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Treatment Outcomes in Trigeminal Neuralgia—A Systematic Review of Domains, Dimensions and Measures

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Key words
- Outcome measures
- Systematic review
- Treatment outcomes
- Trigeminal neuralgia

Abbreviations and Acronyms
BNI: The Barrow Neurology Institute Pain Intensity Scale
BPI: Brief Pain Inventory
COS: Core Outcome Set
MVD: Microvascular decompression
QOL: Quality of life
TN: Trigeminal neuralgia
VAS: Visual analogue scale

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BACKGROUND: **Trigeminal neuralgia (TN) is a painful disorder characterized by sudden electric shock–like pain. It is a rare condition for which multiple treatments are available, including medical and surgical. The best treatment option is yet to be defined, and this is related to the lack of definition in the treatment outcomes and outcome measures. The aim of this systematic review was to summarize all the outcomes and outcomes measures that have been published to date and highlight variability in their use.**

METHODS: **We have conducted a literature search using a wide range of databases (1946–2019 for medical and 2008–2019 for surgical treatment), for all intervention studies in TN. Four hundred and sixty-seven studies were selected for data extraction on TN classification, data collection method, intervention, and treatment outcomes mapped to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT guidelines).**

RESULTS: **Most studies collected data on pain ($n = 459$) and side effects ($n = 386$) domains; however, very few collected data on the impact of treatment on physical ($n = 46$) and emotional functioning ($n = 17$) and on patient satisfaction ($n = 35$). There was high variability on outcome measures used for pain relief ($n = 10$), pain intensity ($n = 9$), and frequency of pain episodes ($n = 3$).**

CONCLUSIONS: **A clear definition of what are the important outcomes for patients with TN is essential. The choice of standardized outcome measures allowing for consistent reporting in TN treatment will allow for comparison of studies and facilitate treatment choice for patients and clinicians thus, improving health outcomes and reducing health care cost.**

INTRODUCTION

The *International Classification of Headache Disorders* defines trigeminal neuralgia (TN) as “A disorder characterized by recurrent unilateral brief electric shock-like pain, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve and triggered by innocuous stimuli.”[1] It is a rare condition, and population-based studies estimate a prevalence ranging from 0.03% (95% confidence interval 0.01–0.08) to 0.3% (95% confidence interval 0.16–0.55).[2] It remains one of the few neuropathic pain conditions for which multiple therapies, including medical and surgical, are available. However, the best treatment option has yet to be identified. The difficulty in defining what the most successful treatment for TN is relates to the fact that there are no clearly defined outcomes; therefore, comparison between treatments is challenging. Outcomes are defined as measures or observations, which are used to assess treatment effects.[3] For the purpose of this review, outcome refers to clinical outcome, which is the result(s) of the medical or surgical treatment of TN on the patient’s health or well-being. To improve comparison of treatments, clearly defined outcomes (what is assessed) and outcomes measures (how to assess outcome magnitude) should be used. Outcome measures are tools used to assess the impact of treatment interventions.

The variability in instruments used to measure treatment outcomes contributes to the difficulties in appraising research results.[3] These difficulties are a reality for clinicians and patients and result in uncertainty when faced with multiple treatment options.

To minimize the discrepancy between studies and results, groups of researchers and clinicians have developed guidelines for the systematic reporting of outcome measures. One such example is the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which has developed recommendations for core outcome domains to be reported in clinical trials of pain disorders.[4]

There have been studies reporting on the use of outcome measures in individual TN treatments, but there has not been a comprehensive review looking at all medical and surgical treatments published to date. The aim of this systematic review was, therefore, to summarize all the treatment outcomes used in the TN literature, to highlight the variability in their reporting, and, additionally, to summarize the instruments used to measure those outcomes.

