Estimation of Clinically Important Change for Visual Analog Scales Measuring Chronic Temporomandibular Disorder Pain

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Aims: *To estimate the clinically important change (CIC) on a 100-mm visual analog scale for pain intensity (VAS-PI) by relating it to the patient's global impression of change (PGIC) in patients with chronic temporomandibular disorder (TMD) pain and to assess the dependency of the CIC on their baseline pain scores.* ***Methods:*** *Data from a prospective cohort study with 588 patients with chronic TMD pain were analyzed. The CIC was estimated over a 3-month period, and receiver operating characteristic methods were used to assess the optimal cut-off point. The PGIC category of "much improved" served as an external criterion. Dependency of absolute and percent change on baseline VAS-PI scores was determined by linear regression analysis.* ***Results:*** *A VAS-PI change score of –19.5 mm and a percent change score of –37.9% were best associated with the concept of CIC. Since patients with high baseline pain required greater absolute reductions in pain to reach a clinically important improvement, percent change scores performed better in classifying improved patients.* ***Conclusion:*** *Providing a standard definition of the CIC adds to the interpretability of study results, ie, the estimates will aid in understanding individual patient outcomes.* J OROFAC PAIN 2010;24:262–269

Key words: chronic pain, minimal clinically important change, temporomandibular disorder

Temporomandibular disorders (TMD) embrace several clinical problems that involve the muscles of mastication, the temporomandibular joint (TMJ), and associated structures.[1] TMD are frequently associated with chronic pain[2] and thus represent a common problem within the community[2–5]; they are known to affect general health,[6] psychological status, and social and economic well-being.[7]

The most accurate and reliable evidence of pain and its intensity is based on the patient's description and self-report. However, individuals vary in subjective ratings that they indicate on scales such as the numerical rating scale (NRS), visual analog scale (VAS), or any of the verbal descriptor scales. Further, small differences in mean pain score may become "statistically significant" with large samples, even though they may be of little clinical significance to the patient.[8,9] Therefore, to advance studies of chronic pain management in TMD patients, it is important to identify the clinically minimal important change that may be used to calculate sample sizes and assess potential differences between the beneficial effects of therapeutic interventions.[10,11]

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In the literature, this parameter is defined as the smallest change in a measurement that signifies an important improvement in a symptom; it can be thought of as how much a patient needs to "feel better" in order to clinically appreciate an improvement.[12]

Although recent studies have been successful in establishing cut-off points associated with the clinically minimal important changes in VAS pain, the criteria were defined on the basis of data from convenience samples of patients with acute pain in emergency department settings.[13,14] Furthermore, these studies considered the minimum level of clinical importance, a criterion that does not best represent a clinically important improvement while, from a methodological point of view, small effects may be more difficult to detect in clinical trials and thus may require larger sample sizes.

The specific aims of the present study were: first, to detect the clinically important change (CIC) on a 100-mm VAS for pain intensity (VAS-PI) that is most closely associated with a clinically important improvement on the commonly used and validated measure of the patient's global impression of change (PGIC); and second, to estimate the dependency of the CIC on the baseline pain scores.

Material and Methods

Patient Selection

Subjects were selected from a consecutive series of TMD patients (2,894 patients) who attended the TMD clinic in the Department of Oral and Maxillofacial Surgery at the Innsbruck Medical University from January 2004 to December 2008. A total of 678 patients, who were recruited for a prospective cohort study of nonsurgical management for chronic TMD pain, were included. Self-report questionnaires were used to measure patient outcomes at baseline and at the 3-month follow-up. The subjects were informed about the study procedure and informed consent was received. The analyses for determining the CIC were performed within this study population. The study was approved by the local ethical committee.

