Comparison of Axis II psychosocial assessment methods of RDC/TMD and DC/TMD as part of DC/TMD-FIN phase II validation studies in tertiary care Finnish TMD pain patients

Running title: Comparing RDC/TMD and DC/TMD Axis II criteria

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Abstract

Background. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) and Diagnostic Criteria for TMD (DC/TMD) include Axis II instruments for psychosocial assessment.

Objectives. The aims were to compare the Finnish versions of Axis II psychosocial assessment methods of the RDC/TMD and DC/TMD and to study their internal reliability.

Methods. The sample comprised 197 tertiary care referral TMD pain patients. The associations between RDC/TMD [Graded Chronic Pain Scale (GCPS) 1.0, Symptom Check List 90-revised (SCL-90R)] and DC/TMD (GCPS 2.0, Patient Health Questionnaire-9 (PHQ-9), PHQ-15) assessment instruments were evaluated using Spearman correlation coefficients,Wilcoxon Signed Rank test, χ^2 test and gamma statistics. The internal reliability and internal inter-item consistency of SCL-90-R, PHQ-9, PHQ-15 and Generalized Anxiety Disorder-7 (GAD-7) were evaluated using Cronbach's alpha coefficient values.

Results. The DC/TMD and RDC/TMD Axis II psychosocial instruments correlated strongly ($p<0.001$). GCPS 1.0 and GCPS 2.0 grades were similarly distributed based on both criteria. The RDC/TMD psychological instruments had a higher tendency to subclassify patients with more severe symptoms of depression and non-specific physical symptoms compared to DC/TMD. The internal reliability and internal inter-item consistency were high for the psychological assessment instruments.

Conclusion. The Finnish versions of the RDC/TMD and DC/TMD Axis II psychosocial instruments correlated strongly among tertiary care TMD pain patients. Furthermore, the Axis II psychological assessment instruments indicated high validity and internal inter-item consistency and are applicable in Finnish TMD pain patients as part of other comprehensive specialist level assessments, but further psychometric and cut-off evaluations are still needed.

Introduction

Temporomandibular disorders (TMDs) are a general term for various clinical signs and symptoms involving the temporomandibular joints (TMJs), masticatory muscles, and associated structures[1]. TMDs are the most common cause of facial pain, affecting approximately 5–12% of the population[1].

The TMD population is heterogeneous and TMD patients differ in their biopsychosocial profiles[2]. Biopsychosocial as well as genetic and environmental factors influence the onset and persistence of TMD[3-5]. Psychological factors, such as symptoms of depression and somatization, as well as psychosocial stress and distress associate with TMD and TMD pain interference[6-12]. Studies have also shown a remarkable prevalence of depression and non-specific physical symptoms among TMD patients (39–75% and 48–77%, respectively)[7.13-14]. Patients with higher TMD pain-related interference/disability have reported significantly higher levels of depression and somatization, worry and poorer coping ability compared to patients with lower levels of pain interference[15].

Adding biobehavioral and biopsychosocial domains to the comprehensive assessment of TMD was noted to be important; this included the assessment of various psychosocial illness impact factors in TMD pain patients[8,16]. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), published in 1992, offered the first standardized system for the TMD researchers for examining, diagnosing, and classifying TMD with biological (Axis I) as well as psychosocial (Axis II) assessment methods[17]. Later on, the international TMD scientific community developed new RDC/TMD-based diagnostic criteria for the screening and comprehensive assessment of TMD: The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)[18]. The DC/TMD criteria provide

international, consistent and valid methods for TMD patient assessments and are suitable for both clinical and research settings[18].

In order to bring the biopsychosocial domain to the comprehensive assessment of TMD, both RDC/TMD and DC/TMD consist of Axis I and Axis II. Axis I involves standardized clinical procedures for establishing TMD clinical diagnoses while Axis II concerns self-report questionnaires assessing especially the pain-related psychosocial and psychological impact of TMD[17-18]. In RDC/TMD, the Axis II protocol includes the following psychosocial factors: pain intensity and pain-related interference (Graded Chronic Pain Scale, GCPS 1.0), depression, and non-specific physical symptoms with or without pain items included (based on the Symptom Check List 90-revised, SCL-90-R)[17,19-20]. The depression scale assesses negative mood, and the non-specific physical symptoms include various complaints of cardiovascular, gastrointestinal, respiratory, and other autonomic systems, reflecting distress aroused by bodily perceptions[17]. In DC/TMD, the Axis II comprehensive protocol includes the following psychosocial factors: pain intensity and pain-related interference (GCPS 2.0) and questionnaires assessing depression symptoms (Patient Health Questionnaire, PHQ-9), anxiety symptoms (Generalized Anxiety Disorder-7, GAD-7) and non-specific physical symptoms (PHQ-15)[18].

The diagnostic validity of the RDC/TMD Axis I protocol has been assessed by Schiffman et al.[21]. Based on Axis II validation projects, the measures for GCPS 1.0 and Axis II psychological instruments (depression and nonspecific physical symptoms)[22-23] were shown to be reliable and valid. In addition, the GCPS questionnaire has been found to be a valid method for assessing the global severity and chronicity of pain and the functional disabilities associated with pain[6,13-14,19,24]. However, some differences have been revealed between RDC/TMD and DC/TMD Axis II scores, as

it has been shown that RDC/TMD subclassified patients more often with severe depression and non-specific physical symptoms compared to DC/TMD[25].