METHODS

A protocol for the systematic review was published in the International Prospective Registry of Systematic Reviews (PROSPERO) (Registration CRD42018118675, December 2018) and followed recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses group.[5]

Search Strategy

A literature search was conducted to include all TN studies in which there was a medical and/or a surgical intervention with a view to capturing all treatment outcomes and the outcome measures used. The searches were performed electronically, with the help of a librarian, and by hand. We searched MEDLINE (Ovid) (1946 to October 2019 for medical treatment and 2008 to October 2019 for surgical treatment), EMBASE (1947 to October 2019 for medical treatment and 2008 to October 2019 for surgical treatment), Cochrane Oral Health Group's Trials Register, CINAHL Plus with Full Text, and PsycINFO. The search of surgical papers was restricted to studies published from 2008 onwards, given that 2 systematic reviews had been published on surgical management of TN.[6,7] Furthermore, international guidelines on the surgical management of TN[8] and a review of quality of reporting of surgical studies, which reviewed the literature up to 2008,[9] also had been published. The search strategy for MEDLINE AND EMBASE can be found in **Appendix A**.

Eligibility Criteria

The inclusion criteria were as follows: 1) intervention studies with a cohort of patients diagnosed with TN; 2) medical and/or surgical intervention; 3) TN cohort ≥10 patients; 4) subjects aged 18 years and older; 5) English language; and 6) full text available.

No discrimination was made concerning the study design, as the aim was to capture all the treatment outcomes and outcomes measures published to date. Studies in which there were 2 or more cohorts (TN and hemifacial spasm, for example) were included but only data relevant to the TN cohort was evaluated.

Screening

The references were organized in EndNote X9 and duplicates removed. Initially, 25 study titles were piloted between 2 reviewers (C.V.N. and R.N.R.). The interrater agreement was 0.60. Following discussion and modification of the piloting sheet to include abstracts, the process was repeated with 50 further studies. The final Kappa coefficient was 0.80.

The body of references was then screened on title and abstract; if no consensus was reached, a third reviewer (J.M.Z.) made the final decision. Three reviewers (C.V.N., R.N.R., and J.M.Z.) subsequently screened full texts, if available, against eligibility criteria.

Data Collection and Synthesis

We have used EPPI-Reviewer 4 software[10] to extract data from the final selected references. Data were extracted by 3 reviewers (C.V.N., R.N.R., and J.M.Z.) on TN classification (classical, idiopathic, and secondary to neurologic disease, Burchiel classification, and unspecified), cohort type (prospective, retrospective, and unspecified), intervention (medical and/or surgical), and treatment outcomes (domain, dimension, and instruments).

Data on outcome domains were captured according to the IMMPACT recommendations.[4] This review includes studies that precede those recommendations, as well as study designs other than clinical trials, but it was decided to use their guidance for a clear and standardized organization of the results. Treatment outcome measures were identified, and where available, data were collected on outcome measure instruments. The complete data extraction code can be found in **Appendix B**.

Statistical Analysis

Descriptive statistical analysis was performed to summarize the number of times outcomes and outcome measures were reported in the TN literature.

RESULTS

Four hundred sixty-seven ($n = 467$) papers were included in the final review and grouped according to TN classification, method of data collection, treatment intervention, and treatment outcomes (domain, dimension, and instruments/measures). **Figure 1** illustrates the flow chart of references.[11]

TN Classification

Just less than one half of the papers (47%) described their TN cohort as classic, idiopathic, secondary to neurologic disease or used the Burchiel classification.[12] One hundred twenty ($n = 120$) studies did not specify the type of TN in their cohort and 47 others used a nomenclature that was not clearly defined, e.g., refractory TN, medically unresponsive TN, and recurrent TN after microvascular decompression (MVD).

Method of Outcome Data Collection

More than one half of the studies reviewed ($n = 254$) collected their data retrospectively. Data were collected prospectively in 131 studies and 81 did not specify how their data were collected.

Intervention

Treatment interventions were divided into medical and surgical; however, data were not collected on the specific medical and surgical treatment modalities. The use of systemic and topical medicines and botulin toxin were included in medical management and all the ablative techniques,[7] neurosurgical procedures (MVD), and laser treatment in surgical management. The majority of studies reviewed were surgical papers ($n = 398$) and a minority combined medical and surgical treatment ($n = 10$).

