Microvascular Decompression for Classic Trigeminal Neuralgia: Determination of Minimum Clinically Important Difference in Pain Improvement for Patient Reported Outcomes

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BACKGROUND: Outcomes studies use patient-reported outcome (PRO) measurements to assess treatment effectiveness, but can lack direct clinical meaning. Minimum clinically important difference (MCID) calculation provides a point estimate of the critical threshold needed to achieve clinically relevant treatment effectiveness. MCID remains uninvestigated for microvascular decompression (MVD), a common surgical procedure for trigeminal neuralgia.

OBJECTIVE: We aimed to determine MCID for the most commonly used PRO measures of pain after MVD: Visual Analog Scale (VAS) and Barrow Neurological Institute Pain Scale (BNI-PS).

METHODS: Sixty consecutive patients with classic trigeminal neuralgia who decided to undergo MVD by a single surgeon were prospectively assessed with VAS and BNI-PS preoperatively and 2 years postoperatively. Three anchors were used to assign each patient's outcome. We then used 3 well-established, anchor-based methods to calculate MCID.

RESULTS: Patients experienced significant improvement in both VAS (9.9 vs 2.0, $P < .001$) and BNI-PS (5.0 vs 1.9, $P < .001$) after MVD. The area under the receiver-operating characteristic curve was greater for BNI-PS than for VAS for all 3 anchors, indicating that BNI-PS is probably better suited for calculating MCID. The 3 MCID calculation methods generated a range of MCID values for each of the PROs (VAS: 1.40-8.87, BNI-PS: 0.95-3.26).

CONCLUSION: MVD-specific MCID is highly variable based on calculation technique. Some of these calculations appear to either overestimate or underestimate the patients' preoperative expectations. When the different MCID methods are averaged, the results are clinically appropriate and consistent with preoperative expectations. The average MCID for VAS is 6.25 and for BNI-PS is 2.44.

KEY WORDS: Barrow Neurological Institute Pain Scale, Facial pain, Microvascular decompression, Minimum clinically important difference, Outcomes research, Trigeminal neuralgia, Visual Analog Scale

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The Visual Analog Scale (VAS)[1,2] and the Barrow Neurological Institute Pain Scale (BNI-PS)[2-4] are 2 of the most frequently employed patient-reported outcome (PRO) tools used by clinicians to rate pain for patients with trigeminal neuralgia (TN). For patients undergoing microvascular decompression (MVD) of the trigeminal nerve for classic TN, these PROs are often used for assessments of surgical effectiveness, but it is unknown exactly what degree of change in the numerical scores is necessary to be considered the minimum clinically important difference (MCID). The MCID can be calculated to establish clinical significance for these PRO tools.

ABBREVIATIONS: AUC, area under the receiver-operating characteristic curve; **BNI-PS,** Barrow Neurological Institute Pain Scale; **CI,** confidence interval; **HTI,** Health Transition Index; **MCID,** minimum clinically important difference; **MDC,** minimum detectable change; **MVD,** microvascular decompression; **PRO,** patient-reported outcome; **SD,** standard deviation; **TN,** trigeminal neuralgia; **VAS,** Visual Analog Scale

The concept of minimal clinically important difference was first defined by Jaeschke and colleagues as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."[5] MCID values describe the smallest change that is important to patients, thereby adding clinical significance to PRO tools.[6] Determining MCID values can help clinicians make better determinations as to the effectiveness of particular medical and surgical interventions and can help establish when they should be used.

Calculation of MCID is variable, and multiple methodological approaches have been described in previous studies.[7,8] Two of the most common approaches include distribution-based and anchor-based calculation.[8] The anchor-based approach is the most frequently used and most accepted method to calculate MCID values.[5,7-9]Anchor-based calculation compares changes in a patient's outcome score with an external criterion that is considered an anchor. It includes patient report, which some have suggested as important in determining clinically important change.[5,8] To date, there is no consensus as to which anchors or anchor-based calculation techniques are superior for determining MCID values.

Although MCID values have been determined for patients undergoing various neurosurgical interventions,[9-11] there have been no studies that have assessed MCID specifically for patients undergoing MVD for pain relief from TN. Therefore, our goals were to document the variability of MCID values obtained via common anchor-based calculations and determine MVD-specific MCID values for VAS and BNI-PS in patients with TN.

