# The Measurement of Pain in Patients With Trigeminal Neuralgia

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Chronic pain in trigeminal neuralgia and related facial pain syndromes is difficult to measure because of its subjective nature. In the neurosurgical literature, the most common approach to evaluating this type of pain has used measurements of pain intensity or percent pain relief. These 1-dimensional instruments do not adequately address the complexity of the measurement of chronic pain, and they have not undergone psychometric testing to assess their reliability and validity in trigeminal neuralgia patients. In this review, we discuss recommendations for developing appropriate pain scales from the chronic pain literature and provide a brief overview of psychometric testing, including the key concepts of reliability and validity. With these issues in mind, we describe the development of the Brief Pain Inventory—Facial, an 18-item questionnaire that measures pain in patients with facial pain syndromes. We conclude that the Brief Pain Inventory—Facial is a first step in the development of an outcome tool that can be used to evaluate multiple dimensions of pain in patients with trigeminal neuralgia.

Approximately 10% of Americans suffer from chronic pain conditions, which are estimated to cost the United States upwards of $80 billion annually in healthcare costs and lost productivity. A significant portion of these patients have chronic orofacial pain, and a subset of these patients present to neurosurgeons with the diagnosis of trigeminal neuralgia. Classic trigeminal neuralgia is a debilitating facial pain syndrome characterized by paroxysmal episodes of sharp, lancinating pain, usually unilateral in nature. A wide range of treatment options exists for this disorder, including medical management, microvascular decompression, radiosurgery, and percutaneous trigeminal ganglion techniques. Any attempt to compare these modalities or to develop effective new therapies requires the availability of reliable and validated pain scales, which have often been lacking in the neurosurgical literature. Surprisingly, in a recent critical review of surgical studies on trigeminal neuralgia, preoperative pain was not measured in 221 of the 222 studies examined, and hence, comparisons with baseline pain were precluded.[1] In addition, pain affects many aspects of patients' lives, but reports in the neurosurgical literature rarely attempt to evaluate quality of life indexes on top of pain intensity.

The purpose of this review is 3-fold. We examine the current pain scales that are commonly used to evaluate the efficacy of interventions in patients with trigeminal neuralgia. We then discuss guidelines from the chronic pain literature on optimal methods of reporting pain outcomes. Finally, we describe our own efforts to develop an improved instrument to measure pain in trigeminal neuralgia patients.

## CURRENT TRIGEMINAL NEURALGIA PAIN SCALES

Pain scales in the neurosurgical literature have typically relied on a single measure of pain intensity or a composite scale of pain intensity and medication use. The prototypical assessment of pain intensity is the Visual Analog Scale (VAS). This instrument consists of a 10-cm line with verbal anchors at each end (eg, ''no pain'' and ''worst pain''); it is a continuous scale that allows the estimation of pain intensity. Over decades of use, the VAS has been demonstrated to be a sensitive, reproducible pain scale in rheumatologic disorders,[2] cancer,[3] degenerative joint disease,[4] and other disease processes. In trigeminal neuralgia, the VAS commonly has been used to determine the efficacy of medical therapies,[5-7] as well as surgical interventions such as microvascular decompression[8] and motor cortex stimulation.[9] Valid alternatives to the continuous VAS are discrete scales that use anywhere from 5 to 11 points[10] to measure pain. The continuous VAS and categorical numerical rating scales are both reproducible measures of a single facet of pain, ie, pain intensity at the time at which the patient completes the survey.

Composite scales in the neurosurgical literature on trigeminal neuralgia usually include 2 elements.[11-15] The first part often involves a measure of pain intensity in 3 to 5 categories specifying the level of pain (eg, none, some, and severe). Alternatively, another method used in some studies is the ''global assessment in change,'' which is usually expressed as a percentage decrease in pain.[16] Categorical

scales assessing global patient well-being have also been used.[17,18] The second part of these composite scales describes the level of medication usage such as no medication use, reduced medication use, and continued medication use. The classification scheme devised by the group at the Barrow Neurological Institute has become widely used and is the prototypical composite scale (Table 1),[15] especially in studies of stereotactic radiosurgery for trigeminal neuralgia.[19-22] Composite scales have been useful because they have allowed some degree of standardization across treatment modalities, but their reliability and validity have not been tested thoroughly. These limitations inspired us to create an improved pain instrument based on recommendations from the pain literature.

