Validation of the MBGR orofacial myofunctional assessment protocol for adults with temporomandibular disorders with disc displacement with reduction

ABSTRACT

Purpose: This study aimed at validating the MBGR Orofacial Myofunctional Assessment Protocol (MBGR Protocol) for adults with Temporal Mandibular Disorders (TMD). Methods: The study sample was composed of 30 adults: 15 with TMD (disc displacement with reduction according to the Research Diagnostic Criteria for Temporomandibular Disorders) and 15 control individuals. The validation process encompassed the content, criterion, and construct of the protocol, as well as its inter- and intra-rater agreement levels and sensitivity and specificity values, considering a 5% statistical significance level. Results: The following validities were confirmed: of content, as the MBGR Protocol covers all functional issues present in patients with TMD; of criterion, with significant correlations between the MBGR and Orofacial Myofunctional Evaluation with Scores (OMES) protocols; of construct, differentiating individuals with and without Orofacial Myofunctional Disorders (OMD) as for pain on palpation and mandible range of motion, with significant correlation between the MBGR clinical evaluation and that using a digital algometer, as well as confirmation of the instrumental assessment for the breathing mode classification. Agreement ranged from poor to very good and from reasonable to very good for the inter- and intra-rater power analyses, respectively. High sensitivity and specificity values were observed. Conclusion: The MBGR Protocol proved to be valid for use in adults presented with TMD with disc displacement with reduction and controls, covering all aspects that enable the analysis of OMD in these individuals.

RESUMO

Objetivo: Este estudo visou validar o Protocolo de Avaliação Miofuncional Orofacial MBGR para adultos com DTM. Método: Participaram 30 adultos, sendo 15 com DTM (deslocamento de disco com redução segundo o Research Diagnostic Criteria for Temporomandibular Disorders) e 15 Controles. O processo de validação envolveu a validade de conteúdo, de critério e de construto, além da concordância inter e intra-avaliador, sensibilidade e especificidade. Considerou-se nível de significância de 5%. Resultados: Foram confirmadas as validades de conteúdo, visto que o Protocolo MBGR abarca todas as questões funcionais presentes em indivíduos com DTM; de critério, com correlações significativas entre o MBGR e AMIOFE; e de construto, diferenciando indivíduos com e sem DMO quanto à dor e mobilidade mandibular, com correlação significante entre a avaliação clínica do MBGR e o uso do algômetro digital, bem como confirmação do exame instrumental para a classificação do modo respiratório. A força de concordância variou de pobre a muito boa para a análise intervalavador e de razoável a muito boa para intra-avaliador. Os valores de sensibilidade e especificidade foram elevados. Conclusão: O Protocolo MBGR mostrou-se válido para aplicação em adultos com DTM com deslocamento de disco com redução e controles, contemplando todos os aspectos que possibilitam a análise das condições oromiofuncionais nesses indivíduos.
INTRODUCTION

Temporomandibular disorders (TMD) are considered a complex musculoskeletal dysfunction of multifactorial etiology\(^{12}\) and are the leading cause of non-odontogenic-related orofacial pain. Signs and symptoms are diverse and may include difficulties associated with mastication and other orofacial functions\(^{22}\), in addition to pain in the face, temporomandibular joint (TMJ) and cervical region, as well as joint noises and limited mandibular range of motion, and are more frequently observed in women\(^{11}\).

Different clinical instruments organized in the form of questionnaires, anamnesis indices, and diagnostic criteria are used in the diagnosis of TMD\(^{44}\). Also, the functional assessment has been listed as an essential step in the diagnostic process, with a view to planning and establishing the appropriate treatment for these individuals\(^{35}\).

For clinical evaluation of the orofacial functions, there are protocols in the literature that include the attribution of scores, thus providing a quantitative analysis of the clinical examination and facilitating the follow-up of case evolution throughout the treatment process\(^{6-8}\). Assessment protocols enable standardization of the examinations by different professionals, contributing to academic qualification and favoring comparison between the results from different study centers\(^{48}\).