PATIENTS AND METHODS

Inclusion Criteria

The institutional review board from our institution approved this study. All patients underwent MVD surgery by a single surgeon (R.A.M.). No patients had previous surgical treatment for TN. To be included, the patient had to have (1) a clinical diagnosis of TN based on presentation symptoms similar to those described by the International Headache Society's Classification[12]; (2) failure of conservative and medical management defined as persistent, breakthrough pain despite multiple antiepileptic drugs in high enough doses to cause medication side effects; (3) pain reported as severe and significantly interfering with their activities of daily living, despite maximum medical and nonsurgical treatments; (4) a preference to undergo MVD; and (5) good candidacy for general anesthesia and suboccipital craniotomy.

Surgical Technique: MVD

Each patient initially underwent successful induction of general endotracheal anesthesia and was then turned in a bean bag into the three-quarter prone position with an axillary roll and the head slightly flexed and turned to expose the left suboccipital portion of the head, which was secured with a standard head holder.[13] An axillary roll was placed, and all pressure points were padded appropriately. The suboccipital portion of the head on the side of the TN pain was then shaved, prepped, and draped in the usual sterile fashion. A straight linear incision approximately 3 to 4 cm in length was then made from the asterion down to the mastoid notch after infiltration with local anesthetic with 1% epinephrine. Subperiosteal dissection was then performed, and self-retaining scalp retractors were placed. A small craniotomy approximately 2 cm in diameter was then performed, and the bone flap was placed on the back table, soaking in Bacitracin irrigation. The cranial defect was then extended laterally and superiorly until there was exposure of the transverse and sigmoid sinus junction. Once this was identified and hemostasis was obtained, the dura was opened and reflected to the junction of the sigmoid and transverse sinuses.

The operating microscope was then used to gently open the arachnoid overlying the cerebellopontine angle, and cerebrospinal fluid (CSF) was slowly released to relax the cerebellum without using brain retractors. The trigeminal nerve at the root entry zone at the pons was then carefully inspected circumferentially for any vascular compression. A standard felt pad, shredded and fluffed, was placed between the trigeminal nerve and any offending vascular structures. The nerve was then again inspected circumferentially to be sure there was no other evidence of compression. The wound was then closed in multiple layers. The craniotomy defect was repaired with a standard titanium plating system.

Patient-Reported Outcome Scales

The VAS and BNI-PS are the 2 PRO measures that were used in this study. The VAS provides an estimate of pain intensity on a continuous scale, with a score of "0" representing "no pain" and a score of "10" representing "worst pain."[2] The BNI-PS rates patients' pain on a scale of 1 to 5, incorporating the degree of dependence on medications (Table 1).

Outcomes Assessment

Patients were prospectively enrolled in the study and available for evaluation at 2-year follow-up. Preoperatively, PRO scores were obtained via face-to-face interviews. Approximately 2 years postoperatively, follow-up PRO scores were obtained via telephone interviews by an independent observer not involved in any aspect of the patients' care.

MCID Anchors

For derivations of MCID values, we used 3 ad hoc anchors that have been used in previous studies, notably by Parker et al.[7,9,11] They included (1) satisfaction with surgery; (2) willingness to have surgery again given experienced outcome; (3) perceived improvement following surgery using the Health Transition Index (HTI) portion of the Short Form-36, which is an established quality-of-life measurement tool.[10,11] (1) The "satisfaction with surgery" anchor functioned by asking patients whether or not they were satisfied with the results of their surgery. Those answering "yes" were labeled as responders, and those answering "no" were labeled as

TABLE 1. Barrow Neurological Institute Pain Scale[a]

Pain Score	Description
1	No pain, no medications
2	Occasional pain, no medications required
3	Some pain, adequately controlled with medications
4	Some pain, not adequately controlled with medications
5	Severe pain or no pain relief

[a]Adapted from Chen and Lee.[2]

nonresponders. (2) The "willingness to have surgery again" anchor functioned by asking patients if they would have the surgery again based on their outcome. Those answering "yes" were labeled as responders, and those that responded "no" were labeled as nonresponders. (3) The "perceived improvement following surgery" anchor was derived from the HTI portion of the Short Form-36 quality-of-life health survey, which rates patients' health state postoperatively in comparison with their health state preoperatively. The choices included "worse," "unchanged," "slightly better," "significantly better," or "completely better." Patients answering "significantly better" or "completely better" were labeled as responders, whereas patients answering "worse," "unchanged," or "slightly better" were labeled as nonresponders.