Outcome Domains, Dimensions, and Measures

For systematization and clarity, outcome data were organized and mapped to the IMMPACT outcome domain recommendations for clinical trials in chronic pain (**Figure 2**).[4] Only 42 of the 467 reviewed studies were published during or before 2003, predating the IMMPACT publication. The IMMPACT Outcome Domains are as follows: 1) Pain; 2) Physical functioning; 3) Emotional

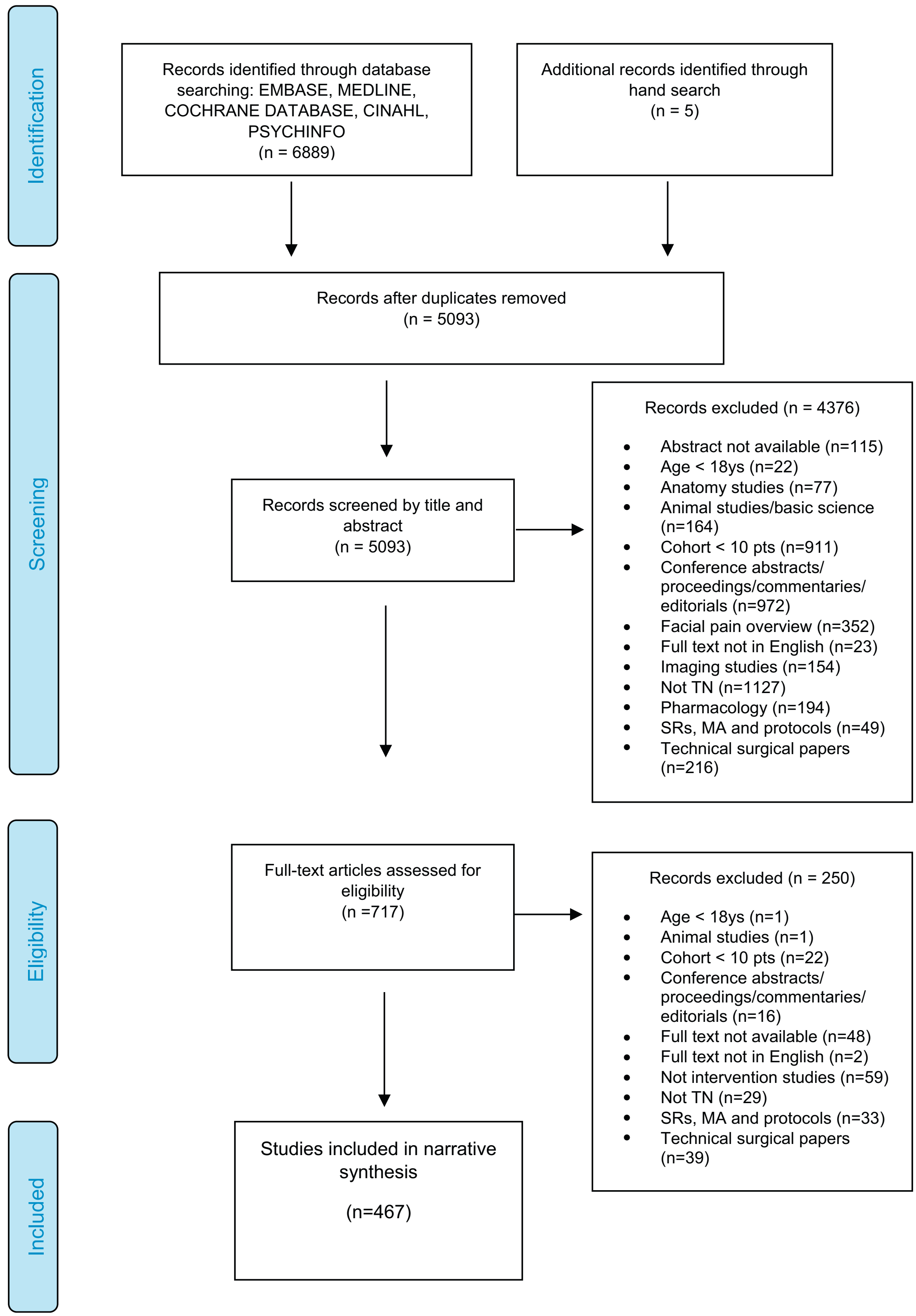

Figure 1. Systematic review flow chart. (Adapted from Moher et al.[11])