In this regard, the Orofacial Myofunctional Assessment Protocol (MBGR Protocol), which has been recently validated for individuals with cleft lip and palate\(^{69,10}\), was designed to provide speech-language pathologists with an instrument to evaluate and diagnose orofacial myofunctional disorders (OMD) and establish a prognosis in Orofacial Motricity\(^{11}\).

Considering that individuals with TMD present OMD, this study aimed to validate the MBGR Protocol for application in adults with this condition, regarding its content, criterion, and construct validity, as well as its inter- and intra-rater agreement levels and sensitivity and specificity values.

METHODS

Study sample

This study was approved by the Human Research Ethics Committee of the aforementioned Institution under process no. 088560/2013.

The medical records of 30 adults aged 19-28 years (mean age of 24 years) were analyzed: 15 individuals (three men and 12 women) with Temporomandibular Disorders (TMD) - Study Group (SG) and 15 healthy individuals (six men and nine women) - Control Group (CG). All participants signed an Informed Consent Form (ICF) before study commencement.

The SG was composed of individuals with good general and oral health, a diagnosis of disc displacement with reduction (DDWR) according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) Axis I\(^{46}\) adapted to Portuguese\(^{12}\), and who were not undergoing treatment for this condition. The CG comprised individuals with good general and oral health, with at least 28 of the permanent teeth and balanced occlusion, absence of bruxism or jaw clenching, and TMD, according to the RDC/TMD, and who did not have the habit of chewing gum.

Exclusion criteria for both groups were as follows: history of neurological disorders, surgery, and head and neck tumor or trauma, presence of periodontal disease, history of orthodontic or Speech-language Pathology (SLP) therapy under progress or undergone within the past year, and chronic use of analgesic, anti-inflammatory or psychoactive drugs.

The SG, in particular, was composed predominantly of individuals from the community who noticed a symptom of TMD and volunteered to participate in the study. Only two individuals had sought treatment and were waiting to start the intervention, with long-term TMD (18 and 86 months). The severity of signs and symptoms of TMD was verified through the application of the Protocol for Multi-Professional Centers for the Determination of Signs and Symptoms of Temporomandibular Disorders (ProTMDMulti - Part II)\(^{13}\). The median obtained indicated mild symptomatology (grade 1) for temporomandibular joint (TMJ) noise and pain in the facial muscles and absent symptomatology (grade 0) for the other signs and symptoms.

MBGR Protocol - Content Validation

A literature search was conducted at the PubMed and LILACS databases for the past 10 years and using the Google Scholar search engine with a crossing of the following keywords/descriptors in Portuguese and English: Temporomandibular Joint, Craniomandibular Disorders, Stomatognathic System, Masticatory System, Breathing, Mastication, Deglutition, and Speech.

Studies available in full that applied orofacial myofunctional assessment in their methodologies and identified changes in breathing, mastication, deglutition and/or speech functions in individuals with TMD were included. Studies that included children and individuals with tumors, anomalies, craniofacial deformities, and using dental prostheses were excluded.

MBGR Protocol - Criterion Validation

The Orofacial Myofunctional Evaluation with Scores (OMES) Protocol\(^{49}\) was taken as the standard for concurrent validity because this protocol was previously validated for youth and adults with TMD and presented 80% sensitivity and specificity\(^{60}\).

Dynamic and static images were recorded using a digital camera (Sony Cyber-Shot DSC-H9), followed by an on-site evaluation of aspects that could not be analyzed through the images. For the application of each protocol, the authors’ guidelines were followed.

On-site evaluations were performed by three speech-language therapists trained and calibrated in the application of the different protocols, and the result was considered when there was a consensus between at least two examiners. Subsequently, the images were analyzed by two examiners with clinical experience and research conducted in the field of Orofacial Motricity.

Criterion validation was performed through the blind analysis of examiner 1 (E1) using the MBGR protocol and that of the other examiner using the OMES protocol. For analysis purposes, only the corresponding items in each protocol were considered.
**MBGR Protocol - Construct Validation**

Data from the clinical examination using the MBGR Protocol in the SG were compared with those in the CG, and the capacity of the MBGR Protocol to differentiate symptomatic from asymptomatic individuals was verified based on the level of Orofacial Myofunctional Disorders (OMD). Also, data from the clinical examination of pain on palpation and breathing mode obtained using the MBGR Protocol were compared with those from the instrumental assessments of Pressure Pain Threshold (PPT) and Peak Nasal Inspiratory Flow (PNIF), respectively.

