Focus Article

Validity of the Research Diagnostic Criteria for Temporomandibular Disorders Axis I in Clinical and Research Settings

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The lack of standardized diagnostic criteria for defining clinical subtypes of temporomandibular disorders (TMD) was the main motive to create the Research Diagnostic Criteria for TMD (RDC/TMD), which were provided to allow standardization and replication of research into the most common forms of muscle- and joint-related TMD. The RDC/TMD offered improvement compared to the older literature: the use of one system classifying TMD subgroups and the introduction of a dual-axis classification. The aim of this Focus Article is to appraise the RDC/TMD Axis I (physical findings). Since the original publication in 1992, no modification of the RDC/TMD has taken place, although research has yielded important new findings. The article outlines several concerns, including diagnostic issues in Axis I, classification criteria, feasibility of palpation sites, the myofascial diagnostic algorithm, the lack of joint tests (compression, traction), and missing subgroups. Using a gold standard examiner may improve calibration and offer better reliability; it does not improve any of the diagnostic validity issues. It is also noted that in the 2004 mission statement of the International Consortium For RDC/TMD-Based Research, the RDC/TMD are also advocated for clinical settings. Clinicians may eagerly embrace the RDC/TMD, believing that the clinical use of the RDC/TMD as a diagnostic procedure is already supported by evidence, but its application is not indicated in clinical settings. The article concludes that given the research developments, there is a need to update the RDC/TMD Axis I in the clinical research setting. J OROFAC PAIN 2009;23:9-16

Key words: classification, diagnosis, RDC/TMD, temporomandibular disorders

Temporomandibular disorders (TMD) is a collective term that embraces a number of clinical problems that involve the masticatory musculature, the temporomandibular joints (TMJs), and associated structures.[1] Difficulties in case definition are one of the major reasons that have obstructed the development of insights into TMD causation and management. This also kept etiologic concepts and management concepts without plausibility alive. The lack of standardized diagnostic criteria for defining clinical subtypes of TMD has led to an initiative to create the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).[2] The RDC/TMD have a dual-axis approach: Axis I (physical findings) and Axis II (pain-related disability and psychosocial status). This article focuses on Axis I; Axis II will not be discussed here. The RDC/TMD have been