Criteria for including a TMD pain patient were: *(1)* the presence of a TMD diagnosis of unilateral arthralgia associated with myofascial pain assigned according to the Research Diagnostic Critera for Temporomandibular Disorders (RDC/TMD)[15]; *(2)* a pain duration of > 6 months and ≤ 5 years; *(3)* a pretreatment VAS-PI score of > 30 mm; *(4)* age between 18 and 70 years; *(5)* ambulatory and able to be treated as an outpatient; and *(6)* available for the study schedule. Criteria for excluding a TMD pain patient were: *(1)* the presence of associated TMD diagnoses such as myofascial pain with limited opening, disc displacements, arthritis, or arthrosis assigned according to the RDC/TMD[15]; *(2)* pain attributable to confirmed migraine, head, or neck pain condition; *(3)* acute infection or other significant disease of the teeth, ears, eyes, nose, or throat; *(4)* debilitating physical or mental illness; *(5)* presence of a collagen vascular disease (ie, positive laboratory tests for immune system disease or presence of clinical criteria required to make a diagnosis of collagen disease); *(6)* presence of fibro - myalgia; *(7)* history of trauma; and *(8)* inability to speak or write German.

The evaluation consisted of the collection of basic demographic information, subject self-report measures, questions of history, and physical examination measures.[15] Each subject completed a visual pain rating to assess severity of pain by using a VAS-PI, ie, patients registered the mean pain perceived on chewing or eating hard foods. This scale has been used extensively in randomized trials[16–19] and has shown good construct validity in comparison with other pain measures.[20–22]

Study Design

A 100-mm VAS-PI was used for determining pain intensity, ranging from 0 (no pain) to 100 (very severe pain). At the 3-month follow-up, patients were asked by the same data collector to repeat the measurement on a VAS-PI, without access to any previous VAS-PI ratings. To detect clinically relevant changes in the PGIC, the concept of the "transition" method was used.[8,11,23–26] The "transition questionnaire" investigates the current pain intensity, compared to the pain intensity at baseline examination, by the question: Please imagine how you would have described your pain intensity 3 months ago. How do you feel today as compared to 3 months earlier as far as your pain perceived on chewing or eating hard foods is concerned? The PGIC was administered at the 3-month follow-up, and patients were asked to score the change on the following scale: *(1)* much improved, *(2)* slightly improved, *(3)* no change, *(4)* slightly worsened, and *(5)* much worse.[9] The definition of "no response to therapy" was the PGIC category of "no change," "slightly worsened," or "much worse." The PGIC was considered as the external criterion.

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Table 1 Baseline Demographic and Clinical Characteristics (n = 588)	
Age in years (mean ± SD)	39.1 ± 15.2
Gender (% female/male)	91.3/8.7
Pain duration in weeks (mean ± SD)	97.9 ± 124.3
VAS-PI (mean ± SD)	50.1 ± 22.2

N = no. of patients; SD = standard deviation; VAS-PI = visual analog scale pain intensity.

Patient's Global Impression of Change

Patients were stratified by the PGIC category, and the mean VAS-PI raw (VAS-PI follow-up – VAS-PI baseline) and percent change scores ([absolute change/VAS-PI baseline] × 100) were calculated within each stratum of the study. To explore this relationship between patients' ratings of change and actual changes on the VAS-PI, the categorical ratings were compared with raw and percent change scores by means of one-way analyses of variance (ANOVAs) followed by post-hoc multiple comparisons (Bonferroni adjustment). Second, Spearman rank correlation coefficients of the categorical rating scale with absolute and percent change in pain on the VAS-PI were calculated.

Clinically Important Change on the VAS-PI

CIC was defined as the difference in mean change from baseline in VAS-PI scores between patients with a "slightly improved" or no response to therapy ("no change," "slightly worsened," and "much worse") and patients with the next higher level of response ("much improved"). In order to determine the threshold levels associated with the "a priori" definition of CIC, the receiver operating characteristic (ROC) method was used. For each analysis, clinical importance served as the dependent variable and either the raw or percent VAS-PI changes served as the independent variable. The a priori definition of CIC was the PGIC category of "much improved." However, since this definition is arbitrary, the VAS-PI changes best associated with "slightly or much inproved" were also calculated. This method has the advantage of synthesizing information on the sensitivity and specificity for detecting important improvement by an external criterion. The area under the ROC curve (AUC) in this setting can be interpreted as the probability of correctly identifying the "clinically important improved" patients from "nonclinically important improved." The area ranges from 0.5 (no accuracy) to 1.0 (perfect accuracy).[27,28] Areas from 0.50 to about 0.70 represent poor accuracy, those from 0.70 and 0.90 are useful for some purposes, and higher values represent high accuracy.[29] Differences between the areas under the ROC curves for the VAS-PI raw and percent changes were investigated using Wilcoxon signed ranks test.