## RECOMMENDATIONS FROM THE CHRONIC PAIN LITERATURE

Pain is inherently difficult to measure because of its subjective nature and the strong influence of social context, emotion, and other nonphysiological variables. Yet its accurate evaluation is of the utmost importance in determining the efficacy of interventions for pain syndromes, many of which are highly resource intensive. Efforts have been made in the chronic pain literature to delineate the optimal methods of measuring pain and interpreting clinical significance of outcome data in pain studies. The multi-institutional Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) has defined 6 core domains to be considered in treatment trials of chronic pain: (1) pain intensity, (2) physical functioning, (3) emotional functioning, (4) participant ratings of improvement and satisfaction with treatment, (5) symptoms and adverse events, and (6) participant adherence to treatment regimens.[23] Specific instruments have been recommended for outcome measurements with these domains in mind (Table 2).[24] Although not every domain needs to be investigated in each study, the IMMPACT group did suggest that at least 2 of the first 4 domains be evaluated to determine clinically relevant changes in pain.[25] The IMMPACT recommendations were designed specifically for clinical trials, but they provide

**TABLE 2.** Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials Recommendations for Core Outcome Measures[a]

| Domain | Measure |
|---|---|
| Pain | 11-Point (0-10) numerical rating scale (preferred) or categorical ratings (eg, none, mild, moderate, severe) of pain intensity |
|  | Use of rescue pain medication |
| Physical functioning | Multidimensional Pain Inventory Interference Scale |
|  | Brief Pain Inventory |
| Emotional functioning | Beck Depression Inventory |
|  | Profile of Mood States |
| Global improvement or satisfaction | Patient Global Impression of Change |
| Symptoms and adverse events | Spontaneous reporting of symptoms and adverse events with open-ended prompts |
| Participant disposition | Participant recruitment and progress information |

[a]Adapted from Reference 39.

standardized guidelines for evaluating treatment outcomes in daily clinical practice as well.[26]

A critical review of the use of pain scales in the neurosurgical literature for trigeminal neuralgia reveals 2 shortcomings. First, the scales typically measure only one of the IMMPACT pain domains, either pain intensity or ratings of pain improvement. Despite the existence of many established chronic pain tools such as the McGill Pain Questionnaire, the Brief Pain Inventory (BPI), and the Leeds Assessment of Neuropathic Symptoms and Signs,[26] only a few neurosurgical studies have used them.[9,27,28] As such, measurements of pain in the neurosurgical trigeminal neuralgia literature generally have been 1-dimensional. This limited methodology is at risk for providing incomplete data on pain outcomes and treatment options. Second, the scales used have not been rigorously tested for their psychometric properties (eg, reliability, validity, and responsiveness) in trigeminal neuralgia patients. Without this validation, data obtained from these scales are more prone to erroneous interpretations.

## NEW TRIGEMINAL NEURALGIA PAIN SCALES

More comprehensive approaches to evaluating pain have begun to be applied in trigeminal neuralgia. Zakrzewska et al[29] created a questionnaire to evaluate postoperative outcomes that included the Short Form-12, a generalized physical and mental health survey; BPI; McGill Pain Questionnaire; Hospital Anxiety and Depression Scale; and 44 surgery-associated questions. In a sample of 305 trigeminal neuralgia

**TABLE 1.** Barrow Neurological Institute Pain Intensity Score[a]

| Score | Pain description |
|---|---|
| I | No pain, no medications |
| II | Occasional pain, no medications required |
| III | Some pain, adequately controlled with medications |
| IV | Some pain, not adequately controlled with medications |
| V | Severe pain or no pain relief |

[a]Adapted from Reference 14.