The introduction of DC/TMD criteria for surveys in other linguistic and cultural contexts requires 2-step validation of the methods. The first step comprises a multi-stage, RDC/TMD-consortium-led and accurate translation process protocol[26]. The Phase I translation process of DC/TMD-FIN included two forward translations, consolidated translation, external independent back translation, expert Finnish panel review and independent external International Consortium review and was approved by the International Network for Orofacial Pain And Related Disorders Methodology (INfORM) (previously The International RDC/TMD Consortium Network) as one of the first five translations in 2015[27]. The second step involves evaluation of the properties and usability in the new linguistic and cultural environment of the 14 different questionnaires translated. This study forms part of the Phase II validation work of the psychosocial and psychological Finnish DC/TMD Axis II questionnaires according to the International consortium guidelines[26].

The aim of this study was to compare the Finnish versions of the Axis II psychosocial and psychological assessment methods of the RDC/TMD and DC/TMD criteria, mainly pain intensity/interference scores (GCPS 1.0 and 2.0, grades I-IV) and levels of depression symptoms (SCL-90R and PHQ-9) and non-specific physical symptoms (SCL-90R and PHQ-15) in Finnish TMD patients referred for treatment in specialist/tertiary care. The aim was also to study the internal reliability of psychological assessment instruments in RDC/TMD and in DC/TMD. The hypothesis of the study is that the psychosocial Axis II assessment methods of the DC/TMD criteria are valid and reliable and comparable to the RDC/TMD methods.

Material and methods

Altogether 197 TMD pain patients, referred for TMD treatment in tertiary specialist care facial pain clinics in Helsinki University Hospital, Kuopio University Hospital, Oulu University Hospital, and Turku University Hospital, Finland, between July 2015 and March 2019, participated in this study. All patients had clinically diagnosed TMD and were aged 17 years or older.

Participation in the study was voluntary and the subjects provided written consent. The Ethics Committee of the Hospital District of Southwest Finland has approved the study (74/1082/2015).

Before the implementation of the study, the Finnish versions of the DC/TMD Symptom Questionnaire, Axis I protocol, and all the Axis II instruments underwent a comprehensive translation process by the International RDC/TMD Consortium according to the Guidelines for Establishing Cultural equivalency of Instruments[26-27]. Accordingly, the team leaders and an external expert review panel, including four Orofacial pain/TMD experts, reviewed the pre-final translations and made recommendations based on the independent external back translation reviews. The consolidated and corrected translations were reviewed by the INfORM consortium prior to this study.

Axis I clinical diagnostics

The clinical Axis I diagnostics was based on the Symptom Questionnaire, the DC/TMD standardized clinical examination protocol and Axis I decision trees and the diagnostic criteria table (DC/TMD-FIN; www.rdc-tmdinternational.org/DC-TMD). The diagnoses included TMD pain-related diagnoses (myalgia, myofascial pain, arthralgia, TMD-related headache) and intra-articular TMJ disorders. Multiple diagnoses were allowed.

The clinical stomatognathic examination was performed according to the protocol by Axis I of the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)[18,28]. The Axis II evaluations and Axis I examinations were performed by the authors PK, RN, KS, and TT-O, who had earlier been calibrated against a reference standard examiner and participated in the three-day reliability training course according to the DC/TMD examiner training protocol in line with the INfORM Consortium guidelines[26,28,29]. Myofascial pain with referral, headache attributed to TMD, and disc displacement without reduction without limited opening showed excellent kappa values (range 0.87–1.00). Fair-to-good reliability was observed for diagnoses of myalgia (k = 0.67), arthralgia (k = 0.71), and disc displacement with reduction (k = 0.64)[29].

Axis II Instruments

The patients were given the questionnaires to be filled in at home, and they were assessed for accuracy with the treating clinicians at the first assessment visit.

1. RDC/TMD-FIN Axis II questionnaires

The RDC/TMD-FIN Axis II questionnaires included the assessment of TMD pain intensity/interference using GCPS 1.0 and the assessment of depression symptoms and nonspecific physical symptoms with and without pain items using SCL-90-R [30].

The RDC/TMD-FIN GCPS 1.0-questionnaire assessed patient-based reports of TMD pain intensity and pain-related interference/disability in three domains during the past 6 months by the questions:

a) CPI score (characteristic pain intensity, range 0-100) (current, worst, average) (range 0–10, 0=no pain, 10=worst pain) (scaled as mean value*10, maximum 100);

b) disability days score (range 0–180 days; 0–3 points), is categorized as follows: 0–6 days = 0 disability days points; 7–14 days = 1 disability days point; 15–30 days = 2 disability days points; 31+ days = 3 disability days points), and

c) disability score by pain interference (range 0–100; 0–3 points) with daily, social and work-related activities (range 0–10, 0=no interference, 10=unable to carry on any activities) (scaled as mean value*10, maximum 100) (score of 0–29 = 0 pain-related activity interference points; score of 30–49 = 1 point; score of 50–69 = 2 points, score of 70+ = 3 points)

The total count of pain interference/disability points (range 0–6 points) towards GCPS 1.0 grading is based on the sum of points for disability days + points for disability score.