Consistency of VAS-PI Change Scores Over Groups of Patients

The consistency of VAS-PI change scores across baseline demographic and clinical variables was investigated using the data of patients who rated their pain as slightly or much improved. Dependency of absolute and percent change on baseline VAS-PI scores was determined by linear regression analysis. The consistency of absolute change over age and pain duration was assessed using Spearman rank correlation coefficients, and the differences between men and women were investigated using an independent *t* test.

Statistical Analyses

The valid use of parametric statistics was verified by testing for normal distribution of the variables (Kolmogorov–Smirnov test, normal distribution assumed when $P > .05$). When the assumption of normality was not met, nonparametric statistics were used. A P value < .05 was considered to indicate statistical significance. Statistical analyses were performed using SPSS (version 10.0 for Windows).

Results

Patient Characteristics

Of the 678 patients included in the trial, 56 patients dropped out and 26 patients failed to complete the questionnaires at the 3-month follow-up. The data of 8 patients could not be used in this analysis because follow-up questionnaires were not interpretable. Descriptive baseline characteristics of the included patients are listed in Table 1. Baseline pain was not related to age (Spearman $r = 0.026$; $P = .551$). Women tended to report greater pain intensity during eating than men, although the difference was not significant (50.6 ± 22.4 versus 47.8 ± 17.2 mm, $P = .387$). Patients with longer pain duration did not report greater pain intensity during eating (Spearman $r = 0.045$, $P = .310$).

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Table 2 Mean Change in Pain on the VAS-PI at 3-Month Follow-up Associated with Categories on Pain-Perceived Rating of Change (n = 588)

	Absolute change (mean ± SD)	% Change (mean ± SD)
Much improved (n = 250)	–39.2 ± 18.6*‡	–69.8 ± 23.0†§
Slightly improved (n = 193)	–10.7 ± 5.1*‡	–22.3 ± 11.6†§
No response (n = 145)	10.2 ± 13.1*	22.4 ± 31.6†
No change (n = 73)	–0.8 ± 2.8‡	–2.4 ± 3.5§
Slightly worsened (n = 27)	12.4 ± 6.6‡	27.7 ± 18.8§
Much worse (n = 45)	26.8 ± 6.1‡	59.4 ± 24.6§

* One-way ANOVA; F = 599.83, $P < .001$ (Bonferroni correction).
† One-way ANOVA; F = 778.77, $P < .001$ (Bonferroni correction).
‡ One-way ANOVA; F = 399.35, $P < .001$ (Bonferroni correction).
§ One-way ANOVA; F = 682.31, $P < .001$ (Bonferroni correction).