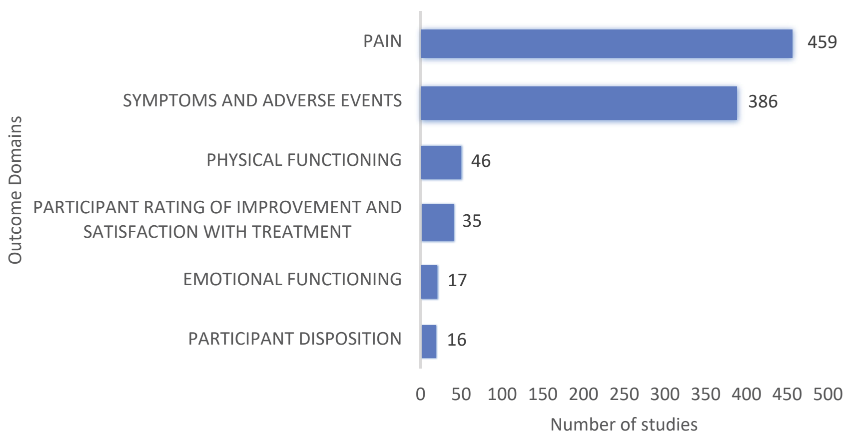

Figure 2. Number of studies divided according to IMMPACT recommendations on Outcome Domains.[4]

functioning; 4) Participant ratings of global improvement/satisfaction; 5) Symptoms and adverse events; and 6) Participant disposition.

With the exception of 8 papers, all studies used pain as an outcome domain (Figure 2 and Table 1).[13-459] Symptoms and adverse events also were described in a high number of papers (n = 386); however, the impact of treatment on physical and emotional functioning was significantly less evaluated, in 46 and 17 studies, respectively (Tables 2 and 3).[460-464] Of the 334 surgical studies that described adverse events, only 62 mentioned mortality rates. Participant disposition was described in 16 studies (3%).

Pain

Pain Relief. Pain relief was used as an outcome dimension in the majority of studies (n = 314). Ten different outcome measures were used for pain relief and 78 of 314 (25%) studies did not use an outcome measure. The Barrow Neurology Institute Pain Intensity Scale (BNI) was the most used pain relief measure in 131 of studies (42%), followed by a Likert scale in 76 (24%) and the visual analogue scale (VAS) in 18 (6%).

Pain Intensity. Pain intensity was used as a treatment outcome dimension in 193 of the 459 studies describing pain as an outcome domain. There were 9 different measures used for pain intensity and 8 studies did not use any. The VAS was the most commonly used measure in 85 studies followed by the BNI (n = 45) and the use of qualitative pain descriptors (n = 32).

Pain Frequency. Only 27 of 459 studies (6%) used pain frequency as a treatment outcome dimension. The majority did not use an outcome measure (n = 15) and 10 indicated the use of a pain diary. One study used a pain vector diagram and another study used The Constant Face Pain Questionnaire.

Physical Functioning

Forty-six studies included at least 1 measure for evaluating physical functioning dimensions, such as quality of life (QOL; n = 34), daily activities (n = 9), pain interference (n = 4), ability to work (n = 2), and disability (n = 1). These are summarized in Table 2 with the references.

Quality of Life. The most used instrument for assessing impact on QOL was the 36-Item Short form Survey Instrument (n = 14), followed by the EQ-5D (5-Question Quality Of Life Instrument) (n = 4), Sickness Impact Profile (n = 2), and Brief Pain Inventory (BPI) (n = 2). The World Health Organization Quality of Life and 12-Item Short Form Health Survey were used in 1 study each. Of note, the BPI facial was used only once.