With the RDC/TMD-FIN SCL-90-R questionnaires, patients reported how much they had suffered (range 0–4, 0=not at all, 4=very much) during the last month from symptoms of depression and non-specific physical symptoms with or without pain items. Mean, median and 95% confidence interval (95% CI) of the sum scores were calculated and patients were classified based on Dworkin & LeResche 1992[17]. Raw mean scale score was computed by adding up the item score for all items answered and dividing by the number of items answered. If less than two thirds of the items were answered, the scale score was set to missing.

1) symptoms of depression (20 questions) were classified as normal <0.535/moderate <0.535 to <1.105 /severe 1.105 +,

2) non-specific physical symptoms (including pain items) (12 questions) were classified as normal <0.500/moderate <0.500 to <1.000 /severe 1.000 +, and

3) non-specific physical symptoms (without pain items) (7 questions) were classified as normal <0.482/moderate <0.428 to <0.857/severe 0.857 +

2. DC/TMD-FIN Axis II questionnaires

The DC/TMD- FIN questionnaires included the sociodemographic background data. For the analysis, marital status was dichotomized as married/cohabiting vs. single (divorced, separated, widowed or never married). Level of education was dichotomized as lower (basic education/high school/vocational school) vs. higher (university of applied sciences/university/master of arts). Working status was dichotomized as employed (working outside home/at home) vs. unemployed (unemployed/student/retired/on disability/retired due to sickness/sick leave/in rehabilitation).

The DC/TMD-FIN Axis II questionnaires included the TMD pain intensity/interference assessment using GCPS 2.0, symptoms of depression (PHQ-9), anxiety (GAD-7) and physical symptoms (PHQ-15)[27].

The DC/TMD GCPS 2.0 questionnaire assessed patient-based reports of TMD pain intensity and pain-related interference/disability based in four domains (three domains (b, c and d) are assessed during the past 30 days) measured by the questions:

a) pain days during the past 6 months (range 0–180 days)

b) CPI score (range 0-100) (current pain, worst pain, average pain) (range 0–10, 0=no pain, 10=worst pain) (CPI, mean value*10, maximum 100);

c) disability days score (range 0–30 days; 0–3 points), categorized as follows: 0–1 days (score 1) = 0 disability days points; 2 days (score 2) = 1 disability days point; 3–5 days (score 3–5) = 2 disability days points; 6+ days (score 6+) = 3 disability days points.

d) disability score by pain interference (range 0–100; 0–3 points) with daily, social and work-related activities (range 0–10, 0=no interference, 10=unable to carry on any activities), scaled to mean value*10, maximum 100, and categorized as: 0–29=0 pain-related activity interference points; 30–49=1 point; 50–69=2 points, 70 and above=3 points).

The total count of pain interference/disability points (range 0–6) towards GCPS 2.0 grading is based on the sum of points for disability days + points for disability scores.

With the DC/TMD-FIN, the patients reported how much they had suffered from various symptoms of

a) depression (PHQ-9-FIN, 9 questions, range 0–3, where 0 is 'not at all' and 3 'nearly every day') during the past 2 weeks; sum score classified as: ≥ 5 mild depression, ≥ 10 moderate depression, ≥ 15 moderate-severe depression, and ≥ 20 severe depression (Schiffman et al. 2014)[18].

b) physical symptoms (PHQ-15-FIN, 15 questions, range 0–2, where 0 is 'not bothered' and 2 'bothered a lot during the past 4 weeks'), sum score classified as: ≥ 5 low symptom severity, ≥ 10 medium symptom severity, ≥ 15 high symptom severity[18].

b) anxiety (GAD-7-FIN, 7 questions, range 0–3, where 0 is 'not at all' and 3 'nearly every day') during the last 2 weeks; sum score classified as: ≥ 5 mild anxiety, ≥10 moderate anxiety, ≥ 15 severe anxiety)[18].

In depression, anxiety and physical symptoms sum scores, missing values were replaced with the mean value of other items. The response was considered as missing for the instrument if there were missing values for more items than the following limits: GCPS 1.0 and GCPS 2.0; CPI 0 items, pain-related activity interference: 1 item, RDC/TMD depression: 8 items, somatization with pain: 4 items, somatization without pain: 2 items, PHQ-9: 3 items, PHQ-15: 5 items, GAD-7: 2 items.

According to the GCPS 1.0 and 2.0, the grades were determined as follows according to Dworkin and LeResche[17] and Ohrbach and Knibbe[31]:

GCPS grade I: low intensity pain (CPI <50) and without or with low disability (0–2 disability points)

GCPS grade II: high intensity pain (CPI ≥50) and without or with low disability (0–2 disability points)

GCPS grade III: 3–4 disability points regardless of CPI value (determined as high disability-moderately limiting)

GCPS grade IV: 5–6 disability points regardless of CPI value (determined as high disability-severely limiting).

