial surgery, statistical researchers and experts in psychology, mainly in charge of establishing scale theoretical framework and items screening; interviews and clinical investigation were conducted by the researcher.

Theoretical framework of scale establishing:

- (1) Theoretical idea and basis.
- (2) Establishing of scale dimensions: according to the concept of QOL and its constitutions proposed by WHO (1993), referring to understanding by Bufingert [9] and Bonomit [10] to HRQOL (Health Related Quality of Life) as well as the concept of modern life quality, generally QOLS specific to chronic pain includes at least four regions (or so called dimensions), namely physical function (or physiology) fields, psychology (or emotion) fields, society (including family relationships) and symptoms.

Establishing of scale items pool

- (1) Review document literature.
- (2) Refer to previous research materials.
- (3) Patients interview.
- (4) Sorted up the obtained items and formed a scale items pool combining with specific module of TN as well as general module amount of QLICD.

Formation of preliminary scale

- (1) Team discussion.
- (2) For aforementioned confirmed items, formed a preliminary survey version scale by adopting 5 Grade Likert-typescale sequence [11].
- (3) Measuring method: issued questionnaires.
- (4) Estimation of sample size.
- (5) Scoring methods for scale: adopted five equidistant grading methods.

Items screening and optimization

Adopted a variety of statistical methods for items screening and adopted SPSS17.0 for statistical processing and analysis of data.

Scale evaluation

- (1) Validity evaluation.

(1) Content validity (2) Construct validity [12] (3) Criteria validity [13].

(2) Reliability evaluation [14,15].

(3) Analysis of responsibility to change.

(4) Feasibility analysis.

Table 1

Correlation coefficient score of each item and dimensions belonging to.

Item	Dimension A	Dimension B	Dimension C	Dimension D
A1	0.671	−0.067	−0.163	−0.010
A2	0.758	0.046	0.459	−0.059
A3	0.673	−0.004	0.506	0.228
A4	0.697	0.563	0.444	0.481
A5	0.827	0.295	0.195	0.239
A6	0.725	0.525	0.080	−0.070
B1	0.329	0.548	0.091	0.126
B2	0.542	0.555	0.254	0.097
B4	0.210	0.704	0.396	0.223
B5	0.301	0.722	0.257	0.502
B6	0.365	0.662	0.237	0.454
B7	0.171	0.739	−0.212	0.079
B8	0.184	0.825	0.485	0.188
B9	0.128	0.826	0.435	0.214
B10	0.126	0.878	0.413	0.312
C1	0.228	0.166	0.810	0.368
C3	0.158	0.269	0.798	0.083
C4	0.087	0.349	0.697	0.268
C5	0.539	−0.018	0.683	−0.148
C6	0.210	0.338	0.756	0.095
D1	−0.202	0.151	0.051	0.688
D2	0.448	0.532	0.469	0.674
D3	0.027	0.521	−0.009	0.797
D4	0.027	0.521	−0.009	0.797
D7	0.359	0.055	0.277	0.523

Table 2

Rank correlation coefficient of each dimension and total score (Spearman).

QOL score	Dimension A	Dimension B	Dimension C	Dimension D
Correlation coefficient r_s	0.672	0.875	0.669	0.701
P	0.001	0.000	0.001	0.005

Results

Form TN QOLS official version

After repeated discussion by focus group and nominal group, formed a preliminary survey version scale by adopting 5 Grade Likert-typescale sequence. The amounts of items achieving standards of six items screening respectively are: rank sum test, responsibility to change analysis, correlation coefficient 1, correlation coefficient 2, factor analysis, Cronbach's α coefficient. After sorting up and modification of certain items by research group, TN QOLS official version has been established as shown in Annex 1.

Scale evaluation

Validity

Construct validity. (1) Correlation analysis reveals that: the correlation between score of each item and dimensions belonging to is the highest as well as low correlation with other dimensions (as shown in Table 1). Except for B1, B2, D7, the other correlation coefficient is greater than 0.6; the correlation coefficient of dimension and dimensions of scale is statistically significant ($p < 0.01$) (as shown in Table 2).