The PPT (in kgf) was measured using a DDK 20 algometer (Kratos Ltd., Cotia, São Paulo, Brazil) equipped with a 12 mm-diameter active tip positioned perpendicularly and bilaterally to the lateral pole of the working condyle in the middle third of the superficial layer of masseter muscle and in the anterior bundle of the temporal muscle, with no jaw clenching. The pressure was gradually applied until the individual informed, by triggering a device, the beginning of pain sensation on the spot. The test was performed twice, and the mean value was calculated.

Breathing was assessed by considering the PNIF (in l/min) during exclusively nasal forced inspiration using a Nasal In-Check® (Clement Clarke International) flow meter. Individuals were requested to perform three breathing cycles in the habitual way and then keep the mouth closed and perform maximum nasal inspiration. The test was performed three times, and the mean value was calculated.

**Inter- and Intra-Rater agreement analyses for the application of the MBGR and OMES Protocols**

In order to test the agreement of the MBGR instrument, the analyses of examiners 1 and 2 (E1 and E2) were used. For inter-rater agreement, 100% of the sample (30 cases) was considered, but E1 and E2 performed the analysis individually, using either the MBGR or the OMES protocols.

In order to test the intra-rater agreement, 20% of the sample (six randomly selected cases) was re-evaluated (retest) by E1. The reassessments were conducted between 15 and 30 days after the initial evaluation, thus avoiding the memory effect.

Agreement was analyzed using the weighted Kappa coefficient, and the values were interpreted.

**Analysis of sensitivity and specificity values**

In this analysis, the sum of the scores of each protocol (MBGR and OMES) was considered. The protocols have an inversely proportional scale, and the cutoff points for the diagnosis were established as follows: (A) the median in each protocol and (B) the 75% and 25% percentiles for the MBGR and OMES protocols, respectively.

Sensitivity was calculated by the number of actual positives, that is, the number of participants diagnosed with OMD by both protocols divided by the total number of participants diagnosed by the OMES protocol.

The number of actual negatives calculated specificity, that is, the number of participants not diagnosed with OMD by both protocols divided by the number of participants not diagnosed with OMD by the OMES protocol.

**Statistical analysis**

The Spearman’s Correlation Test ($r_s$) was used for correlations, and the values were interpreted. The Mann-Whitney and Student’s $t$-tests were applied for two paired samples in the comparison between the SG and CG. For the inter- and intra-rater agreement analyses, the linearly weighted Kappa coefficient (Kw*) was applied.

The data were processed using the Excel (Microsoft® Office), OriginPro-8 (OriginLab©), MATLAB (MATrix Laboratory), MedCalc (Microsoft® partner) and Minitab® software. A significance level of 5% ($p<0.05$) was adopted for all statistical analyses.

**RESULTS**

**MBGR Protocol - Content Validation**

Fourteen studies were selected after a literature review on functional changes presented by patients with TMD[5,14-26] according to the inclusion and exclusion criteria adopted (Chart 1).

Thus, it was possible to verify that the MBGR Orofacial Myofunctional Assessment Protocol (MBGR Protocol) includes the aspects described in the literature to identify Orofacial Myofunctional Disorders (OMD) in individuals with Temporal Mandibular Disorders (TMD), and the extraoral/postural characteristics, orofacial mobility, mastication pattern and time, mastication efficiency, characteristics of the oral phase of deglutition, as well as phonetic and general aspects of speech.

**MBGR Protocol - Criterion Validation**

Percentage of agreement between the MBGR and Orofacial Myofunctional Evaluation with Scores (OMES) protocols (examiner E1) was higher than the disagreement percentage for all the aspects analyzed, and the following category agreement percentages were found: tongue and tongue mobility (100%), breathing (96.7%), lip mobility (93.3%), palate (90%), lips (86.7%), deglutition (83.3%), and mastication (80%).

Negative correlations were observed in the concurrent validity analysis between the MBGR and OMES protocols because they present inversely proportional scales (Table 1). For the items mobility of the lips and tongue, it was not possible to apply the correlation test due to data homogeneity.