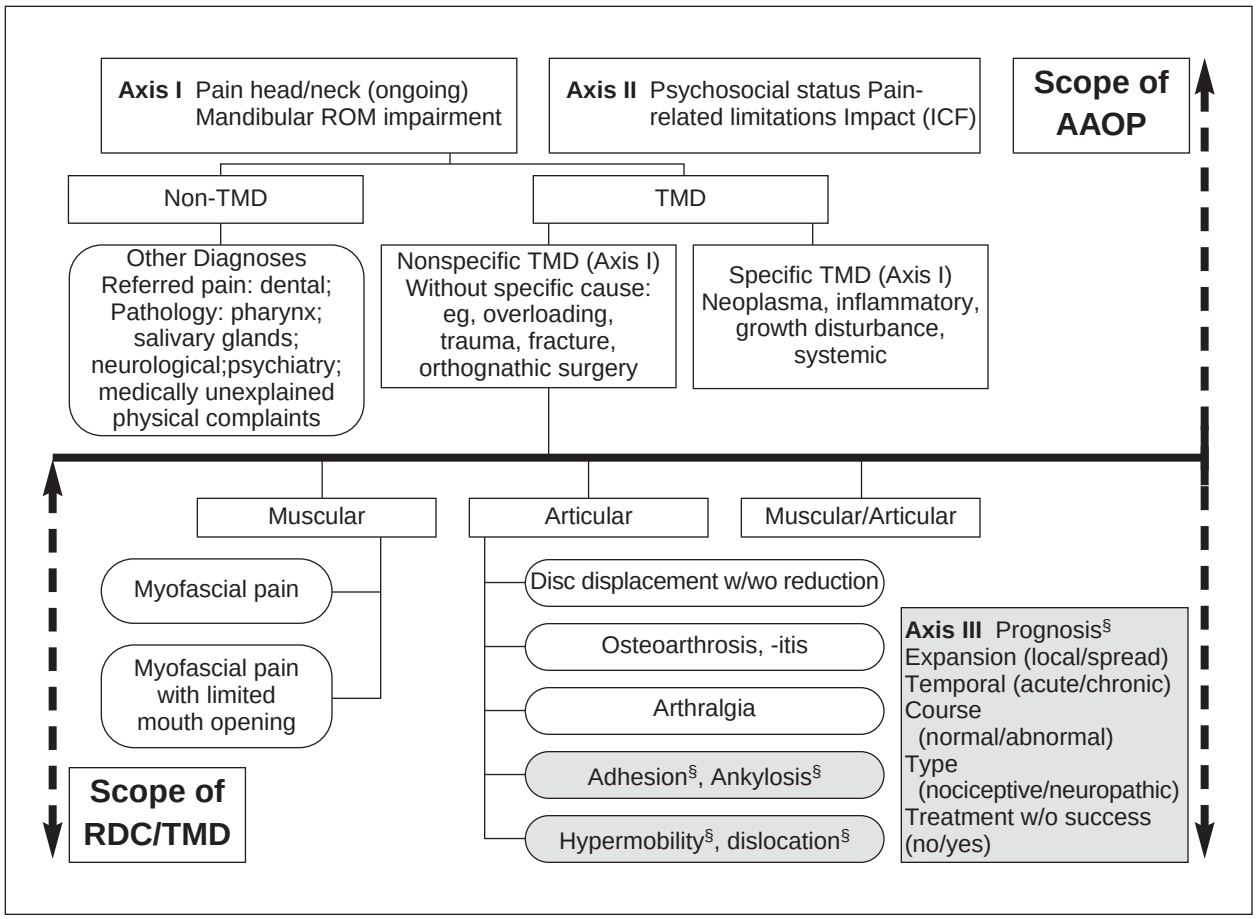

Fig 1 Flowchart of the diagnostic process in suspected painful TMD. Axis I represents physical conditions. Non-TMD: other conditions presenting pain in the head and the neck and mandibular range of motion (ROM) limitations. Specific TMD: conditions with a known substratum (eg, neoplasms, growth disturbances, systemic disease). Nonspecific TMD: conditions related to overloading or trauma surpassing the adaptation capacity; generally divided into non-articular (muscular) and articular subgroups. Axis II represents psychosocial factors, increasingly important when chronicity plays a more prominent role. Both Axis I and II need integrated attention as of the start of the consultation in order to get a comprehensive view on the patient characteristics and to make a treatment and evaluation plan. Note that the scope of the RDC/TMD is much narrower than the AAOP classification.
§Nonspecific TMD classifications and Axis III, not part of the RDC/TMD. Axis III represents additional clinical considerations such as pain characteristics, medication, and results of previous therapy related to prognosis. ICF: international classification of functioning, disability, and health (WHO). Modified from Steenks et al.[29]

offered to allow standardization and replication of research into the most common forms of muscle- and joint-related TMD as musculoskeletal conditions. The standardization of comparable descriptions of individuals, clinical examination methods, and results of clinical investigations has been a major objective. In clinical research, reliable and valid criteria need to be available for case definition, etiology, prognosis, diagnosis, and therapy.

Since the original publication in 1992, no modification of the RDC/TMD has taken place, although research has yielded important new findings. Originally, the RDC/TMD were intended for clinical research purposes.[2] The strengths and limitations of these criteria for clinical practice were not considered.[2] However, in the 2004 website mission statement of the International Consortium for RDC/TMD-Based Research, the core tool (RDC/TMD) is not only advocated for clinical research purposes, but also for clinical settings: "Our goal is to advance scientific knowledge of temporomandibular disorders and related pain conditions based on the use of a common set of tools applicable to both research and clinical settings."[3] As a result, clinicians are using the RDC/TMD in clinical settings or are invited to do so. Use in clinical settings raises the question of whether the RDC/TMD