Statistical analysis

The demographic data and DC/TMD Axis I diagnoses were compared between genders using χ^2 and Mann-Whitney U tests. CPI, pain interference, disability days (DD), disability points and GCPS grades were compared between the two measurements, GCPS 1.0 (RDC/TMD) and GCPS 2.0 (DC/TMD), using Spearman correlations and Wilcoxon Signed Rank test. Testing was performed separately for original values and categorized points.

Cronbach's alpha coefficient values were used to evaluate the internal reliability and internal inter-item consistency for the psychological assessment instruments, and their associations between RDC/TMD and DC/TMD criteria were evaluated using Spearman correlation coefficients in continuous scales and cross tabulations, χ^2 test and gamma statistics in ordinal variables. Analyses were conducted using SPSS 25.0 and $p<0.05$ was considered statistically significant.

RESULTS

Demographic data and Axis I diagnoses

The sociodemographic background information and DC/TMD Axis I sub-diagnoses as well as the total number of pain-related diagnoses and joint disorders by gender are presented in Table 1. The mean age of the patients was 43.3 years (SD 16.7, range 17 to 83 years) and the majority were women (n=158, 80%). The majority of the patients were married/cohabiting and had lower education. There were no significant gender-related differences in the sociodemographic background.

The total number of Axis I pain-related diagnoses was higher than the number of joint disorders. Myalgia and arthralgia were the most prevalent sub-diagnoses. Women showed significantly higher prevalence of arthralgia diagnoses as compared to men. The mean number of all Axis I diagnoses was 2.90. Overall, the majority of the study sample subjects had at least two different TMD pain-related diagnoses or two combined TMD pain-related diagnoses and joint disorders.

Comparison of GCPS 1.0 and GCPS 2.0 Axis II instruments in RDC/TMD and DC/TMD

When comparing the GCPS scoring items between RDC/TMD and DC/TMD, the items were strongly correlated (Spearman correlation coefficients, $p<0.001$ for all), but the scores were higher in CPI and in pain-related interference in GCPS 1.0 than in GCPS 2.0 (Wilcoxon signed-rank test) (Table 2).

The distribution of GCPS scoring items and grading details are presented in Table 3. Significant differences in distributions between GCPS 1.0 and 2.0 were seen in CPI, pain interference and DD points (in CPI and pain interference, GCPS 1.0 categorized more patients to the most severe group compared to GCPS 2.0, whilst in DD points, GCPS 2.0 categorized more patients to the most severe group compared to GCPS 1.0).

Total Disability Points (based on pain interference and disability days points) were similarly distributed with no statistical difference based on both GCPS 1.0 and GCPS 2.0 (Table 3). The distributions of patients in GCPS 1.0 and GCPS 2.0 grades were also similar between both versions. Approximately 40% of the patients were classified in GCPS grades III and IV based on both GCPS 1.0 and GCPS 2.0.

Comparison of Psychological Axis II assessments (depression and non-specific physical symptoms) according to RDC/TMD vs. DC/TMD

Cronbach's alpha coefficient values indicated high internal reliability and good internal inter-item consistency for the psychological assessment instruments used in the present study sample. The internal reliability values of the RDC/TMD SCL-90R instruments were 0.93 on depression, 0.87 on non-specific physical symptoms with pain items and 0.83 on non-specific physical symptoms without pain items. Similarly, the internal reliabilities of the DC/TMD instruments were 0.85 on PHQ-9, 0.81 on PHQ-15, and 0.91 on GAD-7.

The distributions of depression and non-specific physical symptom instrument sum scores based on both RDC/TMD and DC/TMD are presented in Table 4. Depression scales in both RDC/TMD and DC/TMD were strongly correlated ($r=0.844$, $p<0.001$), as were PHQ-15 and SCL-90R non-specific physical symptoms, both with ($r=0.806$, $p<0.001$) and without ($r=0.728$, $p<0.001$) pain items.

The distribution of patients into different severity subcategories (based on the original cut-off-ranges[17,18]) of depression and non-specific physical symptoms assessments according to RDC/TMD vs DC/TMD is presented in Table 5. RDC/TMD instruments showed significantly higher frequencies in the most severe subcategories in both depression and non-specific physical symptom assessments compared to DC/TMD instruments (as 49% and 24% of the same patients were misclassified as "normal or low" in DC/TMD subcategories, respectively; Table 5). The distribution of patients into different severity subcategories of anxiety according to GAD-7 was as follows; 112 (58.6%) patients were subclassified in "no", 49 (25.7%) in "mild", 17 (8.9%) in "moderate", and 13 (6.8%) in "severe" subcategory.

The associations and severity distributions of depression and non-specific physical symptoms subcategories between DC/TMD and RDC/TMD criteria and anxiety are presented in Table 5 and in Figure 1. The original cut-offs of the RDC/TMD criteria[17] subclassified patients into higher subcategories of depression and also into higher non-specific physical symptoms subcategories when compared with the original cut-offs of the DC/TMD criteria[18].