MCID Anchor-Based Calculations

Three previously reported anchor-based calculation methods to determine MCID values were chosen for this study, as used by Parker et al.[7,9,11] They included (1) "average change," (2) "minimum detectable change," and (3) "change difference." (1) With the "average change" calculation method, MCID equals the average difference in pain preoperatively to postoperatively for those patients labeled as responders. (2) With the "minimum detectable change" (MDC) calculation method, MCID equals the smallest change that can be considered above the measurement error, calculated here with the 95% confidence level. Thus, MCID equals the upper value of the 95% confidence interval (CI) for the average change score in the group of patients labeled as nonresponders. (3) With the "change difference" calculation method, MCID equals the difference in the average change scores for the groups of patients labeled as responders and nonresponders. To determine the probability that these MCID values would accurately delineate between responders and nonresponders, we calculated the area under the receiver-operating characteristic curve (AUC). The AUC values can range from 0.5, where delineation equals that of pure chance, to 1.0, where all patients are correctly delineated.[7,9]

RESULTS

Sixty consecutive patients (47 women, 13 men) undergoing MVD were prospectively enrolled in the study, and all patients were available for evaluation at approximately 2-year follow-up (mean 2.2, median 2.0 [95% CI: 1.9, 2.4], and range 1.4-3.3). No patient received subsequent surgical treatment for TN in the 2-year follow-up period. The mean ± standard deviation (SD) age was 53.4 ± 12.3 years at the time of MVD. At the time of presentation, VAS and BNI-PS were 9.90 ± 0.54 and 4.97 ± 0.18, respectively. Two years postoperatively, each of the outcome measures assessed demonstrated significant improvement in our patient population. The mean ± SD change (improvement) score for VAS and BNI-PS were 7.87 ± 2.98, and 3.05 ± 1.10, respectively (Figure). For the HTI anchor, 3 (5%) patients assessed themselves as "worse," 2 (3%) as "unchanged," 8 (13%) as "slightly better," 20 (33%) as "significantly better," and 27 (45%) as "completely better." For the satisfaction with surgery anchor, 51 (85%) patients answered "satisfied," whereas the remaining 9 (15%) answered "not satisfied." For the surgery again anchor, 50 (83%) patients answered "yes" to willingness to have surgery again, whereas the remaining 10 (17%) answered "no" (Table 2). No patients

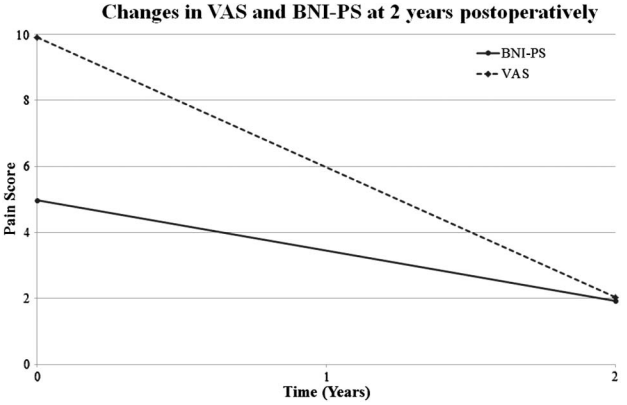

FIGURE. *Baseline and 2-year scores for patients undergoing microvascular decompression (MVD). Each patient-reported outcome (PRO) questionnaire revealed improvement at 2 years postoperatively. The mean ± SD change (improvement) scores for Visual Analog Scale (VAS) and Barrow Neurological Institute Pain Scale (BNI-PS) were 7.87 ± 2.98 and 3.05 ± 1.10, respectively.*

experienced death, coma, or paralysis. The following complications occurred in our cohort (patient numbers are listed in parentheses): pseudomeningocele (4), CSF leak (3), hydrocephalus requiring ventriculoperitoneal shunt (2), transient diplopia (2), facial weakness/hearing loss (1), and wound infection (1).

Visual Analog Scale

Based on calculation method, the MCID threshold ranged from 1.40 to 8.71 for the HTI anchor; 2.0 to 8.87 for the satisfaction with surgery anchor; and 2.36 to 8.45 for the surgery again anchor (Table 3). For all anchors, the smallest threshold was derived from the "change difference" approach and the largest from the "minimum detectable change" approach.

Barrow Neurological Institute Pain Scale

The MCID threshold ranged from 0.95 to 3.26 for the HTI anchor; 1.33 to 3.22 for the satisfaction with surgery anchor; and 1.26 to 3.26 for the surgery again anchor (Table 3). For all anchors, the smallest threshold was derived from the "change difference" approach and the largest from the "average change" approach.

Comparison of Anchor and MCID Calculation

The MCID values varied based on calculation methods (Table 3). The AUC was slightly greater for the surgery again anchor than for the HTI and satisfaction anchors when the VAS was used. The AUC was slightly greater for the satisfaction anchor than for the HTI and surgery again anchors when the BNI-PS was use. For the VAS, the "MDC" approach consistently produced the largest MCID value, whereas the "change difference" approach consistently produced the smallest MCID value. For the BNI-PS, the "average change" approach consistently produced the largest MCID value, whereas the "change difference" approach consistently produced the smallest MCID value.