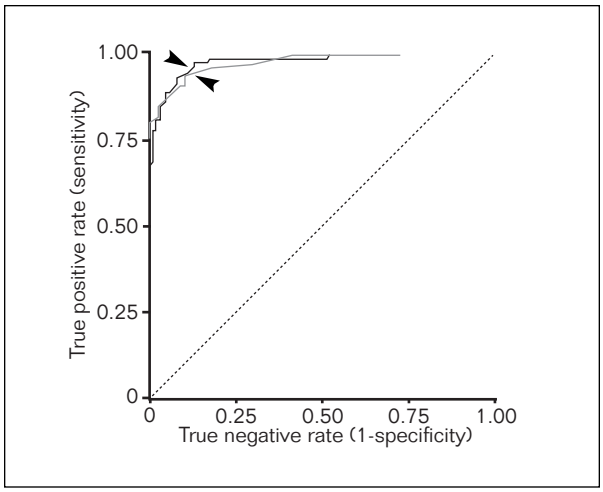

Fig 1 ROC curve illustrating relationship between sensitivity and complement of specificity (100-specificity) for raw (straight line) and percent change (dotted line) in VAS-PI at 3-month follow-up, using "much improved" as external indicator. The AUC in this setting can be interpreted as the probability of correctly identifying the "clinically important improved" patients from "nonclinically important improved." A line that runs diagonally across the figure from lower left to upper right will have an AUC of 0.5; this represents an instrument that does not discriminate. The arrowheads on curve show optimal cut-off points (–19.5 and –37.9%), corresponding with the maximum sum of sensitivity and specificity.

Patient's Global Impression of Change

ANOVAs showed that absolute and percent change scores on the VAS-PI were significantly different between groups based on the patients' ratings of change (Table 2). Both absolute and percent change scores were significantly different between much improved patients and slightly improved, unchanged, slightly worsened, or much worsened patients ($P < .001$). Statistically significant changes were found in absolute and percent change scores between the "much improved," "slightly improved," and "no response to therapy" group ($P < .001$), respectively. The association between patient-perceived ratings of change and actual change scores was supported by high correlations for absolute (Spearman $r = –0.91$, $P < .001$) and percent changes (Spearman $r = –0.92$, $P < .001$), respectively.

Clinically Important Change on the VAS-PI

Figure 1 presents the ROC curves for absolute and percent change on the VAS-PI at the 3-month follow-up, associated with patients' ratings of "much improved." Both raw and percent change scores had good diagnostic power in identifying much improved patients, with AUCs of 0.974 (95% confidence interval [CI]: 0.97–0.99, $P < .0001$) and 0.980 (95% CI: 0.970–0.990, $P < .0001$), respectively. The optimal cut-off point for an absolute change in pain was –19.5 mm, corresponding to a sensitivity of 0.93 (95% CI: 0.89–0.96) and specificity of 0.92 (95% CI: 0.88–0.94). The best cut-off for percent change from baseline was –37.9%, with a sensitivity of 0.97 (95% CI: 0.94–0.99) and a specificity of 0.89 (95% CI: 0.85–0.92) (Table 3). For VAS changes best associated with "slightly or much improved," a raw change of –4.5 (AUC: 0.995, 95% CI: 0.992–0.998, $P < .0001$) and percent change of –6% (AUC: 0.998, 95% CI: 0.996–1.000, $P < .0001$) were shown. The AUCs for the VAS-PI raw and percent change scores were nearly identical (Wilcoxon signed ranks test, $P > .05$).

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Table 3 Analysis for Both Raw Change and Percent Change in VAS-PI Score Best Associated with Two Definitions of CIC (n = 588)

VAS score type/ categorical descriptor of pain	AUC ± SEM (95% CI)	Change (optimal cut-off points)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
Raw change				
Much improved	0.974 ± 0.005 (0.967–0.987)	–19.5	0.93 (0.89–0.96)	0.92 (0.88–0.94)
Slightly or much improved	0.995 ± 0.002 (0.992–0.998)	–4.5	0.97 (0.95–0.99)	0.97 (0.92–0.99)
Percent change				
Much improved	0.980 ± 0.005 (0.970–0.990)	–37.9	0.97 (0.94–0.99)	0.89 (0.85–0.92)
Slightly or much improved	0.998 ± 0.001 (0.996–1.000)	–6.0	0.99 (0.99–1.00)	0.98 (0.92–0.99)