DISCUSSION

The study evaluated the distribution and correlation of psychosocial and psychological assessment values as well as the internal reliability of the RDC/TMD-FIN and DC/TMD-FIN Axis II psychological

instruments in TMD pain patients referred to tertiary specialist care. Specifically, this study focused on RDC/TMD-FIN and DC/TMD-FIN assessments of the grading of chronic pain severity, i.e. pain intensity and pain-related disability (GCPS 1.0 and GCPS 2.0, respectively) and the assessments of depression symptoms (SCL-90R and PHQ-9, respectively) and non-specific physical symptoms (SCL-90R with and without pain items in RDC/TMD, PHQ-15 in DC/TMD). The present study forms one part of the validation research (stage 16[26]) in Phase II field tests for establishing cultural equivalency of the translated Finnish versions of the DC/TMD Axis II psychosocial instruments using a sample of Finnish TMD pain patients in tertiary care. The number of patients has been established to be approximately 200 per setting based on the guidelines by the INfORM[26].

The present study showed that the Finnish versions of the psychosocial assessment methods (GCPS pain intensity/disability) of the RDC/TMD and DC/TMD Axis II instruments correlated strongly in TMD pain patients referred for assessment and treatment in specialist/tertiary care. The distributions of GCPS 1.0 and 2.0 grades in this study sample were relatively similar. Although the scores of pain intensity (CPI) and pain-related interference showed higher values in GCPS 1.0 compared to GCPS 2.0, the scoring points of disability days (based on the number of disability days) were higher based on GCPS 2.0 than on GCPS 1.0. These differences may be due to the different time frames used in GCPS 1.0 and GCPS 2.0 (6 months vs. 30 days, respectively). Whilst a 6-month evaluation period may give more information about pain intensity/interference over a longer time period, the shorter 1-month timeframe has been stated to be more reasonable to assess the ongoing pain status[31].

Based on GCPS 1.0, the distribution of TMD patients into different grades has been presented previously in several studies[6,13-15,24], but due to DC/TMD still being a relatively new protocol[18],

there is so far a very limited amount of previous literature on GCPS 2.0. A comparison of GCPS 1.0 and 2.0 was conducted in the Israeli study by Reiter et al.[25] based on samples of TMD patients in the Orofacial Pain Clinic, assessed according to the RDC/TMD for 142 patients and according to the DC/TMD for 157 patients. No significant differences were reported between the distribution of grades of GCPS 1.0 and GCPS 2.0, which is in accordance with the present study.

There are only a few earlier studies investigating the DC/TMD psychological assessment instruments (PHQ-9, GAD-7, PHQ-15) in TMD patients[25,32,33]. In the present study, non-specific physical/somatic symptoms assessments (PHQ-15 vs. SCL-90R) showed strong correlation between RDC/TMD and DC/TMD criteria, although the symptoms were subclassified as more severe according to the original RDC/TMD cut-offs in comparison with the original DC/TMD cut-offs[17,18,31]. The results are in accordance with Reiter et al.[25], who also compared RDC/TMD and DC/TMD in Israeli patients, and with Su et al.[32], who evaluated Dutch TMD patients using DC/TMD, although larger variation appeared regarding the non-specific physical symptoms in Reiter et al.[25] than in the present study or in Su et al.[32]. The variation might be due to the differences in the study samples as well as in cultural background. In the present Finnish study, the same patient sample was assessed by both RDC/TMD and DC/TMD, whereas the Israeli study[25] used two study samples, separate ones for RDC/TMD and DC/TMD. In general, the PHQ-15 instrument included in the DC/TMD criteria has shown to have good reliability and high validity to detect patients with severe somatic symptoms[18,34], and PHQ-15 has also been used as a screening instrument for non-specific somatic symptoms in Chinese patients in tertiary hospital[35] and primary care in the Netherlands[36], as well as with psychiatric outpatients in South Korea[37] and in Swedish population normative data[38].

In terms of clinical utility, the interpretation of the use of cut-offs cannot be made based on this study. Using both DC/TMD and RDC/TMD Axis II psychological assessment instruments, no or mild depression symptoms seemed to be quite consistently detected, as the "normal" subscale based on RDC/TMD SCL-90-R corresponded well to either the "normal" or "mild" depression symptoms based on PHQ-9. However, the more severe subcategories were more often misclassified, as the majority (88%) of the patients in "moderate" depression subscale based on RDC/TMD were classified as "no" or "mild", based on PHQ-9. Further, even half of the patients in "severe" subscale based on RDC/TMD were classified as "no" or "mild" based on PHQ-9. The subscales for non-specific physical symptoms showed better matching, except in the most severe subcategories, as 24% of those classified as "severe" based on RDC/TMD were subclassified as "low" based on PHQ-15.

Depression instruments showed strong correlation between RDC/TMD and DC/TMD criteria, although SCL-90R in RDC/TMD subclassified patients more easily to severe depression subcategories compared to PHQ-9 in DC/TMD, which is in accordance with the study by Reiter et al.[25]. In addition, the distributions of PHQ-9 presented by Su et al.[32] were similar with the present study results; in both of these studies, moderate depression symptoms were expressed by approximately a tenth of the patients and severe depression symptoms by less than a tenth. The differences may be at least partly due to the different questions and subcategories in the cut-offs as well as a different timeframe. The items of SCL-90-R are scored during the time period of one month on a five-point Likert scale, while PHQ-9 includes a time period of two weeks on a four-point Likert scale.