Two studies did not use an outcome measure and 8 used a different measure (Quality of Life Impact Scale, 0–100 scale (2 studies used this measure), Trigeminal Neuralgia Quality of Life Assessment Scale, Epilepsy Surgery Inventory-55, 10-point Quality of Life Scale, Wong Baker FACES scale, and a 5-Point Scale).

Daily Activities. Activities of daily living was the most commonly used instrument (n = 4) followed by the Penn Facial Pain scale (n = 1). One study did not use an outcome measure and 4 studies used different measures (Brief Fatigue Inventory, Karnofsky Performance Status Scale, Category Point Scale, yes/no questionnaire).

Pain Interference. The only instrument used to evaluate pain interference was the BPI facial (n = 4), which is the only instrument specific for facial pain.

Ability to Work. Only 2 measures were used to evaluate ability to work; one study used a Likert scale and a second study used the Self Perceived Productivity Scale.

Disability. The Pain Disability Index was used in 1 study only.

Emotional Functioning

Three dimensions were assessed in this domain: depression (n = 5), anxiety (n = 3), and catastrophizing (n = 1). Some studies combined anxiety and depression (n = 12). Please refer to Table 3 for references.

Anxiety and Depression. The combination of anxiety and depression was evaluated by the use of Hospital Anxiety and Depression Scale in 9 studies, and 1 study did not use an outcome measure. One other measure was found in 2 studies—the Research Diagnostic Criteria.

Depression. To evaluate depression alone, the Beck Depression Inventory was used in 3 studies followed by the Hamilton Depression Scale (n = 1) and the Patient Health Questionnaire-9 (n = 1).

Anxiety. To evaluate anxiety, only 2 instruments were used, the Beck Anxiety Inventory (n = 2) and the Hamilton Anxiety Scale (n = 1).

Catastrophizing. Only one study evaluated catastrophizing, with the aid of the Pain Catastrophizing Scale.

Table 1. Pain Dimensions and Outcome Measures Identified in the Systematic Review

Outcome Dimension	Outcome Measure	Reference Numbers
Pain relief (314)	Barrow Neurology Institute Pain Intensity Scale (BNI)	13-143
	No outcome measure	144-221
	Likert scale	66,219,222-295
	Visual analogue scale (VAS)	13,294,296-311
	Numeric Rating Scale (NRS)	296,312-316
	Modified BNI	317,318
	Marseille scale	41,63,319
	MVD evaluation score	320,321
	Regis classification	112,322
	Burchiel classification	323
	Other	324
Pain intensity (193)	VAS	32,42,96,123,124,145,164,168-170,195,219,220,241,248,295,298,299,301,302,304-307,309,310,325-383
	BNI	15,22,39,44,46,49,55,56,62,68,74,82,127,128,195,202,210,339,355,360-362,384-406
	Qualitative pain descriptors	150,184,186,188,191,192,218,295,366,385,407-428
	NRS	31,35,71,145,235,266,278,298,304,314-316,413,429-440
	Brief Pain Inventory (BPI)	34,48,127,311,438,441-447
	McGill Pain Questionnaire	22,214,241,278,344,356,357,446-448
	No outcome measure	116,117,225,292,449-452
	Verbal Pain Scale (VPS)	214,295,363,367,409,453,454
	Verbal Numeric Pain Scale (VNPS)	49,188,455
	Other	324
Pain frequency (27)	No outcome measure	159,160,207,208,349,350,354,373,432,433,444,452,456-458
	Pain diary	188,278,292,295,309,330,376,380,438,459
	Pain vector diagram	453
	The Constant Face Pain Questionnaire	241

MVD, microvascular decompression.

Satisfaction with Treatment

Only 35 studies (7%) reported on patient ratings of improvement and satisfaction with treatment. The majority of studies ($n = 17$) used a Likert Scale to rate their patient satisfaction with treatment, whereas 2 studies used a Patient Satisfaction Scale and one other a VAS scale. Nine studies used the Patient Global Impression of Change to rate change with treatment. Three studies did not use an outcome measure and 4 studies used 4 other outcome measures (QUASU - Satisfaction with Treatment and Medical Team; Satisfaction Survey; The Patient Global Rating of Efficacy and Safety; and The Wong Baker FACES scale).