have appropriate diagnostic specifications, or whether they only classify certain, non-specific temporomandibular conditions. In the materials and methods section of many articles on TMD, it is nowadays the rule rather than the exception to find expressions such as "the authors followed the RDC/TMD to diagnose the patients" or "patients were diagnosed according to the RDC/TMD." Apart from the fact that authors usually did not report if they had received RDC/TMD-related training and calibration, one has to bear in mind that shortcomings of parts of the RDC/TMD have been reported.[4,5] Nonetheless, the call for refinement and revision welcomed by the RDC/TMD group in their original publication[2] of 1992 has not yielded any change thus far. Interestingly, the scope of the RDC/TMD is much narrower than that of the American Academy of Orofacial Pain (AAOP) or the International Headache Society (IHS) classifications, which have been offered for the clinical identification of TMD and orofacial pain (Fig 1).[6] The criteria used in the latter classification are not meant to be rigid inclusion criteria, but rather to provide clinical guidance for diagnosis. The aim of the present article is to appraise the RDC/TMD Axis I in terms of

1. The examination protocol
2. The diagnostic algorithms
3. Reliability and validity issues
4. The advocated use in clinical settings

Clinical Examination

In the RDC/TMD, only palpation, pain on jaw opening (assisted, unassisted), and left and right excursions are evaluated. Questions only refer to the side (R/L/both), and to whether muscles, TMJs, or both (yes/no/not applicable) are involved.[2] Temporomandibular pain and temporomandibular (dys)function are evaluated separately.

In the RDC/TMD, there is an unbalance in the number of muscular and articular palpation sites (20:4). This may lead to the probability of an overrepresentation of muscular (Group I) conditions at the expense of articular pain conditions (Group III). In different populations throughout the world for which the RDC/TMD are used, prevalence of Group I disorders exceed Group III pain conditions without exception. The non-clinical approach of dichotomizing between temporomandibular pain and temporomandibular dysfunction also adds to this phenomenon. The RDC/TMD palpation technique requires applying a calibrated force to the site and then questioning the patient for pain or pressure.[3] The RDC/TMD palpation technique is, therefore, limited to this question only, whereas palpation clinically should be used to evaluate other qualities as well, such as muscle tonus, contrast between contraction and relaxation, specific pathology (tissue characteristics such as swelling and stiffness), and the provocation of other signs and symptoms.

The reproduction of the main complaint of the patient is not included in the RDC/TMD in general, nor in the palpation protocol. One of the most important characteristics of TMD conditions is aggravation by mandibular function (eg, chewing, yawning, speaking). In the RDC/TMD examination protocol there is no cross-correlation between findings. Instead, it is more or less a grand sum. The only correlation between the complaint and the examination is the indication by the patient of the location of pain and the interpretation of the examiner as to whether the pain is muscular or articular. But the site of pain does not predict the source of pain. The examination protocol does not allow for appraising other signs and symptoms that are provoked through palpation as well. There is neither cross-correlation between history and clinical examination, nor between range of mandibular motion or other orthopedic tests and signs and symptoms of TMD aggravated by movement. In fact, clinical reasoning such as pattern recognition, or a hypothetical-deductive approach, is not included in the RDC/TMD.[7] When more findings point to a defined symptom profile, the probability that such a profile exists in a given subject is increased. Since a diagnostic method also needs to take care of specific pathology not only in the muscles and TMJs, but also in the other tissues (salivary glands, lymph nodes, or soft tissues that may refer pain in the areas of interest of the RDC/TMD), specific TMD need to be ruled out first.[6] The original 1992 publication agrees and states that uncommon non-articular conditions as well as systemic articular disease must be ruled out first.[2] However, in the 2004 website information of the International Consortium for RDC/TMD-Based Research, this requirement is no longer mentioned.[3] Moreover, pathology not referred to in the original publication, such as growth disturbances and neoplasia, also need to be ruled out first. The clinician following all information provided in the RDC/TMD website group must rely on an implied diagnostic validity of the RDC/TMD. However, due to the classification process of the RDC/TMD in sus-

pected TMD, this protocol allows for pathology to be overlooked when not ruled out first (Fig 1, upper half).

The questioned ability to palpate some of the muscle regions (submandibular area, posterior mandibular area, lower head of the lateral pterygoid muscle) has been discussed in the literature.[8–14] Inclusion of these elements in the diagnostic protocol increases the probability of false positive results, mainly myofascial in character.