(2) Factor analysis results reveal that: four common factors were abstracted after analysis on 30 items specified in TN QOLS with an accumulated variance contribution rate of 65.817%. The result is consistent with theoretical conception by adopting maximum variance rotation. Four common factors belong to four dimensions respectively. The included factors of each dimension is consistent with theoretical conception. From Table 3 it can be seen that: factor 1 is mainly reflects B8–B10 in terms of physical dimension, namely impact on appetite and sleep (appetite, energy and sleep);

Table 3
Factor analysis of questionnaire construct validity.

Item	Factor 1	Factor 2	Factor3	Factor 4
A1	−0.149	0.531	0.001	−0.101
A2	0.009	0.880	−0.203	0.083
A3	−0.136	0.841	−0.109	0.172
A4	0.428	0.650	0.367	−0.060
A5	0.147	0.813	0.201	−0.095
A6	0.425	0.566	0.007	−0.107
B1	0.099	0.020	0.352	0.663
B2	0.127	0.271	0.265	0.643
B4	0.286	0.184	0.069	0.639
B5	0.016	0.161	0.615	0.588
B6	−0.013	0.185	0.601	0.648
B7	0.224	0.215	0.094	0.830
B8	0.916	0.007	−0.066	0.253
B9	0.932	−0.051	−0.041	0.175
B10	0.920	−0.053	0.122	0.002
C1	0.483	0.143	−0.092	0.224
C3	0.704	−0.037	−0.079	0.415
C4	0.471	0.137	0.142	0.219
C5	0.557	−0.121	−0.145	0.367
C6	0.460	0.323	−0.458	0.143
D1	0.490	−0.133	0.677	−0.033
D2	0.382	0.322	0.573	−0.073
D3	0.228	0.012	0.918	0.037
D4	0.228	0.012	0.918	0.037
D7	−0.073	0.221	0.610	0.123

factor 2 mainly reflects A1–A6, namely occurrence of the illness; factor 4 mainly affect physical dimensions B4–B7, namely side effects on long-term applying analgesic drugs (impact on dizziness, mental clarity, focus, memory); factor 3 reflects on D1–D4, D7, namely impact of pain on society activities and interests on life. In addition, C1, C3–C6 load on factor 1 is higher, shows that psychological factors is closely related to patient's sleep and energy, can be interpreted as caused by poor sleep, overall structure has good validity.

(3) Criterion associated reliability: the correlation coefficient between TNQOLS total score and WHOQOL-BREF is 0.654. The correlation coefficient of each dimension and TNQOLS is 0.527, 0.668, 0.702, 0.711 respectively; the correlation coefficient of SF-36 is −0.606. The correlation coefficient between incidence, physical symptoms, psychological and social functions and SF-36 total score are −0.507, −0.674, −0.743, −0.707 respectively. (As shown in Table 4).

Table 4
Correlation coefficient between each dimension of PHNQOLS, total score and SF-36, WHOQOL-BREF.

	Incidence	Physical symptoms	Psychological functions	Social functions	QOLS total score
WHOQOL-BREF	0.5271	0.6683	0.7023	0.7114	0.6547
SF-36	−0.5078	−0.6745	−0.7431	−0.7076	−0.6063

Table 5
Cronbach's α coefficient and split-half reliability of TNQOLS scale.

	Incidence	Physical symptoms	Psychological functions	Social functions	TNQOLS
Cronbach's α	0.8362	0.8116	0.7817	0.7714	0.8663
Coefficient split-half reliability	0.7719	0.7524	0.7382	0.8895	0.7542

Table 6
Score comparison before and after radiofrequency thermo coagulation (average value $\pm$ standard deviation).

	Incidence	Physical symptoms	Psychological functions	Social functions	TNQOLS (total score)
Initial score	25.36 $\pm$ 3.49	34.78 $\pm$ 4.12	18.28 $\pm$ 5.08	19.34 $\pm$ 2.79	97.76 $\pm$ 15.48
Score after 4 weeks	10.96 $\pm$ 2.57	22.08 $\pm$ 3.36	11.76 $\pm$ 3.02	12.82 $\pm$ 4.33	57.62 $\pm$ 13.28
t Value	7.112	7.328	7.236	7.682	7.466
P value	0.000	0.000	0.000	0.000	0.000

Reliability

(1) Cronbach's α coefficient: the Cronbach's α of TNQOLS total score is 0.8663. The Cronbach's α coefficient of TN incidence, physical symptoms, psychological and social functions is 0.8362, 0.8116, 0.7817 and 0.7714 respectively. All values are greater than 0.7 (as shown in Table 5).