Adverse Events

Data on adverse events and side effects were collected in 83% of the studies. Of the 59 medical studies, 85% described side effects. Outcome measures were used in only 3 studies—The Liverpool Adverse Event Profile ($n = 2$) and the A-B Neuropsychological Assessment Schedule ($n = 1$).

On the surgical studies group, side effects and adverse events were collected in 334 (84%). The most reported side effect was numbness ($n = 220$) and the Barrow Neurology Institute Numbness Scale was administered in 62 studies. A Likert scale was used once to assess degree of numbness. One other surgical study used the Landriel Ibanez classification, but the majority of studies limited their reporting to the passive description of the cohort side effects opposed to using an instrument to collect the data.

Patient Disposition

Patient disposition is not considered a treatment outcome. This domain refers to the patient navigating through a study and often presented in a flow diagram.

Guidance on reporting for the different types of studies has been published by the EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research) (https://www.equator-network.org/) and endorsed by medical and surgical journals.[9] It has been accepted that the

Table 2. Physical Functioning Domain and Outcome Measures Identified in the Systematic Review

Outcome Dimension	Outcome Measure	Reference Number
Quality of life (34)	36-Item Short form Survey Instrument (SF-36)	41,122,124,344,354,355,360,361,382,425,444,446,460,461
	5-Question Quality of Life Instrument (EQ-5D)	67,266,356,391
	Sickness Impact Profile	349,432
	Brief Pain Inventory	73,344
	World Health Organization Quality of Life (WHOQOL-100)	35
	Brief Pain Inventory Facial	462
	12-Item Short Form Health Survey (SF-12)	463
	Quality of Life Impact Scale	332
	0—100 Scale	71,170
	Wong Baker FACES scale	324
	Trigeminal Neuralgia Quality of Life Assessment Scale	261
	Epilepsy Surgery Inventory-55	362
	5-Point Scale	214
	10-Point Quality of Life Scale	364
Daily activities (9)	Activities of Daily Living	41,278,357,413
	Penn Facial Pain Scale	464
	Karnofksy Performance Status Scale	41
	Brief Fatigue Inventory	443
	Category Point Scale (CPS)	367
	Yes/no questionnaire	292
Pain interference (4)	Brief Pain Inventory—Facial (BPI-Facial)	64,72,442,445
Ability to work (2)	Likert scale	391
	Self-Perceived Productivity Scale	357
Disability (1)	Pain Disability Index	356

reporting of the patient progression in clinical trials should be illustrated by a CONSORT diagram (Consolidated Standards of Reporting Trials)[465] and, in the case of observational trials, the STROBE statement (Strengthening the Reporting of Observational studies in Epidemiology) should be followed.[466]

In this review, we have identified 16 studies in which there was information about patient progression—CONSORT diagram ($n = 4$), STROBE reporting ($n = 5$) and 7 illustrated their information with a diagram but did not follow any specific guidance.

DISCUSSION

This systematic review provides a summary of the outcomes and outcome measures that have been used in the medical and surgical treatment of TN to date, performed by clinicians from varied backgrounds, and it highlights the variability in the methodology of studies and choice of outcome measures employed.

Pain: Outcome Dimensions and Outcome Measures

The degree of pain relief as well as the level of pain intensity have been the most commonly used dimensions in chronic pain studies.[467,468] Similar to what others have found in the TN surgical literature,[6,7,9] the most common pain dimension reported was pain relief. In the context of TN, however, there seems to be no consensus in what should be the primary outcome dimension in trials of TN. Studies that use either pain intensity or pain relief as their outcome of interest are difficult to compare. Pain intensity refers to "how intense the pain is," whereas pain relief refers to "how much pain relief" has resulted from a certain treatment and so requires a baseline assessment.[469] Some authors have attempted to clarify if pain relief ratings and pain intensity ratings are comparable. For example, Jensen et al.[470] looked at a cohort of 248 postsurgical patients (knee replacement vs. laparoscopy) whose outcomes were pain intensity (VAS and Verbal Rating Scale) and pain relief (VAS). They had hypothesized that the differences in sensitivity to detect change would be similar in both cohorts; however, this was not supported. They