Diagnostic Algorithms

If ongoing pain is present, the algorithm for Group I conditions considers the number of painful palpation sites and regions.[2] At least three of the 20 sites/regions suggested in the RDC/TMD need to be painful, and one needs to be on the same side as the ongoing pain.[2,3] Given the natural sensitivity of various structures in the regions, the number of three painful palpation sites as a cutoff point is arbitrary. Peripheral and central sensitization due to other conditions such as pulpitis or sinusitis may easily lead to exceeding the threshold of three painful muscle sites. The use of this algorithm may further explain the overrepresentation of myofascial pain conditions in prevalence studies using the RDC/TMD protocol.[15] If the criterion of one painful site on the same side of the ongoing pain is raised to three painful sites on the side of the ongoing pain, the prevalence of Group I conditions drops 50% in an Asian population, ie, from 76%[15] to 31.4%.[16] If such a relatively minor change has such an enormous consequence, one may wonder about the validity and relevance of much of the prevalence research presented in the past years using the RDC/TMD.

The Group II (disc displacements) algorithm lacks some criteria[4,17,18] that also need to be taken into consideration, such as

- The degree of jaw opening
- Elimination of TMJ clicking in a 1- to 4-mm protrusive jaw position
- Loudness of the click during mandibular opening and closing, and on resistance during closing
- Clicking not only on opening and closing, but also on protrusion and laterotrusion to the opposite side

The Group III (arthralgia, arthritis, arthrosis) algorithm is based on palpation and ongoing pain only. Compression, retrusion, and joint play (traction test) are not part of this algorithm. The presence of an inflammatory condition (arthritis) is more probable if compression and traction tests are positive for TMJ pain provocation, compared to palpation only. Pain only provoked during palpation might also indicate other conditions spreading pain to the TMJ, eg, based on sensitization. Cross-correlation with the history is paramount to establish TMJ-related pain. In examination protocols originating from Scandinavian schools, these tests are included,[19,20] but they do not receive attention in the RDC/TMD.

Reliability and Validity

The reliability of range-of-motion measurements through the years and in all studies has scored high.[21] The signs and symptoms of nonspecific TMD conditions do fluctuate (joint clicking, TMD-related pain).[22] Short- and long-term fluctuations of clicking, pain, and range of motion have led to the concept of smallest detectable change, in order to define clinically relevant differences before and after therapy.[22] Although palpation has scored much lower, the RDC/TMD heavily rely on scores related to palpation of musculoskeletal structures as the closest gold standard,[2] comparing this method with the positive diagnosis for fibromyalgia (12 out of 14 palpation sites).[2] The reliability of RDC/TMD diagnoses, despite the fact that the clinicians are well calibrated by a gold standard examiner, is low (intraclass correlation 0.06 to 0.58).[23] The reliability protocol of the RDC/TMD consortium explicitly states that "24 (alternatively, 20 or 16, but must be in multiples of 4) subjects must have TMD symptoms, and a high proportion of subjects must be symptomatic (eg, of 24 subjects 18 to 20 symptomatic and 4 to 6 nonsymptomatic). Subjects with only a Group II or Group III diagnosis should not be used; they are generally not symptomatic enough."[4] These requirements seem to introduce selection bias, because they do not take into account the clinical reality of many patients seen in clinical practice with a clinical profile that does not match this requirement.[20] The benefit of the gold standard examiner is well appreciated for providing highly calibrated clinicians, but calibration to what kind of measurement and in which context? The use of a gold standard examiner does not solve the validity issues. As an example, the reliability of an established mandibular position can be checked through a split cast technique with multiple wax records. The registration can be reliable, but it does not give any clue whether the mandibular position found is beneficial for the patient.

Comparison of clinical RDC/TMD diagnoses and magnetic resonance imaging (MRI) findings in patients with myofascial pain or arthralgia/osteoarthrosis in combination with myofascial pain did not yield specifications that endorse the use of the RDC/TMD.[5] The authors conclude that the clinical diagnoses for subdivision into myogenous and arthrogenous pain were not always confirmed by MRI. MRI findings were common in both patients with myogenous and arthrogenous TMD pain. "According to the results of this study on the clinical diagnosis, it is obvious that the criteria for the diagnoses, including images, need to be continuously reviewed,"[5] especially regarding validity.