patients, the questionnaire was determined to be reproducible and acceptable to patients. A more concise survey was proposed but not tested in patients. Jawahar and colleagues[30] designed a different questionnaire intended to evaluate pain in trigeminal neuralgia patients treated with Gamma Knife radiosurgery. This questionnaire included items derived from the VAS; McGill Pain Questionnaire; Short Form-36, a longer form of the Short Form-12; and a patient satisfaction scale. In 52 patients, the questionnaire was used to ascertain the efficacy of Gamma Knife in trigeminal neuralgia and to identify predictors of successful treatment. Obviously, the measurement of multiple domains of pain allows a more comprehensive assessment of patient health outcomes. However, the major tradeoff is a practical one, time and patient compliance. Patients may be reluctant to fill out multipage questionnaires and sometimes even resort to ''satisficing'' responses simply to complete the survey. Thus, a large and lengthy battery of tools measuring all 6 domains as described by the IMMPACT recommendations may be necessary or justifiable only in the clinical trial setting.

## DEVELOPMENT OF THE BPI–FACIAL

The ideal pain scale for use in a neurosurgeon's office would effectively examine several domains of pain in a time-efficient manner. This scale would be applicable to patients undergoing different treatment modalities and yield data that could be easily analyzed and compared. Building on the IMMPACT recommendations and previous instruments, we independently developed a pain scale specifically for patients with facial pain syndromes.[31] We decided to concentrate on the first 2 domains of the IMMPACT recommendations: pain intensity and physical functioning. As the basis for our scale, we chose to use the BPI, a simple, carefully validated, and widely used questionnaire in the field of chronic pain.[32-35] This instrument is composed of 11 items on an 1-point scale (0-10). Four questions center on pain intensity, and the remaining 7 questions deal with the interference of pain with general life activities. On the basis of a review of the trigeminal neuralgia literature and the opinions of expert practitioners in the neurosurgical treatment of facial pain, we added 7 items focusing on the interference of pain with orofacial activities (Table 3). These additional items were screened in a group of 10 patients for ambiguity. The entire 18-item instrument was called the BPI–Facial.

We next administered the BPI–Facial in a convenience sample of 156 patients with facial pain who presented to a single neurosurgeon's office. Of these patients, 156 were clinically diagnosed with Burchiel type 1 (ie, classic) trigeminal neuralgia, and the remaining 42 patients had a diagnosis of either Burchiel type 2 trigeminal neuralgia or atypical facial pain.[36] The results of the questionnaire in this patient sample enabled us to test the psychometric properties of the BPI–Facial.

**TABLE 3.** Brief Pain Inventory–Facial[a]

| Factor | Item |
|---|---|
| Pain intensity | Current pain |
| | Worst pain in last week |
| | Least pain in last week |
| | Average pain in last week |
| Interference in general activities | General activity |
| | Mood |
| | Walking ability |
| | Normal work |
| | Relations with other people |
| | Sleep |
| | Enjoyment of Life |
| Interference in face-specific activities | Eating a meal |
| | Touching one's face |
| | Brushing or flossing teeth |
| | Smiling or laughing |
| | Talking |
| | Opening one's mouth widely |
| | Eating hard foods |

[a]The first 11 items represent the original Brief Pain Inventory.

## PSYCHOMETRIC TESTING

Psychometrics is the study of constructing and interpreting measurement instruments. Although it originated in the fields of psychology and educational assessment, its principles are applicable to many other areas, including medical and surgical practice.[37] Rigorous psychometric testing is essential in determining whether legitimate inferences can be made from a particular instrument. The 2 principal concepts in psychometrics are reliability and validity. Reliability can be defined as the consistency of results from one assessment to the next. Different metrics of reliability exist, including internal consistency, the degree to which items in an instrument measure the same construct; temporal stability (ie, test-retest reliability), the reproducibility of results at different points in time; and interrater variability, the variation in outcomes when assessments are administered by different individuals. Validity describes the accuracy of the interpretation of an instrument in the context of the intended purpose of the instrument. Traditionally, validity has been separated into 3 types: content, criterion, and construct.[37] In the clinical sense, content validity evaluates the correlation between the items in an instrument and the symptoms of the disease being investigated. Criterion validity measures the strength of the relationship between an instrument and a ''gold standard'' test or a relevant future outcome. Often considered to be the most important form of validity, construct validity refers to how well an instrument measures the theoretical construct it is designed to assess.