Table 3. Emotional Functioning Domain and Outcome Measures Identified in the Systematic Review

Outcome Dimension	Outcome Measure	Reference Number
Anxiety and depression (12)	Hospital Anxiety and Depression Scale (HADS)	214,344,356,432,446-448,462,463
	Research Diagnostic Criteria (RCD)	341,342
	No outcome measure	82
Depression (5)	Beck Depression Inventory (BDI)	335,372,444
	Hamilton Depression (HDRS)	354
	Patient Health Questionnaire-9 (PHQ9)	67
Anxiety (3)	Beck Anxiety Inventory (BAI)	335,372
	Hamilton Anxiety Scale (HARS)	354
Catastrophizing (1)	Pain Catastrophizing Scale (PCS)	447

have confirmed that even though related, pain relief and intensity mean slightly different things, as patients report pain relief even when pain intensity ratings are the same or even greater than presurgery. Their conclusions point to the need of a clear definition of the primary outcome and a clear choice of a validated tool capable of capturing it.[470] In addition, pain intensity may remain the same but patient's ability to cope with it may change, and this would be reflected in measures looking at aspects such as activities of daily living. Baseline data before surgical procedures are rarely reported and yet they are crucial to determine the true impact of a treatment. TN is an episodic pain; it is interesting to see that little attention is given to this specific characteristic. To date, no instruments have been designed to capture the effects of treatment on the number and frequency of TN attacks. Degn and Brennum[453] have attempted to capture these data in a cohort of patients undergoing glycerol injection, MVD, and rhizotomy by plotting pain intensity (Verbal Numerical Rating Scale) with frequency of daily pain per month. Their data were used to design a pain vector diagram to illustrate, in a composite outcome, the effects of treatment. Another temporal aspect of pain is duration of pain-free status over time, which has been illustrated in the literature with Kaplan–Meier survival curves.[9] It is almost certain that patients would value information about which treatment provides absence of pain for the longest period of time, and it might be that plotting pain relief outcome data over time is the correct way of doing it, however, rigorous reporting of follow-up times are essential for data accuracy.

The VAS and BNI intensity scales are the most used tools to capture data on pain intensity. Both scales also were used to retrieve information on pain relief. Given that VAS is a single-item scale and BNI is a composite scale, it is not possible to compare data captured by these instruments, especially as they are measuring different pain dimensions and the BNI includes data on medication use. Despite their wide use in TN, neither the VAS nor the BNI have been validated for their use in TN cohorts.[7,471,472] It is not clear whether patients complete the scales or whether the data are retrieved from the medical records.

Finally, we should stress that the use of outcomes that are designed specifically for a single study, or which have been modified and derived from other instruments, for example modified BNI[317,318] and have not been validated for TN are neither reliable nor reproducible and comparison of study results is flawed.

Data-Collection Method

The retrospective collection of data, specifically, the interviewing of patients, months or years after their treatments were done, raises the question of recall bias and it can be influenced, for example, by severity of pain at time of recall.[473]

Of note, in one of the studies, family members of deceased patients were contacted to obtain information about their condition.[235] The experience of pain is a very personal one and it is unreasonable to expect that others can provide information, except if stated early on, that the outcome collected is not patient reported. If the information sought is related to effects of treatment on someone's level of pain, then the patient is the only valid source of information.[474]

Domains Other Than Pain

There has been extensive research highlighting the impact of chronic pain in mood and QOL.[475] Tölle et al.[476] and Zakrzewska et al.[447] described the high impact of TN pain on activities of daily living as well as on emotional functioning; however, the reporting of TN impact on QOL has been sparse.[477] Of the 8 different instruments used for emotional functioning, only one, the Hospital Anxiety and Depression Scale, has been validated for TN. The BPI facial has been validated in a cohort of patients with TN,[478] but its uptake, in studies published since 2010 and included in this review, is low, being used in 4 studies to assess pain interference[64,72,442,445] and in one to assess impact on QOL.[462] Interpreting the effects of TN on the emotional and physical health will also depend on the appropriateness of these instruments for their use in a TN cohort.