**MBGR Protocol - Construct Validation**

Table 2 shows that there was a statistically significant difference ($p<0.05$) between the Study (SG) and Control (CG) groups regarding the aspects of pain on palpation and mandibular range of motion, and that there were no statistically significant differences for the other items. Because of the two items in which the groups differed, the SG had a higher total score than that of the CG, with a $p$-value close to 0.05.

A negative correlation was verified between the data from the instrumental assessment of Pressure Pain Threshold...
| Author (year) | Sample | Myofunctional Assessment Procedures | Results / Identified OMD | Level of evidence |
|--------------|--------|-----------------------------------|--------------------------|------------------|
| Ferreira et al.\(^6\) | - 81 adults  
- Aged 18-41 years  
- Groups divided according to TMD and occlusion | - Clinical evaluation of mastication and deglutition (OMES)  
- Mastication time and frequency | - Changes in mastication behavior  
- Higher chewing frequency | 3 |
| Melchior et al.\(^14\) | - 1 woman with TMD  
- Aged 35 years | - Orofacial myofunctional evaluation with scores (OMES)  
- Electromyography | - Speech with mandibular deviation and lip  
- Preferred unilateral mastication on the right side  
- Atypical deglutition  
- Changes in orofacial mobility  
- Muscle imbalance  
- Post-treatment improvement | 5 |
| Ferreira et al.\(^16\) | - 44 subjects of both genders  
- Aged 21 years on average  
- Group with mild TMD (n=23)  
- Control group (n=21) | - Orofacial myofunctional evaluation with scores (OMES)  
- Evaluation of mandibular kinematics during unilateral mastication | - Worsening of the general myofunctional status (appearance and posture of lips and tongue, lips and mandible mobility, and deglutition)  
- Lower oxygen extraction capacity | 3 |
| Ferreira et al.\(^16\) | - 30 adult women  
- Group with moderate TMD (n = 20)  
- Control group (n = 10) | - Orofacial myofunctional evaluation with scores (OMES)  
- Measurement of masseter oxygen saturation during unilateral mastication | - Worsening of global myofunctional status (appearance and posture of lips and tongue, lips and mandible mobility, and deglutition)  
- Lower oxygen extraction capacity | 3 |
| Melchior et al.\(^17\) | - 5 women  
- Aged 50-61 years  
- After low-intensity laser therapy | - Orofacial myofunctional evaluation with scores (OMES) before and after orofacial myofunctional therapy | - Improvement of orofacial functions after orofacial myofunctional therapy | 3 |
| Rodrigues et al.\(^18\) | - 52 individuals of both genders  
- Aged 18-60 years  
- TMD group (n=27)  
- Control group (n=25) | - Clinical and electromyographic evaluation of mastication  
- Analysis of mastication efficiency | - Larger number of mastication strokes and longer mastication time  
- Greater electromyographic activity of the masticatory muscles  
- No impairment of mastication efficiency | 3 |
| Ferreira et al.\(^18\) | - 76 adults  
- Group with chronic TMD (n = 46)  
- Control group (n = 30) | - Orofacial myofunctional evaluation with scores (OMES)  
- Electromyography | - Changes in appearance/posture, mobility, mastication, and deglutition  
- Higher frequency of unilateral mastication  
- Longer mastication time | 3 |
| Weber et al.\(^23\) | - 70 women  
- TMD group (n = 34)  
- Control group (n = 36) | - Clinical evaluation of mastication and deglutition (OMES)  
- Cephalometric analysis of the position of the mandible and hyoid bone | - Chronic unilateral mastication  
- Changes of lip and tongue posture during deglutition  
- Lower position of the hyoid bone in relation to mandible | 3 |
| Maffei et al.\(^27\) | - 10 adults  
- Both genders  
- TMD group | - Videofluoroscopic evaluation of mastication and deglutition | - Preferred unilateral mastication with the presence of compensatory tongue movements  
- Signs of oropharyngeal dysphagia | 4 |
| Stuginski-Barbosa et al.\(^25\) | - 60 women  
- Group with myofascial pain syndrome  
- Control group | - Clinical assessment of deglutition | - Atypical deglutition | 3 |
| Busanello-Stella et al.\(^29\) | - 16 adults of both genders  
- Aged 19-51 years  
- Group with bruxism and orofacial pain | - Clinical evaluation of mastication, intra- and extra-oral aspects, sensitivity, tension and mobility | - Unilateral mastication | 4 |
| Matos and Sekito\(^46\) | - 44 individuals of both genders  
- Aged 43 years on average  
- TMD group | - Visual clinical examination of the habitual position of the lips and tongue  
- Pain on palpation | - Almost half of the individuals presented altered habitual tongue posture  
- Pain on palpation  
- Absence of pain/tongue posture relationship | 4 |
| Felício et al.\(^51\) | - 40 women (adolescents, adults and elderly)  
- TMD group  
- Control group | Clinical evaluation of mastication and deglutition | - Preferred unilateral mastication  
- Atypical deglutition | 3 |
| Pereira et al.\(^20\) | - 135 adults  
- Both genders  
- TMD group (n = 15)  
- Control group (n = 120) | - Mastication performance evaluation  
- Bite force | - Inefficient mastication  
- Reduced bite force | 3 |
demonstrating that the lower the PPT on the instrumental examination, the higher the occurrence of pain on palpation on the clinical examination. Existing correlations can be considered moderate, demonstrating that the MBGR Protocol enabled the identification of TMD signals.