## PSYCHOMETRIC PROPERTIES OF THE BPI–FACIAL

The concept of test reliability is a fundamental way of quantifying the amount of error, random and systemic, inherent in a measurement tool.[38] In other words, reliability measures how reproducible the results of the test are under different conditions. Test-retest reliability is a standard index of the temporal stability of a tool. Because only the results of a single test administration were available for analysis, we could not determine the test-retest reliability of the BPI–Facial. However, we did measure the Cronbach $\alpha$, which is commonly used as a measure of the internal consistency of a psychometric test score for a sample of test takers.[39] The Cronbach $\alpha$ will generally increase as the intercorrelations among test items increase. It is thus an estimate of one aspect of test reliability. On measures of internal consistency, the BPI–Facial performed remarkably well (Cronbach $\alpha = 0.94$ for the total instrument, no negative terms for interitem correlations).

In addition to reliability, validity is important in the development of a measurement tool. Unfortunately, no gold standard method for assessing pain exists for trigeminal neuralgia, and thus criterion validity could not be determined. To address the validity of the BPI–Facial, we resorted to other methods. We surveyed 3 experts in the field who regularly evaluate patients with facial pain syndromes to read the BPI–Facial. They concluded that it sampled the relevant clinical symptoms of trigeminal neuralgia, evidence of the content validity of the instrument. Construct validity was assessed in 2 separate ways. Using factor analysis, a technique for grouping related variables into generalized classes known as factors, we confirmed our hypothesis that the BPI–Facial measures 3 distinct aspects of pain: pain intensity, interference with general activities, and interference with facial-specific activities. In addition, scores in 2 of these 3 factors, specifically pain intensity and interference with general activities, were observed to be significantly higher in patients with atypical facial pain syndromes compared with patients with classic trigeminal neuralgia.

Based on these indirect but commonly used statistical techniques for determining reliability and validity, we conclude that the BPI–Facial is a novel tool that can used to effectively measure pain in patients who present to a neurosurgeon with a diagnosis of facial pain.

## FUTURE DIRECTIONS

The BPI–Facial achieves several objectives in developing a sound instrument for evaluating chronic pain in trigeminal neuralgia. It is short and straightforward, yet it capably assesses 2 domains of pain defined in the IMMPACT recommendations, pain intensity and physical functioning. The BPI–Facial also begins to assess emotional functioning via the items ''mood'' and ''enjoyment of life'' in the original BPI. This questionnaire also has been tested for aspects of reliability and validity in its target population, patients with facial pain syndromes.

Moving forward, we plan to study the test-retest reliability of the BPI–Facial, as well as the sensitivity of the test to changes in pain following medical and neurosurgical interventions. Plus, the addition of a few items to the BPI–Facial would enable it to adequately cover almost every IMMPACT core pain domains. For example, a standard method of assessing mood disorders in the outpatient setting is the Hospital Anxiety and Depression Scale.[40] There have been suggestions in the literature that this 14-item scale can be replaced effectively with 2 questions.[21,41] Adding these questions or similar questions to the BPI–Facial would bolster its evaluation of emotional functioning. A single question regarding patients' global impression of change[42] and a standard measure of adverse effects based on the treatment modality in question also would help the BPI–Facial become more comprehensive. This revised instrument would obviously require new psychometric testing. Nevertheless, we believe that the BPI–Facial provides a rigorously created and tested method of measuring pain in trigeminal neuralgia patients.

## CONCLUSIONS

The accurate measurement of chronic pain is crucial for determining the efficacy of surgical and medical therapies. To measure such pain, we need thoughtfully constructed instruments with proven reliability and validity. Although neurosurgical studies on trigeminal neuralgia traditionally have not used such tools, there have been some recent attempts to apply the recommendations of the IMMPACT consortium on measuring chronic pain in clinical studies. We developed the BPI–Facial as a tool to assess 2 domains of pain in trigeminal neuralgia patients, and we have performed initial studies to assess its reliability and validity in a group of $>150$ patients who presented to a neurosurgeon's office. Thus, the BPI–Facial is a useful instrument to measure pain in patients with trigeminal neuralgia, and we encourage neurosurgeons who care for this population to report their outcomes using this newly created tool.

### Disclosure

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