The reporting of side effects should go beyond a narrative list and incorporate how individual side effects might affect patients' QOL or what the impact on daily living is. As illustrated by Akram et al.,[9] the side effects of treatment might impact more on a patient's QOL than the pain itself.

There might be a few practical explanations for the poor reporting on domains other than pain. First, reporting on multiple outcome domains would require more comprehensive questionnaire(s) that could be a burden to patients, risking a poor response rate and validity of results. Second, time might be a limiting factor for researchers who need to administer, collect and analyze all the data. Patients may not be made aware of their relevance and so not complete them. Finally, although attempts have been made to improve reporting of outcomes in studies on TN, journal editors have not insisted on more comprehensive reporting.[9]

Limitations

The inclusion of a large number of studies to summarize information on outcomes and outcome measures in the treatment of TN created a heterogeneous data set, which was challenging to organize. The studies were not appraised on their scientific rigor, as we wanted to capture the diversity of outcomes and outcome measures available in the literature. Due to the volume of results, our data extraction on outcomes was limited to identifying the outcome measure instrument used and for the majority of the studies we failed to retrieve information concerning the timing and method of questionnaire administration. Although guidance from IMMPACT is to be considered in clinical trials, due to the lack of available guidance for the reporting of outcomes in TN studies, we decided to map our results to their recommended 6 core domains. We acknowledge that these outcomes might not comprehensively reflect the ones patients with TN consider important and that fewer may be required when reporting other types of studies. Finally, our search included English-language literature only, and we might have left out relevant research published in other languages (language bias).

Recommendations for Future Research

Following this work, it is our aim to develop a Core Outcome Set (COS) for the treatment of TN. COS is a group of defined outcomes that should be consistently collected and measured in all trials of a specific condition.[479]

We aim to seek guidance from IMMPACT, where possible, but we will not limit it to this, as there might be other outcome dimensions relevant to the TN population, for example, frequency of pain episodes, duration of pain-free episodes, and fear of attacks in between episodes. We will also follow recommendation from COMET (Core Outcome Measures in Effectiveness Trials) and COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) initiatives for methodological guidance.[480] One of the fundamental steps in the COS-development process will be to confirm whether patient's views on outcomes map to the currently used instruments and if not, the validity of tools needs to be tested for their ability to detect change over time—what is the value of a composite measure opposed to a single item measure? For example, patient global impression of change may cover all the required features and has been shown to be useful in neuropathic pain.[481]

A TN COS could be used in all prospective trials and could consistently capture data that can be compared between studies improving patient health and reducing health care expenditure. We acknowledge the complexity of this process and that it will take time to take into account all stakeholders views.

CONCLUSIONS

Patients and clinicians currently have no reliable way of comparing outcomes in TN especially between medical or surgical treatments. Trials of medical therapies are said to be positive if 50% of patients are pain free,[482] whereas surgical outcomes require 100% pain relief if they are said to be successful.

The variability in the reporting outcomes as well as the lack of validation of the instruments highlights the need for a partnership between different stakeholders—patients, patient groups, clinicians, researchers—in the preparation of a well-defined core set of outcomes and there are examples in the chronic pain field where this partnership has proved to be successful.[483,484]

Until there is a rigorous process for gathering TN treatment outcome data, which includes defining the primary outcome of importance to patients, the lack of consistency between studies will continue to account for the difficulties patients and clinicians have in identifying the best treatment option for each individual patient as this can vary significantly. This is of particular importance, given the range of treatments currently available for TN and, in addition, as not all patients opt for surgical therapies.

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DECLARATION OF COMPETING INTEREST

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