(2) Split-half reliability: the split-half reliability of TNQOLS total score is 0.7542. The split-half reliability of TN incidence, physical symptoms, psychological and social functions is 0.7719, 0.7524, 0.7382 and 0.8895 respectively (as shown in Table 5).

Responsibility to change: the difference on incidence, physical symptoms, psychological and social functions of patients after radiofrequency thermo coagulation are statistically significant ($P < 0.01$) (as shown in Table 6).

Feasibility analysis

(1) Reacceptance: a total of 140 scales issued at initial evaluation, and all of them were returned with a recovery rate of 100%; generally, the recovery rate of scales shall be up to 85% of investigation objects. Thus, the recovery rate of the scale is good.

(2) Completion rate of the scale: completion rate of the scale refers to the proportion of patients accounting for all patients. At evaluating of responsibility to change of the scale, selected 40 research objects at random and applied radiofrequency thermo coagulation at initial evaluation. Performed telephone follow-up four weeks later and conducted evaluation once more. 40 patients completed the scale for two times with a completion rate of 100%. Thus, it can be considered that the completion rate of the scale is excellent.

(3) Completion time of the scale: generally, it is easy to acceptable if the completion time of the scale is within 20 min. The Min. duration of the initial evaluation is 3 min, and 7 min at Max. with an average duration of 3.55 min; Min. duration of the second evaluation is 4 min, and 8 min at Max. with an average duration of 4.55 min. Thus, it can be seen that the scale is simple and easy to understand. The time required to finish the scale is ideal.

Discussion

Preparation strategy of the scale

Starting from clinical data and self-evaluation of patients with TN, combining with general module of chronic diseases patients

QOL scale, strictly referring to specific decryption of scale development and evaluation and following principles and requirements of scale, the research established a research group, set up scientific theoretical framework, determined that TN scale shall include four dimensions, namely disease symptoms, physical symptoms, psychological and emotional and society functions, and preliminarily determined an items pool including 37 items which have laid a work foundation for further scale items screening.

Items screening at scale

Items screening is a key issue during preparation of QOLS. During the process, we shall be following high sensibility, strong independency, good determinacy and strong representativeness [16]. Consequently, the research adopted joint screening through various approaches for alternative items. Correlation coefficient, factor analysis and Cronbach's α are essential indicators of scale validity and reliability. Certain assessment methods of QOLS of the research are adopted on items screening which ensure the quality of items selected from the aspects of internal consistency as well as stability. The research followed the aforementioned six items screening and finally obtained seven items satisfying items. Eventually, a test version of TN QOLS has been obtained including four dimensions, namely TN symptom (six items), physical symptoms (nine items), psychological and emotional (five items) and social function (five items), 25 items in total.

Scale evaluation

Validity

According to WHO QOLS establishing principle, widely referring to a variety of QOL universal scale and special scales, combining with previous research data and patients interview data collected by the topic group, the items pool established by the research group has authenticity as well as specificity; the scale conducted screening and optimization strictly following routinization and obtained final recognizing from oral and maxillofacial surgery expert, psychology, QOL experts, personnel of medical statistics. Therefore, it is considered that the scale has good content validity.

Construct validity refers to matching degree of scale construction conceived and measurement results. Four common factors were abstracted after analysis on 30 items specified in TN QOLS with an accumulated variance contribution rate of 65.817%. The result is consistent with theoretical conception by adopting maximum variance rotation. The correlation coefficient between all dimensions and scale total scoring is greater than 0.65. The correlation between each item and dimension belonging to is good. The correlation coefficient presents significant correlation which indicates that TNQOLS has good construct validity. Factor analysis reveals that: there is great correlation between B4 (dizziness), B5 (clarity of thinking), B6 (attention), B7 (memory) and factor 4. There is correlation between B8 (appetite), B9 (energy), B10 (sleep) and factor 1) which can be interpreted that the physical symptoms of TN is mainly presented as sleep quality and appetite resulted from side effects of long-term drug taking which is closely bound up negative emotions. Long-term dropping of sleep quality and body's tolerance will cause depression, anxiety of patients, which will aggravate frequency and extent of the pain in adverse. Therefore, patients have to increase the dosage and side effects of patients.

Correlation analysis reveals that: item B1 (chest distress), B2 (tinnitus), D7 (economic problems) and lower dimension correlation. The possible reason is that: intensity of pain disturbs patient's memory on symptom frequency and lead to unclear description.