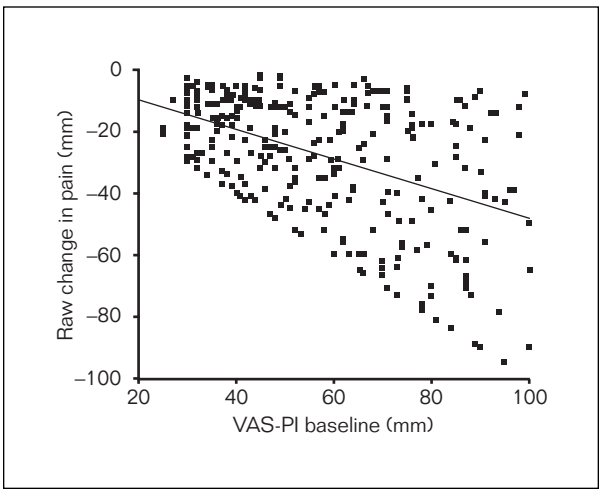

Fig 2 Scatter plot of raw change in pain in slightly to much improved patients related to baseline pain intensity (n = 443). The straight line represents the linear regression line through the data points (r^2 = 0.23, P < .001), demonstrating the dependency of CIC on baseline pain.

Consistency of VAS-PI Change Scores Over Groups of Patients

The results from the ROC analyses indicated that percent change scores performed slightly better in identifying much improved patients than absolute change scores. This dependency of CIC on baseline pain was confirmed by analysis of the change scores of slightly or much improved patients (n = 443). The relation between absolute change in pain and baseline pain is illustrated in Fig 2. Patients with high baseline pain required greater absolute reductions in pain to reach slightly or much improvement (Spearman r = –0.401, P < .001), while patient's baseline pain ratings were not related to percent change scores (Spearman r = 0.045, P = .348). The magnitude of both absolute and percent change in pain was not related to age or pain duration (Spearman rank correlation test, P > .05).

Discussion

A novel approach, at least in the TMD literature, in establishing cut-off points associated with clinically important changes in VAS-PI scores was used in this study. The CIC represents a preliminary step in the development of clinical criteria that may be used to assess potential differences between the beneficial effects of therapeutic interventions. The size of the CIC for improvement of 37.9% of the baseline scores may be comparable and consistent with the clinically important changes determined in other studies. Using the same methodology, several authors addressed a similar question using the NRS. In an extensive analysis from 10 completed placebo-controlled clinical trials of chronic pain, Farrar et al concluded that a reduction of two points or a reduction of approximately 30% in the 0 to 10 PI-NRS represented a clinically important difference.[25] In another study of chronic musculoskeletal patients conducted by Salaffi et al, a reduction of approximately two points or a reduction of 33% of the NRS pain scores from baseline was associated with the highest degree of improvement on the PGIC

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category ("much better"). These cut-off points had excellent accuracy and were judged appropriate for use in the interpretation of clinical studies' results, as well as in clinical care and in the design and analysis of future clinical trials of chronic musculoskeletal pain therapy.[30] Furthermore, the values were consistent with the recommendations of the Outcome Measurement in Rheumatoid Arthritis Clinical Trials study group. In their report, a 36% change in pain score was shown to be best associated with the expert's opinion that the improvement had been clinically important.[31]

In the present study, the interaction between baseline pain scores and magnitude of the CIC was investigated. The data suggest that patients with higher levels of pain might identify greater reductions in VAS-PI scores as clinically meaningful than would patients with lower levels of pain. These results are consistent with those of other authors using the VAS and NRS pain scores to investigate minimal important changes. Todd found a mean minimal important change of –13 mm in VAS pain scores, while patients with baseline VAS scores between 34 and 66 mm described a minimal important change of –17 mm, and those with a baseline VAS score of ≥ 67 mm a minimal important change of –28 mm.[14] Bird and Dickson observed that –19 mm represented the mean minimal important change in VAS pain scores, whereas for patients with pain scores between 67 and 100 mm, a minimum difference of –28 mm was needed for a perceptible change in pain severity.[13] In addition, Farrar et al and Salaffi et al found that higher baseline scores required larger raw changes in NRS pain scores to represent a clinically important difference.[25,30] This difference of the change in pain perception on the basis of the amount of baseline pain confirms the idea that patients with high baseline pain need larger reductions in pain to consider themselves improved. The ROC analyses also indicate that the diagnostic accuracy of the VAS-PI in discriminating between "clinically important improved" and "nonclinically important improved" patients increases when change scores are expressed as a percent change from baseline. Thus, CIC may be best represented as a percent change from baseline.