TABLE 2. Baseline and Follow-up PRO Scores, Patient Characteristics and Comorbidities, and Anchor-Based Responses[a]

	Preoperatively	2-Year Follow-up	Difference
PRO scores			
VAS[b]	9.90 ± 0.54	2.03 ± 2.96	7.87 ± 2.98
BNI-PS[b]	4.97 ± 0.18	1.92 ± 1.06	3.05 ± 1.10
Patient characteristics			
Age[b]	53.4 ± 12 years	55.6 ± 12 years	
Sex (female)	78%	78%	
Comorbidities			
Hypertension	45%		
Hyperlipidemia	17%		
Arthritis	15%		
Major depressive disorder	13%		
Migraines	12%		
Diabetes mellitus	10%		
Fibromyalgia	7%		
Possible Multiple sclerosis[c]	3%		
Anchors			
Surgery again anchor			
Stated "Yes," would have surgery over again based on experienced outcome	N/A	83%	
Satisfaction anchor			
Stated "Yes," satisfied with the results of surgery	N/A	85%	
HTI anchor: would rate health state after surgery as:			
"Worse"	N/A	5%	
"Unchanged"	N/A	3%	
"Slightly better"	N/A	13%	
"Significantly better"	N/A	33%	
"Completely better"	N/A	45%	

[a]PRO, patient-reported outcome; VAS, Visual Analog Scale; BNI-PS, Barrow Neurological Institute Pain Scale; HTI, Health Transition Index.
[b]Mean ± standard deviation.
[c]Two patients in our study presented with a questionable diagnosis of multiple sclerosis, unrelated to their trigeminal neuralgia. Both of these patients had magnetic resonance imaging suggesting vascular compression at the trigeminal root entry zone and no multiple sclerosis plaques visualized.

The AUC was greater for the BNI-PS than for the VAS for all 3 anchors, respectively, indicating that BNI-PS is probably better suited for calculating MCID. The high degree of variability among the different MCID calculation methods suggests that some of the calculations appear to overestimate (average change and MDC) or underestimate (change difference) the MCID based on the patients' preoperative expectations. An average of these different MCID calculations results in an MCID of 6.25 for VAS and 2.44 for BNI-PS with MVD for TN. This MCID value is more clinically appropriate and consistent with patients' preoperative expectations.

DISCUSSION

MVD for TN is unusual among most surgical procedures for pain, in that the quantifiable pain relief from surgery is very high relative to other pain procedures. Simultaneously, the possibility of complications unrelated to pain relief leading to reduced patient satisfaction, unwillingness to have surgery again, or poorly perceived outcome after surgery is also relatively high in comparison with other pain-relieving procedures. Additionally, patients' preoperative expectations are generally higher in TN patients preparing for MVD in comparison with other pain patients preparing for surgery. These 3 features of MVD explain why the "average change" and the "MDC" calculations overestimate the MCID, whereas, simultaneously, the "change difference" calculation underestimates the MCID.

The "average change" MCID calculation reflects the average difference in pain preoperatively to postoperatively in responders. Patients with TN who are considering surgery generally have preoperative pain rated at 9 or 10 on the VAS, because the pain from TN is often referred to as the worst pain known to mankind.[14] It is generally accepted that MVD provides excellent pain relief for the majority of patients.[15-17] The pain relief achieved in our cohort was very high, with most patients improving to a 2 or less on the VAS after MVD. This calculates to an "average change" MCID of 8.0, 8.17, or 8.26 depending on the anchor used. Obviously, with such a dramatic improvement of pain, this is an overestimate of the MCID.

The "MDC" represents the upper value of the 95% CI for the average change score calculated in the group of patients labeled as nonresponders. This value also overestimates the MCID because

TABLE 3. The 3 MCID Calculations Generated a Range of Values for Each of the PROs Assessed[a]

	VAS			BNI-PS		
Anchor-Based Approach	**HTI**	**Satisfaction**	**Surgery Again**	**HTI**	**Satisfaction**	**Surgery Again**
Average change	8.17	8.0	8.26	3.26	3.22	3.26
MDC (95% CI)	8.71	8.87	8.45	3.06	2.78	2.88
Change difference	1.40	2.0	2.36	0.95	1.33	1.26
AUC (CI)	0.6023 (0.417, 0.785)	0.6318 (0.394, 0.849)	0.6580 (0.451, 0.854)	0.7054 (0.544, 0.859)	0.7919 (0.602, 0.931)	0.7630 (0.561, 0.926)
SN	.72	.70	.78	.74	.80	.78
SP	.57	.58	.60	.60	.68	.70
Average	6.25			2.44		