Data from the clinical examination of breathing mode and those from the instrumental assessment of Peak Nasal Inspiratory Flow (PNIF) were homogeneous, considering that only one individual in the CG presented oronasal breathing and that there was no statistically significant difference between the groups for the instrumental assessment. Thus, it was found that both groups (SG and CG) are similar with respect to the nasal respiratory function and that the instrumental assessment confirmed the data obtained through the clinical examination using the MBGR Protocol.

Inter- and Intra-Rater Agreement Analyses for the Application of the MBGR and OMES Protocols

Table 4 shows the inter- and intra-rater agreement values for the evaluations performed using the MBGR Protocol. Agreement ranged from poor to very good and from reasonable to very good for the inter- and intra-rater power analyses.

Analysis of sensitivity and specificity values

Table 5 shows that the MBGR Protocol presented good sensitivity and specificity values for both cutoff points adopted, with the median as the best cutoff point, considering that there is a greater balance between them. The values found indicate that the MBGR Protocol presents the good capacity to identify individuals with and without OMD. Thus, the use of the MBGR Protocol could be beneficial for the early diagnosis and treatment of TMD.
Table 4. Inter- and intra-rater agreement in the application of the MBGR Protocol according to the Weighted Kappa Coefficient

| MBGR items                        | Weighted Kappa | Standard error | Agreement (%) | Strength of agreement |
|-----------------------------------|----------------|----------------|---------------|-----------------------|
|                                   | Inter | Intra | Inter | Intra | Inter | Intra | Inter | Intra |
| Extraoral examination             | 0.94  | 0.65  | 0.027 | 0.172 | 86.67 | 50.00 | a     | b      |
| Intraoral examination             | 0.74  | 0.55  | 0.085 | 0.2    | 70.00 | 50.00 | b     | c      |
| • Tongue                          | 1.00  | 0.74  | 0       | 0.165 | 100.00| 50.00 | a     | b      |
| • Hard palate                     | 0.20  | 0.80  | 0.152  | 0.118 | 83.33 | 83.33 | e     | b      |
| • Teeth and occlusion             | 0.96  | -     | 0.026  | -     | 86.67 | 100.00| a     | -      |
| Mobility                          | 0.51  | 0.74  | 0.097  | 0.096 | 46.67 | 83.33 | c     | b      |
| • Lips                            | 0.06  | -     | 0.051  | -     | 80.00 | 100.00| e     | -      |
| • Tongue                          | 0.84  | 0.57  | 0.091  | 0.353 | 83.33 | 83.33 | a     | c      |
| • Mandible                        | 0.64  | 0.86  | 0.115  | 0.155 | 63.33 | 83.33 | b     | a      |
| Function                          | 0.96  | 0.54  | 0.016  | 0.15  | 83.33 | 16.67 | a     | c      |
| • Breathing                       | 0.79  | 0.29  | 0.202  | 0.157 | 93.33 | 16.67 | b     | d      |
| • Mastication                     | 0.95  | 0.46  | 0.036  | 0.338 | 90.00 | 50.00 | a     | c      |
| • Deglutition                     | 1.00  | 0.97  | 0       | 0.018 | 100.00| 83.33 | a     | a      |
| • Speech                          | 1.00  | 0.93  | 0       | 0.054 | 100.00| 66.67 | a     | a      |