In the Finnish population, the Finnish version of the SCL-90 has indicated its reliability as a psychiatric screening instrument[39], although it should be noted that the Finnish community

sample scored consistently higher than the American community on all subscales, and the normative scores should therefore be used with caution[39]. No normative data on the distribution of PHQ-9 exist in the Finnish population, which is why no comparisons can be made between general population data and the findings in the present study. However, PHQ-9 has been indicated in other studies to be valid for e.g. screening depression in normal adult populations[40] as well as in rheumatoid arthritis patients[41] and in psychiatric clinical settings[42].

In PHQ-9, the present study used the cut-off scores set by the INfORM[31] similarly as in the study of Reiter et al. (2017)[25]. It has been shown that the original English-language version of PHQ-9 has high sensitivity (88%) and specificity (88%) at a cut-off score of 9 to detect major depressive disorder when compared with a structured psychiatric interview[43], whereas the SCL—90-R has shown poor assessment efficacy for most of the subscales in Norwegian patients[44]. It should be noticed that the original English PHQ-9 used in DC/TMD has been adapted from the Primary Care Evaluation of Mental Disorders (PRIME-MD) and it is a validated tool in mental health for assessment of depressive symptoms[43]. The nine items of the PHQ-9 are based directly on the nine diagnostic criteria for major depressive disorder in the DSM-IV[43]. Thus, choosing other than the PRIME-MD instruments, which are included in DC/TMD, might result in lack of comparability with other DC/TMD study settings, which might again significantly limit the implementation and comparative evaluations of the DC/TMD. However, further studies, especially inter-culturally, are still needed regarding the suitability of the original English cut-off ranges of the PHQ-9 and PHQ-15 PRIME-MD instruments in other languages.

Anxiety has proven to be among the biopsychosocial risk factors in the persistence of TMD[18,33,45] and therefore, and because it forms the new psychological assessment method in DC/TMD, the distribution and internal reliability of GAD-7 was reported here in addition to other psychological

instruments assessing depression and non-specific physical symptoms. In RDC/TMD, no specific instrument was included in screening anxiety symptoms and thus no comparison between RDC/TMD and DC/TMD criteria could be made on anxiety symptoms. The present study results indicated that based on GAD-7, the prevalence of anxiety symptoms was relatively high in TMD patients, as 15.7 % of the patients suffered from moderate or severe anxiety (8.9% moderate and 6.8% severe anxiety). In their study, Reiter et al.[25] showed that 7.6% of the patients suffered from moderate anxiety and 4% from severe anxiety, which is in accordance with the results of this study and those of Simoen et al.[33]. In addition, Simoen et al.[33] reported higher levels of anxiety symptoms among consecutive TMD pain patients compared to the general population in Belgium. In Finland, the corresponding prevalence in high health care utilizers in the Northern Finland Birth Cohort 1966 was shown to be lower[46], and GAD-7 was shown to be valid and useful tool for screening for anxiety disorders in primary health care.

The present study investigated the internal reliability and internal inter-item consistency of the psychological assessment instruments of both RDC/TMD and DC/TMD (depression, non-specific physical symptoms and also anxiety in DC/TMD), showing high Cronbach alpha values (0.84 or higher) for all the instruments. These results showed that the translated Finnish versions of the RDC/TMD and DC/TMD psychological assessment instruments are valid for screening depression and non-specific physical symptoms. Furthermore, the DC/TMD-FIN psychological instruments, including GAD-7, also showed to be valid and can thus be applicable for screening anxiety symptoms in TMD pain patients. Based on earlier validation studies, RDC/TMD Axis II questionnaires (SCL-90-R for depression and non-specific physical symptoms, GCPS1.0) have indicated to be valid[23,47]. Ohrbach et al.[23] evaluated the validity of the psychometric properties of the RDC/TMD Axis II instruments in screening psychological status and disability in a multi-center study in clinical and community settings (n=626). The study assessed internal consistency,

temporal stability, and convergent and discriminant validity, concluding that the RDC/TMD Axis-II Depression and Graded Chronic Pain instruments have clinically relevant and acceptable psychometric properties for validity, reliability and utility for identifying TMD patients with high levels of distress, pain, and disability[23]. The validity of the original English version of the DC/TMD has been evaluated through a multiphase process presented by Schiffman et al. (2014)[18]. Similar validation studies are still lacking regarding DC/TMD criteria and instruments, especially in comparative intercultural samples.

The strength of this research was the relatively large study sample size which was set according to the guidelines of the INfORM consortium[26]. The Axis I Symptom Questionnaire, clinical protocol and the Axis II instruments used here are internationally valid instruments and they have been translated to Finnish language based on the comprehensive INfORM translation guidelines[26]. In addition, the questionnaire evaluations and the clinical examinations were performed by examiners calibrated and reliability-trained for DC/TMD-FIN Axis I clinical examination. It should be noted that the Axis II instruments are for screening purposes of psychosocial factors, not for diagnosis. To show potential intercultural variation, in Axis II questionnaire assessments (SCL-90R, PHQ-9, PHQ-15, GAD-7) raw mean and median scores were calculated in addition to the subclassifications with the original English cut-off ranges. Further studies are clearly indicated to study intercultural differences as DC/TMD translations in over 30 countries worldwide become available, as well as to compare their differences to earlier studies using RDC/TMD criteria. Furthermore, the study sample comprised TMD pain patients from tertiary care at the comprehensive Axis II assessment level and the psychological instrument results presented here are not applicable for TMD patients in primary care. In addition, the patient material did not allow comparison between females and males in Axis II evaluations. It should also be noted that there are various other biopsychosocial risk factors comprehensively evaluated e.g. in the OPPERA