[a]MCID, minimum clinically important difference; MDC, minimum detectable change; AUC, area under the receiver-operating characteristic curve; CI, confidence interval; SN, sensitivity; SP, specificity; HTI, Health Transition Index; VAS, Visual Analog Scale; BNI-PS, Barrow Neurological Institute Pain Scale.

many patients who had excellent pain relief might still respond to our anchors by stating that they were not satisfied because of their higher than usual expectations preoperatively or if they experienced a complication, which tends to be less tolerated compared with other pain procedures. Specifically, these patients in the "nonresponding" group often went from 10 to 1 or 2 on the VAS. This is a unique situation and certainly overestimates the MCID. Furthermore, because of this phenomenon in which some patients had outstanding pain relief but were still classified as nonresponders, we may infer that, although this terminology is standard in outcomes studies, "responders" vs "nonresponders" may not be the most appropriate terms to describe these groups of patients.

Finally, the "change difference" method of calculating MCID tends to underestimate the MCID. Because the "change difference" represents the difference in pain improvement between responders vs nonresponders, and, in our cohort, both of these groups achieved significant pain relief, there is only a small difference between the 2 groups. The reason for "change difference" underestimating MCID is the same as the reason for "MDC" overestimating MCID, ie, many of the nonresponders actually represent patients who were disappointed even though they achieved excellent pain relief. Because the surgeon who performed these procedures has had excellent success in relieving pain in patients with classic TN, when describing the operation and expected outcomes preoperatively, expectations for excellent pain relief are very high. This is a unique problem with MVD for classic TN, which contributes to an overestimating "MDC" and an underestimating "change difference."

In order to balance out the calculations that overestimate and underestimate MCID, we chose to average the MCID calculations, and the result was an MCID of 6.25 for VAS and 2.44 for BNI-PS. These calculations are much more appropriate for this cohort of patients and clinically make sense. Many of the patients in our cohort, when asked preoperatively what the minimum improvement in VAS would warrant proceeding with the MVD surgery, stated at least a 50% improvement in pain, which is similar to the final MCID calculation of 6.25 for VAS.

Limitations

This MCID analysis has several limitations. The most important is that MCID calculations are probably influenced by baseline pain severity, and, in our study, the baseline pain was very high in every patient. It is difficult to calculate MCID if not enough patients have poorer outcomes. Because few patients in this cohort reported no pain relief after surgery, the "responders" vs "nonresponders" were not balanced. Because many experts believe that pain relief after MVD is measured as "all or nothing," many patients with substantial, but incomplete, pain relief fall into the category of "nonresponders." An additional limitation is our small sample size of 60 patients with a follow-up time of only 2 years. A final limitation is in the selection of anchors, which have been quite variable in the literature.

CONCLUSION

MVD-specific MCID is highly variable based on calculation technique. Because the average change and MDC overestimates MCID, but the change difference underestimates MCID, the average of these calculations appears to be most appropriate for determining MCID. Based on the averaging method with all 3 anchors, MCID following MVD for TN is 6.25 points for VAS and 2.44 points for BNI-PS.

Disclosures

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COMMENTS

The present article of 60 patients with trigeminal neuralgia treated with MVD evaluates a minimum clinically important difference (MCID) calculation for the 2 patient-reported outcomes (Visual Analogue Scale and Barrow Neurological Institute Pain Scale) to estimate the critical threshold needed to achieve clinically relevant treatment effectiveness. This is the first article that applies this outcome assessment to trigeminal neuralgia.

Some of the limitations for this MCID analysis such as the small sample size and short follow up-time have been discussed in the article. Further limitations include the use of a static, 1 time measurement, and the absence of Kaplan-Meier data plots, more complete information (range) of time that patients were followed, and mention of complications. These numerous limitations make it questionable as to the reliability, reproducibility, and usefulness of the above analysis.

As other studies have shown, the above report also confirms that many patients with trigeminal neuralgia view partial pain relief as clinically important and indicative of treatment effectiveness.

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The studies objectives were to document the variability of minimally clinical important difference values obtained via common anchor-based calculations and determine MVD-specific MCID values for VAS and BNI-PS in patients with trigeminal neuralgia. The study demonstrated variable findings depending on the method used to calculate the MCID. The study also emphasized the importance of capturing pain score differences in this population and identified notable underscoring of total changes seen in the study with use of the MCID. Limitations include a small sample size (n = 60) and the inability to define MCID findings by baseline severity.

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