Set WHOQOL-BREF, SF-36 scale as the standard of QOL measurement. Calculated correlation coefficient of each dimension of TN QOLS and the two scales. TNQOLS presents positive correlation

with WHOQOL, while presents negative correlation with SF-36. Since it is different from SF-36, the higher score of TNQOLS, the worse QOL will be. Thus, the two scores present negative correlation. According to the analysis results, the absolute value of correlation coefficient is 0.5–0.7. The correlation is not very high which indicates that TNQOLS has certain correlation with the other two universal scale and special scales, however it is not completely relevant. It reveals the specificity and independence of TNQOLS, as well as reflects the necessity of scale.

Reliability

Reliability is mainly applied to evaluate internal consistency and stability of the scale. The research mainly evaluated the reliability of the scale from Cronbach's α and split-half reliability.

The Cronbach's α of TNQOLS is 0.8663. The Cronbach's α coefficient of TN disease syndromes, physical symptoms, psychological functions and social functions is 0.8362, 0.8116, 0.7817 and 0.7714 respectively. The split-half reliability of TNQOLS is 0.7542. The split-half reliability of four dimensions are 0.7719, 0.7524, 0.7382 respectively.

Responsibility to change

Responsibility to change is used to investigate the scale whether the detection is significant, with slight changing capability along with time variation. By paired t test analysis scale before and after the overall responsibility to change, the results revealed that t value is 7.446, $p < 0.01$. In addition, the score of each dimension and total score is less than that before treatment which indicate that the QOL of patients has been improved after treatment. The overall responsibility to change of the scale is excellent.

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Competing interests

None declared.

Ethical approval

Not required.

Annex 1

TN QOLS

Occurrence of TN (Dimension A)

1. What is your pain intensity?
Painless Mild pain Moderate pain Severe pain Extreme pain
2. Will your TN induced or aggravated by daily wash gargle?
Never Occasionally Sometimes Frequently Always
3. Will your TN induced or aggravated by facial muscle activity?
(Such as talking, feeding, smiling)
Never Occasionally Sometimes Frequently Always
4. Will your TN induced or aggravated by touching local skin or mucous membrane?
Never Occasionally Sometimes Frequently Always
5. Do you take any drug to alleviate the pain?
Never Occasionally Sometimes Frequently Dependent on drug
6. Will the facial muscles twitch violently when the pain attacks?
Never Occasionally Sometimes Frequently Always

Physical symptoms (Dimension B)

1. Do you feel chest distress and flustered when the pain attacks?
Never Occasionally Sometimes Frequently Always
2. Do you have tinnitus when the pain attacks?
Never Occasionally Sometimes Frequently Always
3. Do you feel dizzy after suffering from TN?
Never Occasionally Sometimes Frequently Always
4. How about your clarity of thinking and agility reaction?
Very poor Poor Common Good Very good
5. How about your ability to concentrate?
Very poor Poor Common Good Very good
6. How about your memory?
Very poor Poor Common Good Very good
7. How about your appetite?
Totally no appetite Poor Common Good Very good
8. How about your energy status?
Very poor Poor Common Good Very good
9. Do you often suffer from pain so intense that you awake from sleep?
Never Occasionally Sometimes Frequently Always

Psychological dimension (Dimension C)

1. Do you feel annoyed or easy to lose your temper?
Never Occasionally Sometimes Frequently Always
2. Do you feel lonely and helpless?
Never Occasionally Sometimes Frequently Always
3. Do you often feel depressed? To what extent? (For example: Can hardly feel happy, no feeling of pleasure, energy dropping, easy to feel fatigued, interest dropping or losing on work, entertainment, sexual life, feel life is not interesting, often cry, consider yourself useless, often self-accusation etc.)
Never Occasionally Sometimes Frequently Always
4. Do you often feel anxious? To what extent? (For example: Concerning about trivial matters without cause, getting nervous, mood blundering, feel restless, fear, flustered shortness of breath, sweating, muscle throbbing pain etc.)
Never Occasionally Sometimes Frequently Always
5. Do you consider that TN affects your physical condition?
Never Slightly To certain extent Greatly Seriously impact

Social dimension (Dimension D)