Caption: Inter = inter-rater (n=30); Intra = intra-rater (n=6). Strength of agreement: a = very good; b = good; c = moderate; d = reasonable; e = poor

Table 5. Sensitivity and specificity values

| Rated aspect | Cutoff point | Median (%) | Percentile (%) |
|--------------|--------------|------------|----------------|
| Sensitivity  | 71.43        | 50.00      |
| Specificity  | 75.00        | 79.17      |

In the criterion evaluation, a comparison between the two protocols showed that the agreement percentage was higher than the disagreement percentage and that there was a statistically significant negative correlation for all aspects to which the test could be applied. The moderate to strong strength of correlation variation found for the aspects considered in the present study may be explained by the differences between the items and the evaluation mode of the two protocols.

As for the construct evaluation, a statistically significant difference was found between the SG and CG regarding the clinical examination of pain on palpation and mandibular mobility. This result corroborates those of studies that reported changes in mandibular mobility\(^{(15,16)}\) and sensitivity to palpation on the masticatory and cervical muscles in individuals with TMD\(^{(14,24)}\).

No statistically significant differences were observed between the groups for the other aspects of the MBGR Protocol. Differences in the scores of mastication, deglutition, and speech were expected, considering that orofacial myofunctional changes in individuals with TMD have been described in the literature\(^{(14,16,19)}\). A possible explanation for these results can be attributed to the characteristics of the SG. They were community individuals who volunteered to participate in the study, but only two of them sought treatment for TMD. Moreover, they had mild, or absence of symptoms and the literature has shown that the severity of TMD has a greater influence on orofacial functions\(^{(14,16,19)}\).

Furthermore, one of the inclusion criteria for the SG was to present a specific diagnosis of TMD with disc displacement with reduction (DDWR). This type of TMD has been considered a common and asymptomatic condition that generally does not require treatment, considering that the structures of this region can adapt, and progression is benign in most cases\(^{(20)}\). This feature of DDWR added to the low symptomatology of the study participants could also justify the absence of difference between the groups with respect to OMD.

Still, regarding the construct evaluation, the negative correlation between the results of the Pressure Pain Threshold (PPT) instrumental assessment and the pain on palpation clinical...
examination of the masseter and temporal muscles is justified by the fact that individuals with TMD, in the presence of lower PPT by algometry, presented higher scores at the MBGR Protocol, unlike participants without this dysfunction, which is in agreement with a study that observed a negative correlation between TMD severity and muscle PPT(29).

Concerning the breathing function, nasal breathing was verified in all participants with TMD, corroborating studies that did not observe changes in this function(15,16,19). Considering that Peak Nasal Inspiratory Flow (PNIF) measurement presents good accuracy in detecting nasal obstructive changes(30), this measure confirmed the clinical findings as the participants showed values indicative of normality, that is, absence of nasal obstruction.

Regarding the inter- and intra-rater agreement, the strength of correlation ranged from moderate to very good for most items. However, weak or reasonable correlation strength was confirmed by instrumental assessment.

Some limitations to this study should be mentioned, such as the small sample size, mainly fin the SG, and the grouping of individuals with other diagnoses of TMD besides DDWR. Therefore, further studies should be conducted with larger samples addressing and separating groups with different diagnoses and severity levels of TMD.

CONCLUSIONS

The MBGR Orofacial Myofunctional Assessment Protocol (MBGR Protocol) is valid for application in adults presented with Temporal Mandibular Disorders (TMD) with disc displacement with reduction (DDWR) and control individuals and is capable of identifying Orofacial Myofunctional Disorders (OMD) and offering a diagnosis of specific changes in this TMD condition, with good sensitivity and specificity values.

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