Clinical Setting

The use of the RDC/TMD has originally been recommended for clinical research purposes. Given the proposed protocols, the main utility is their use in epidemiological clinical research.[2] Looking at the above-mentioned shortcomings, the further extension to clinical settings as indicated in the RDC/TMD consortium mission statement[3] and related studies[23] has not been substantiated in the dental literature. Clinicians may eagerly embrace the RDC/TMD under the false impression that the clinical use of these criteria is already supported by evidence. The RDC/TMD gained professional acceptance because an initiative was needed desperately at the time to create a consensus in case definition. The group and its outstanding 1992 publication deserve credit for that. Since that time, however, updates have not taken new findings into consideration. The problem with implementation in clinical settings is not only based on the lack of updates. The 1992 publication states "there is no reason to view the RDC/TMD as limiting the scope or method of inquiry for a particular investigator or study."[2] But how should a remark in an evidence-based journal that "the clinical examination procedures used to ascertain a diagnosis of TMJ arthralgia are not clear and do not appear to follow the RDC/TMD, as the authors cite in their text, since auscultation is not used in this diagnostic system" be interpreted as valid?[24] The authors used the RDC/TMD but were criticized because they added auscultation.[25] This is contrary to what is stated in the original publication.[2] Likewise, it would be presumptuous for editors and reviewers to reject manuscripts dealing with TMD only because the RDC/TMD were not used. To improve the RDC/TMD, it is not sufficient to add or leave out what a certain clinical investigator finds appropriate. Improvement would require a much more fundamental change in the RDC/TMD and related matters.

The concept of multiple diagnoses is highly recommended in the clinical context of diagnosing subtypes of TMD. Pure one-category subtypes of TMD are scarce in the real world.[18,19] A diagnostic system preferably should also address treatment decisions. The RDC/TMD do not yet offer such information.

Discussion

The RDC/TMD were developed from empirical data that came from longitudinal epidemiological research,[2] and derived from the clinical diagnostic criteria for TMD.[2,5,20] The modifications from these clinical diagnostic criteria were not accounted for in the original 1992 publication, in which the clinical diagnostic criteria for TMD were compared with seven other systems and found to be superior on the basis of quantitative expert-based criteria.[2] Given the existing shortcomings and the clinical research developments, suggestions for an update of the RDC/TMD Axis I may involve:

- Cross-correlation between history and clinical examination (eg, the reproduction of the main complaint of the patient)
- Additional clinical categories (eg, joint dislocation, hypermobility, disc displacement with catching, posterior disc displacement, adherence/adhesions)
- Update of criteria for anterior disc displacement with reduction
- Inclusion of other clinical tests (eg, TMJ compression, traction for TMJ arthritis)
- Fewer muscle palpation sites with a better balance between articular and non-articular palpation
- The use of additional palpation techniques to accommodate ruling out of pathology
- Exclusion of extra- and intraoral palpation regions (eg, posterior mandibular region [RDC/TMD clinical examination form 8g], submandibular region [RDC/TMD clinical examination form 8h], and lateral pterygoid area [RDC/TMD clinical examination form 10a])
- Re-evaluation of the Group I, II, and III algorithms regarding the number of palpation sites
- Inclusion in the RDC/TMD consortium statement of restrictions regarding the diagnostic specifications as to calibrated examiners and

clinical research purposes as well as the need to diagnose pathology and orofacial pain conditions first

The initiative by the International Consortium for RDC/TMD-Based Research is a good basis for beginning an evaluation. The researchers and clinicians involved can improve the RDC/TMD to address the clinical needs of the profession, namely improvement in assessment and classification focused on the typical TMD found among clinical patients rather than in population samples. The remarks mentioned above are meant as a positive contribution to this process, and they are certainly not limiting. Therapies need to be cost-effective, so researchers also need to realize the costs of research projects and perform only those replication studies that add to the body of knowledge. More RDC/TMD studies on the reliability of the existing examinations that have been studied repetitively are not cost-effective. Calibrated examiners perform better than uncalibrated examiners,[26] underlining the essentiality of (continuous) calibration when using the RDC/TMD protocol in clinical research.