The definition of CIC does not imply a straightforward classification. The classification the present study used of "nonclinically important improved" patients, including both "slightly improved" and "no response to therapy" patients, may be seen as relatively arbitrary. However, changes in pain may need to exceed the cut-offs defined by investigators to be considered "minimal detectable responses." Concepts for patient-perceived, relevant improvements on the VAS-PI, defined as "adequate pain treatment,"[32] "important improvement or recovery,"[33] or "considerable improvement,"[34] support this assumption. As such, the cut-off for important improvement seems to answer the growing need for definite, relevant response criteria as opposed to minimal detectable responses.[35,36]

The knowledge of the CIC is necessary for sample size calculations of trials designed to show improved efficacy, and it is also useful to clinicians in interpreting the effect of treatment in an individual patient.[10,11] Although the study included chronic pain patients with a TMD diagnosis of arthralgia associated with myofascial pain, these results may not generalize to all chronic pain syndromes. In addition, extrapolation of these findings to studies with periods of observation longer than 12 weeks, especially long-term studies, should be undertaken with caution. Beside baseline pain scores, other components such as the duration and frequency of pain and the patient's response to pain are known to influence their perception of overall improvement. There is a growing amount of evidence to suggest that comorbidity of pain-associated disability and psychological variables such as anxiety and depression, in connection with sociodemographic variables, may be an indicator for more severe pain behavior, which has a central role in the chronification of pain processes.[37] In this study, these other factors were not evaluated, but the high degree of relationship between change in VAS-PI score and the PGIC strongly supports the concept that pain intensity is a major component of the patient's global response.[38]

The application of the PGIC scale as an external criterion has been criticized by Just et al.[39] The authors have questioned the validity of this measure, especially in the presence of significant psychiatric overlay. Although the PGIC is usually applied as a relevant response criteria and for comparison to other outcome measures,[31,40–42] it may not be perfect as a gold standard, but this should not become a barrier for ongoing research in determining CIC. This study presents an investigation into meaningful changes in pain from the patient's perspective that combines the strengths of both the PGIC and the CIC.

Another issue concerns the generalizability of the findings. In the current sample, only patients who were managed with nonsurgical management for TMD pain were included. The relatively chronic nature of their pain condition may have influenced patients' ratings of their pain and improvement. To determine the generalizability of

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the study, the findings should be confirmed in different clinical settings. Moreover, the magnitude of CIC may very well differ for other outcome domains, such as physical functioning, global health status, or quality of life. Since the procedures for assessing CIC can be applied to all patient-reported outcomes, meaningful improvements from the patient's perspective can also be determined for these outcome domains.

Another concern is the exclusive focus on patients with a RDC/TMD diagnosis of arthralgia associated with myofascial pain. The patients were referred from general practitioners or dentists and, therefore, were prone to be those who really are in need for specialist care. However, although the study population may be fairly representative of the average case-mix of primary care patients with chronic TMD pain, these results may not generalize to all chronic TMD pain syndromes. Other populations with TMD pain may have different patient profiles and, consequently, may differ in their global impression of change. Further research on this topic is warranted.

Finally, no attempt was made to standardize the time of pain assessment, ie, define the "reference period," to compensate for fluctuating pain levels which may have had an effect on the assessment of pain. Further, patients have to be able to recall their initial state and compare this with their current state to be able to judge the change in pain intensity, which may introduce bias. To address this isssue, Wassell et al[38] used daily diaries of VAS-PI to separate "nonimprovers" from "improvers." In this study, visual assessment of VAS pain/time plots showed distinct pain/time patterns that could validate a numeric definition of complex pain recovery.

In conclusion, providing a standard definition of the CIC adds to the interpretability of study results. As absolute changes in pain associated with CIC were highly dependent on baseline pain, percent change scores may perform better in classifying improved patients.

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