Validation of the 2020 International Classification of Orofacial Pain Criteria for Diagnosing Local Myalgia in an Academic Clinical Setting in Thailand

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Abstract

1) *Introduction*: The International Classification of Orofacial Pain (ICOP) is a new classification system for diagnosing orofacial pains, which was published in December 2020, however, it still lacks validation for academic teaching purposes. This study aimed to validate ICOP for the masticatory local myalgia diagnosis in a Thai academic clinical setting by comparing with the reference standard Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). 2) *Objectives*: To determine the sensitivity, specificity, and inter-rater reliability of ICOP criteria for the diagnosis of local myalgia while comparing with the DC/TMD. 3) *Methodology*: This retrospective study extracted data from clinical charts in the Occlusion and Orofacial Pain Clinic, Chulalongkorn University, Thailand. Two independent clinicians graduated in TMD and Orofacial Pain specialty made the diagnosis based on ICOP and DC/TMD criteria. The diagnostic values of ICOP criteria were analyzed using DC/TMD diagnosis as a reference standard. 4) *Result and Discussion*: We screened 119 TMD patients retrospectively and found 103 local myalgia, 16 non-local myalgia were equal to 1 when compared to DC/TMD. The inter-rater reliability for ICOP criteria was 0.973 (*p*-value < 0.01). 5) *Conclusions*: This study indicates that the recently reported ICOP criteria could be used as an alternative to DC/TMD for diagnosing local myalgia towards the purpose of academic teaching in clinical settings. Future validation studies on ICOP criteria will evaluate the sensitivity and specificity of different myalgia diagnoses.

Keywords: Temporomandibular Disorders, Masticatory Muscles, Local Myalgia, ICOP, DC/TMD.

1. Introduction

Myalgia is defined as masticatory muscle pain condition affected by jaw movement, function, or parafunction and replication of this pain occurs with palpation testing (Schiffman et al., 2014). The prevalence of myalgia is the highest in temporomandibular disorders ranging from 0.4-27.8% of the total population (Manfredini et al., 2011; Mishra, 2019). In 2020, the myofascial pain treatment market grew with a compounded annual growth rate of 4% (Data Bridge Market Research, 2021). That growth partly showed the world's health concerns for myofascial pain and at the same time reflects an increase in the medical burden. Therefore, an accurate and effective diagnostic process and early disease identification will be the keys to reduce the global burden of this health condition.

In 1992, The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) was introduced as the first classification for muscle pain in the orofacial region. Later on, a revised Diagnostic Criteria for TMD (DC/TMD) was developed and validated in 2014 with high sensitivity and specificity (0.9 and 0.99, respectively). For decades, DC/TMD has been commonly used and considered as a reference standard for the diagnosis of myalgia. In the DC/TMD classification, myalgia is subcategorized into local myalgia, myofascial pain with spreading (MFP with spreading) and MFP with referral according to pain location during palpation. Then, local myalgia is diagnosed as myalgia without spreading or referral pain when palpation (Schiffman et al., 2014) (Figure 1).

International Classification of Orofacial Pain (ICOP) was established and reported in late 2020 (International Headache Society, 2020). The ICOP is considered a comprehensive classification for orofacial pains because it has combined the International Classification of Headache Disorders, 3rd edition (ICHD-3) with the DC/TMD. Moreover, it was also aligned to the International Classification of Diseases 11th Revision

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(ICD-11) according to the International Association for the Study of Pain (IASP) criteria. The combination of existing classifications makes ICOP more generalizable and could be eventually used as a common language among pain specialists. In the ICOP classification, myalgia, headache attributed to TMD and tension-type headache (TTH) are combined into the myofascial orofacial pain (MOP) group (Figure 1). Theoretically, ICOP criteria could be used to specifically diagnose local myalgia. However, the ICOP criteria has not been yet validated, hence the aim of this study was to perform such validation while diagnosing local myalgia and strengthen the MOP diagnosis for further academic, clinical and research purposes. Additionally, one of the most important reasons for TMD under-treatment and misdiagnosis is the lack of diagnostic training for TMD conditions in academic clinical settings (Reissmann, Behn, Schierz, List, & Heydecke, 2015). This gap of knowledge led us to propose a validation process towards further utilization of ICOP criteria as intended learning outcome for academic teaching and training purposes.



Figure 1 Myalgia diagnostic subgroups according to the DC/TMD classification (*left*) and MOP diagnosis subgroups according to the ICOP classification (*right*)

2. Objectives

1. To determine the sensitivity, specificity of ICOP criteria when compared to DC/TMD criteria for the diagnosis of local myalgia.