studies that are not assessed in the current DC/TMD Axis II criteria. These include, for example, poor health, comorbid diseases, poor sleep quality, stress, catastrophizing and coping, which are associated with TMD and its chronicity[2,3,5,10,14,15,47,48]. Further psychometric research and especially comparative intercultural studies regarding the subcategorization of patients as well as regarding other risk factors in patient subtyping are still needed to guide the clinicians in the up-to-date assessment and treatment of TMD pain at various levels of the health care system.

In conclusion, the translated Finnish versions of the psychosocial and psychological assessment methods of the RDC/TMD and DC/TMD Axis II instruments correlate strongly in TMD pain patients referred for assessment and treatment in specialist/tertiary care. The internal reliability of the psychological assessment instruments in the Finnish RDC/TMD-FIN and in DC/TMD-FIN criteria was high, indicating high validity of these instrument translations. Based on the original English cut-offs, the SCL-90R instrument of RDC/TMD subclassified patients more easily to subcategories of severe depression symptoms or subcategories of severe non-specific physical symptoms in comparison with PHQ-9 or PHQ-15 in DC/TMD, respectively. The DC/TMD Axis II instruments, i.e. GCPS 2.0 (30-day time-frame version), PHQ-9, PHQ-15 and GAD-7, are applicable for screening assessment of psychological and psychosocial factors in Finnish TMD patients, but in order to evaluate the appropriate national cut-offs ranges in PHQ-9 and PHQ-15, further psychometric studies are needed to allow comparison with other samples and Finnish population norms. Until further research is available, caution is recommended in the use of the original cut-off-points scoring of the PHQ-9-FIN, PHQ-15-FIN, and these scores should be interpreted mainly qualitatively and in relation to other Axis II assessment instruments as part of other comprehensive specialist level assessments.

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Table 1. Distribution of sociodemographic background and DC/TMD Axis I sub-diagnoses (presented as n(%) and χ^2-test), and mean number (with (SD) and Mann-Whitney U test p-value) of age, pain-related diagnoses and joint disorders in 197 TMD pain patients referred to the tertiary specialist care for TMD treatment in four facial pain clinics in the University hospitals of Finland.

		All (n=197)	Men (n=39)	Women (n=158)	p
Sociodemographic background					
Age (mean, SD)		43.3 (16.7)	47.6 (18.4)	42.5 (16.3)	.189
Marital status[1]	Married/cohabiting	122 (61.9)	24 (61.5)	98 (62.0)	.956
Education[1]	Lower	116 (58.9)	24 (64.2)	92 (57.7)	.700
Working status[1]	Employed	98 (49.7)	21 (55.3)	73 (47.4)	.385
Axis I pain-related diagnoses					
Myalgia		142 (72.1)	25 (65.8)	117 (74.1)	.306
Myofascial pain with referral		93 (47.2)	15 (39.5)	78 (49.4)	.273
Arthralgia		140 (71.1)	22 (57.9)	118 (74.7)	.040
TMD attributed headache		79 (40.1)	13 (34.2)	66 (41.8)	.394
Axis I joint disorders					
Disc displacement					
-with reduction		34 (17.3)	5 (12.8)	29 (18.4)	.413
-with reduction with intermittent locking		3 (1.5)	1 (2.6)	2 (1.3)	.486
-without reduction without limited opening		57 (28.9)	9 (23.1)	47 (29.7)	.408
-without reduction with limited opening		24 (12.2)	2 (5.1)	22 (13.9)	.133
Degenerative joint disease		39 (19.8)	7 (18.4)	32 (20.3)	.800
Distribution of Axis I diagnoses					
Pain-related diagnoses	Mean (SD)	2.33 (1.37)	2.03 (1.48)	2.40 (1.34)	.149
	Md (Q_1-Q_3)	3 (1-4)	2 (1-3)	3 (1-4)	
Joint disorders	Mean (SD)	.57 (.66)	.46 (.64)	.60 (.66)	.219
	Md (Q_1-Q_3)	0 (0-1)	0 (0-1)	0.5 (0-1)	
All diagnoses	Mean (SD)	2.90 (1.59)	2.49 (1.48)	3.00 (1.60)	.075
	Md (Q_1-Q_3)	3 (2-4)	2 (0-4)	3 (2-4)	

[1] for background information, data were missing for 1 man and 4 women.

Table 2. Distributions of CPI, disability days (DD) and pain interference based on GCPS 1.0 (RDC/TMD) and GCPS 2.0 (DC/TMD), their mutual correlation, and p-value for systematic difference in 197 TMD pain patients referred to the tertiary specialist care for TMD treatment in four facial pain clinics in the University hospitals of Finland.