1. Is your life or work affected by the pain?
Never Slightly To certain extent Greatly Seriously impact
2. Is the relationship between you and your families affected by the pain?
Never Slightly To certain extent Greatly Seriously impact

3. Does the pain affect you to participate in social activities?
Never Slightly To certain extent Greatly Seriously impact
4. Does the pain affect your entertainment?
Never Slightly To certain extent Greatly Seriously impact
5. Is your life affected by economic problems seriously?
Not affected Slight Common Greatly Seriously impact

References

- [1] Fishbain DA, Hall J, Meyers AL, et al. Does pain mediate the pain interference with sleep problem in chronic pain? Findings from studies for management of diabetic peripheral neuropathic pain with duloxetine. *J Pain Symptom Manage* 2008;36(6):639–46.
- [2] Gary JM. Chronic widespread pain and fibromyalgia: should reports of increased mortality influence management. *Curr Rheumatol Rep* 2005;7(5):339–41.
- [3] Cheour M, Ellouze F, Zine I, et al. Beck inventory depression assessment in chronic pain patients. *Tunis Med* 2008;86(12):1074–8.
- [4] Mehvish S, Barkat MQ. Phytochemical and antioxidant screening of *Amomum subulatum*, *Elettaria cardamomum*, *Embolica officinalis*, *Rosa damascene*, *Santalum album* and *Valeriana officinalis* and their effect on stomach, liver and heart. *Matrix Sci Med* 2018;2(2):28–33.
- [5] Elliott TE, Renier CM, Palcher JA. Chronic pain, depression, and quality of life: correlations and predictive value of the SF-36. *Pain Med* 2003;4(4):331–9.
- [6] Jessop J. Treatment for trigeminal neuralgia. Choice of procedures is wide. *BMJ* 1997;314(7079):519–20.
- [7] Park SJ, Ahn S, Woo SJ, Park KH. Extent of exacerbation of chronic health conditions by visual impairment in terms of health-related quality of life. *JAMA Ophthalmic* 2015;17:1–9.
- [8] Chong-Hua W, Li G, Xiao-Mei L, et al. Development of the general module for the system of quality of life instruments for patient with chronic disease: items selection and structure of the general module. *Fac Public Health* 2005;19(11):723–6.
- [9] Wang LS, Sun ZQ, Cai TS, Zhou ZG. Development and evaluation of quality of life scale for patients with type 2 diabetes mellitus. *Zhong Nan Da Xue Xue Bao Yi Xue Ban* 2005;30(1):21–7.
- [10] Mahmood HK, Barkat MQ, Zeeshan U, Kamran Q. Phytochemical and antioxidant screening of *Anaclyus pyrethrum*, *Apium graveolens*, *Boerhaavia diffusa*, *Cinnamomum cassia blume*, *Cuscutis melo linn*, *Cuscutis Sativus linn*, *Daucus sativus*, *Foeniculum vulgare*, *Trachyspermum ammii* and their effect on various human ailments. *Matrix Sci Pharma* 2018;2(2):06–14.
- [11] Ferrell BR, Dow KH, Grant M. Measurement of the quality of life in cancer survivors. *Qual Life Res* 1995;4(6):523–31.
- [12] Bonomi AE, Patrick DL, Bushnell DM, et al. Quality of life measurement: will we ever bestisfled. *Clin Epidemiol* 2000;53(11):19–23.
- [13] Hartley J, Betts LR. Four layouts and a finding: the effects of changes in the order of the verbal labels and numerical values on Likert-type scales. *Int J Soc Res Methodol* 2010;13(1):17–27.
- [14] van der Linde JA, van Kampen DA, van Beers LW, van Deurzen DF, Terwee CB, Willems WJ. The Oxford Shoulder Instability Score; validation in Dutch and first-time assessment of its smallest detectable change. *J Orthop Surg Res* 2015;10(1):146.
- [15] Alcalar N, Ozkan S, Kadioglu P, Celik O, Cagatay P, Kucukyuruk B, et al. Evaluation of depression, quality of life and body image in patients with Cushing's disease. *Pituitary* 2013;16(3):333–40, <http://dx.doi.org/10.1007/s11102-012-0425-5>.
- [16] Sikorskii A, Noble PC. Statistical considerations in the psychometric validation of outcome measures. *Clin Orthop Relat Res* 2013;471(11):3489–95, <http://dx.doi.org/10.1007/s11999-013-3028-1>.