The use of the RDC/TMD in clinical research also raises questions as to the generalizability of the results. The recently published prospective cohort study titled "Predictors of onset of facial pain and temporomandibular disorders in early adolescence"[27] is a good example of the problems of case definition and thus generalizability. This study is scientifically the strongest that has been performed thus far on etiology, and the authors performed an enormous task in an excellent way. When the authors describe predictors of facial pain they do not indicate a diagnosis but merely a symptom. When they mention TMD based on the RDC/TMD, the authors should consider if they diagnosed TMD in the 89 out of their sample of 1,310 children 11 to 14 years of age.[27] For example, in patients with migraine, palpation of the RDC/TMD palpation sites and regions according to the diagnostic algorithm will probably reveal 100% with myofacial pain. Is a TMD Group I condition in such a context appropriate? Should the myofascial pain condition be treated or should the diagnosis be migraine and the patient be treated as such? Meeting the RDC/TMD criteria does not necessarily predict the underlying condition. For example, patients with the Ehlers-Danlos syndrome (EDS) more often have dislocations of the mandible than patients with TMD[28] and these patients have EDS and, as a result, dislocation of the mandible. This is important not only for semantics, but also because patients need to be diagnosed correctly (sometimes EDS is disclosed by the TMD/orofacial pain specialist) and because it has consequences for their management. When using these criteria in the general population, "diagnosing" individuals and classifying them into the different RDC/TMD Group I, II, III conditions does not indicate any need for therapy, let alone prevention. Research diagnostic criteria are research classification criteria.[29] The use of an algorithm as such in a given classification system does not necessarily justify a preference for use as a clinical classification system.[30] The outcome of the algorithm is as strong as the criteria it is based on. The use of well-defined operational criteria is preferred; but other characteristics may still be more decisive as to the choice of a classification system. The choice between the use of the AAOP classification and the RDC/TMD classification must also be seen in this perspective. The lack of a gold standard to diagnose nonspecific TMD (unlike systemic disease, pathology, and growth disturbances) does not hamper the classification too seriously, since these TMD are diagnosed per exclusion. Once causality issues are solved, gold standard tests may become available.

The role of the dentist as a clinical researcher is to be a clinician first. More precisely, research is inferior to patient values and not the other way around. The reliability of clinical tests used in the various systems does not differ if appropriate training and calibration (in research and in clinical settings) are performed.[21] But we are well aware that the AAOP and IHS classifications (and the seven other appraised diagnostic systems)[2] are also compromised by some of the validity problems in the case of the RDC/TMD. However, each clinical researcher should realize that the AAOP and IHS classifications have been proposed for clinical guidance only, whereas the RDC/TMD were proposed mainly for research purposes.[2] Thus, the authors prefer the AAOP and IHS classifications over the RDC/TMD (Fig 1) for clinical classification, which was their proposed purpose.[6,31]

From the perspective of therapy, decisions are generally driven not only by classified subtypes of TMD, but also by other factors such as patient preferences, comorbidities, and prognosis (Axis III).[29] If therapeutic decisions are restricted to RDC/TMD Axis I and II categorizing only, this would mean patient neglect. In the clinical research practice of TMD, there is also a need to define subgroups with the help of an updated

RDC/TMD in order to be able to comment better on the therapeutic options in the TMD subgroups.

A review and commentary section as to basic sciences and clinical sciences was included in the original publication.[32,33] The thoughts expressed in this Focus Article are meant to improve the use of the RDC/TMD Axis I for clinical research purposes.

Conclusion

The RDC/TMD were a step toward a consensus of classification systems, allowing standardization and replication of research. However, after 15 years, an update is needed for their use in the research setting. Their general application is not indicated in clinical settings. To improve the use of the RDC/TMD in the clinical research setting, the RDC/TMD should be more clinically oriented and shown to have more clinical validity with respect to the main complaints of TMD patients with or without underlying pathology, eg, through correlating findings between history and clinical examination, or indications of the first-choice imaging modality. To be a diagnostic system, the RDC/TMD also need to address therapeutic decisions.

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