Measures	n	Mean	95% CI	Md	Q_1-Q_3	Min-Max	r[1]	p[2]
CPI							0.873	<0.001
GCPS1.0	192	58.4	55.5-61.3	60	46.7-73.3	10-100		
GCPS2.0	191	53.2	50.1-56.4	53.3	36.7-70.0	0-100		
Disability days							0.854	n.a.
GCPS1.0	181	18.7	13.0-24.5	0	0-20	0-180		
GCPS2.0 score	187	3.0	2.4-3.5	1	0-7	0-10		
Pain-related activity interference							0.863	<0.001
GCPS1.0	192	40.2	35.7-44.6	36.7	10-66.7	0-100		
GCPS2.0	189	34.1	30.1-38.2	30.0	6.7-60.0	0-96.7		

[1] Spearman correlation coefficients (r) between the measures, $p < 0.001$ for all

[2] systematic difference between the measures (Wilcoxon Signed Rank test).

Table 3. Distribution of Characteristic Pain Intensity (CPI), pain interference and disability days (DD) scoring points and GCPS grades (I-IV) based on GCPS 1.0 (RDC/TMD) and GCPS 2.0 (DC/TMD) in the 197 TMD pain patients referred to the tertiary specialist care for TMD treatment in the four facial pain units in the University hospitals of Finland.

		GCPS 1.0		GCPS 2.0		p[1]
		n=180	%	n=184	%	
CPI (0-100)	0	0	0	2	1.0	<0.001
	1-50	55	28.6	74	38.8	
	≥50	137	71.4	115	60.2	
Pain-related activity interference points (0-3)	0	81	42.2	89	47.1	0.002
	1	35	18.2	34	18.0	
	2	29	15.1	37	19.6	
	3	47	24.5	29	15.3	
Disability days (DD) points (0-3)	0	112	61.8	103	55.1	<0.001
	1	11	6.1	9	4.8	
	2	24	13.3	21	11.2	
	3	34	18.8	54	28.9	
Total disability points (DP) (0-6)	0	74	40.9	81	43.6	0.157
	<3	38	21.0	29	15.6	
	3-4	28	15.5	31	16.6	
	5-6	41	22.6	45	24.2	
GCPS Grade	I	48	26.7	61	33.1	0.480
	II	63	35.0	47	25.6	
	III	28	15.6	31	16.8	
	IV	41	22.7	45	24.5	

[1] Wilcoxon signed rank test

Table 4. Distributions of psychological assessment scales of RDC/TMD and DC/TMD in 197 TMD pain patients referred to the tertiary specialist care for TMD treatment in four facial pain clinics in the University hospitals of Finland.

	n	Mean	95% Cl	Md	Q_1-Q_2	Min-Max
Depression symptoms						
SCL-90-R DEP (0-4)	188	0.9	0.8-1.0	0.7	0.3-1.3	0-3.1
PHQ9 (0-27)	192	5.6	4.8-6.3	4	2-8	0-22
Non-specific physical symptoms						
- SCL-90R SOM with pain items (0-4)	189	1.2	1.1-1.3	1.1	0.6-1.7	0-4
- SCL-90R SOM without pain items (0-4)	189	1.0	0.9-1.1	0.9	0.3-1.6	0-4
PHQ15 (0-30)	193	10.1	9.3-10.8	9	6-13	0-29
Anxiety						
GAD-7 (0-21)	191	5.1	4.4-5.8	4	2-8	0-21

r= 0.844 (PHQ-9 vs. SCL-90R DEP); r=0.806 (PHQ-15 vs. SCL-90R SOM with pain; r= 0.728 (PHQ-15 vs. SCL-90R SOM without pain); $p<0.001$ for all.

Table 5. Crosstabulations of the Axis II psychological assessment scores* of RDC/TMD-FIN (SCL-90R depression and non-specific physical symptoms with pain items) and DC/TMD-FIN (PHQ-9, PHQ-15) among the 197 TMD pain patients referred to the tertiary specialist care for TMD treatment in four facial pain units in the University hospitals of Finland (χ^2-test and gamma statistics, p-values <0.001).

			RDC/TMD depression subscale
DC/TMD PHQ-9	Normal	Moderate	Severe
	n=76 (40.5%)	n=51 (27.1%)	n=61 (32.4%)
No n=101 (52.5%)	68	26	4
Mild n=53 (27.6%)	5	19	26
Moderate n=23 (12.0 %)	0	5	16
Moderate-severe n=12 (6.3%)	0	1	11
Severe n=3 (1.6%)	0	0	2
Gamma=0.896, p<0.001			
			RDC/TMD 'non-specific physical symptoms with pain items' subscale
DC/TMD PHQ-15	Normal	Moderate	Severe
	n=33 (17.5%)	n=55 (29.1%)	n=101 (53.4%)
No n=26 (13.5%)	18	7	1
Low n=77 (39.9%)	14	35	24
Medium n=49 (25.4%)	1	11	35
High n=41 (21.2%)	0	1	38
Gamma=0.863, p<0.001			

*based on original cut-offs ranges[17,18]

Figure legends

Figure 1. Distribution (%) of the TMD pain patients based on the Axis II psychological assessment (depression and non-specific physical symptoms) scores* of RDC/TMD-FIN (SCL-90R) and DC/TMD-FIN (PHQ-9, PHQ-15) and GAD-7 in the study sample (n=181/197).

*based on original cut-offs ranges[17,18]