2. To determine the inter-rater reliability of ICOP criteria for diagnosing local myalgia.

3. Materials and Methods

This retrospective study was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand (certificate number: HREC-DCU 2022-106). Data were obtained from Thai citizens who were diagnosed with local myalgia at the Chulalongkorn University Occlusion and Orofacial pain Clinic. Exclusion criteria include patients with pain in other structures other than masticatory muscles (such as joint pain, neck or back pain) and the presence of systemic factors related to pain symptoms (e.g. fibromyalgia). The sample size was calculated using the formula (written in Excel, Microsoft Office 2019 version) from a previous report of the expert team who developed the RCD/TMD and DC/TMD (Schiffman et al., 2010). Hence, the estimated sample size for this study was 119 myalgia cases.

Clinical data from 119 local myalgia subjects was extracted from the Occlusion and Orofacial Pain Clinic database according to a previous report (Nguyen, Vanichanon, Bhalang, & Vongthongsri, 2019). All subjects were examined, and data was recorded in the medical charts by Thai Board certified specialists. The individual data included a full DC/TMD Axis I evaluation and pain parameters followed the Graded Chronic Pain Scale (GCPS). The raw data was screened and cleaned by the main investigator. Then, the data set was numbered in order from 1 to 119 and rearranged in random sequences available by an online randomization

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software (Random.org, Randomness and Integrity Services Ltd, Ireland). All randomly consolidated data were sent to two raters, which are clinicians graduated in TMD and Orofacial Pain at the Department of Occlusion and Orofacial Pain, Faculty of Dentistry, Chulalongkorn University. The raters independently reviewed the data and recorded the diagnosis for each patient based on DC/TMD and ICOP criteria. A third rater reviewed and evaluated the clinical data to produce a final decision, in case of disagreement between the two initial raters, and then sensitivity and inter-rater agreement was calculated. A good performance for specific diagnostic criteria was consider with a sensitivity greater than 0.7 and a specificity greater than 0.95 (Dworkin & LeResche, 1992).

The descriptive statistics (proportions, mean, and standard deviation (SD)) were obtained for all subject characteristics within each diagnostic category. As appropriate, bivariate analyses to study the significance of the differences across the ICOP and DC/TMD were conducted with Fisher's exact test (categorical variables). Cohen's kappa coefficient used for calculating interrater reliability. All analyses were conducted using IBM SPSS Statistics for Windows, version 28 (IBM Corp., Armonk, N.Y., USA). The level of significance was set at 5%.

4. Results and Discussion

4.1 Results

A total of 119 individuals was diagnosed with myalgia according to DC/TMD, the predominance was female, accounting for 68.9%, mean age was 34.13 ± 12.28 . Myalgia subjects showed a mean duration and frequency of pain of 450.44 ± 1024.34 days and 8.86 ± 4.96 days/2 weeks, respectively. Moreover, 103 myalgia cases (86.55%) had local pain while the remaining subjects (13.45%) had referred pain (Table 1).

Table 1 Myalgia patient characteristics	
Female Sex, n (%)	82 (68.9)
Age, years (mean ±SD)	34.13 ±12.28
Pain duration, days (mean ±SD)	450.44 ±1024.34
Pain intensity, 0-10 (mean ±SD)	5.22 ±1.92
Pain frequency, days/2 weeks (mean ±SD)	8.86 ±4.96
Number of subjects with localized pain, n (%)	103 (86.55)

Next, 119 myalgia cases were divided into two groups, the positive local myalgia group had 103 subjects and the negative group with non-local myalgia had 16 subjects (Table 2). The ICOP diagnostic classification was then completed for all subjects and these were recoded and matched with the DC/TMD subtypes (Table 2). Following the diagnostic classification according to ICOP criteria, more than half of the subjects (56.3%) were diagnosed with acute MOP, 20.2% with chronic MOP high frequent without referral, 11.8% with chronic MOP high frequent with referral, 10.1% with chronic MOP frequent without referral and the remaining were chronic MOP frequent with referral.

The two raters performed with a good agreement while diagnosing for MOP subtypes according to DC/TMD as per inter-rater reliability of 0.973 (p < 0.01).

Based on the ICOP and DC/TMD diagnostic criteria, we matched and recoded the local myalgia with subtypes from the ICOP classification. Local myalgia coincides with acute MOP, chronic MOP infrequent, chronic MOP frequent without referral, and chronic MOP high frequent without referral subtypes. The non-local myalgia group coincides with chronic MOP frequent with referral and chronic MOP high frequent with referral. Hence, Table 3 shown the sensitivity, specificity, positive predictive value, negative predictive value in diagnosis local myalgia compared with DC/TMD. All results were all equal to 1.

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			Local myalgia by DC/TMD		
			Local	Non-local	Total
			Myalgia	myalgia	n (%)
			n (%)	n (%)	
	Acute MOP	(2.1.1)	67	0	67
			(56.3)		(56.3)
	Chronic MOP frequent without	(2.1.2.2.1)	12	0	12
	referral		(10.1)		(10.1)
MOP by ICOP	Chronic MOP frequent with	(2.1.2.2.2)	0	2	2
(diagnostic code)	referral			(1.7)	(1.7)
	Chronic MOP high frequent	(2.1.2.3.1)	24	0	24
	without referral		(20.2)		(20.2)
	Chronic MOP high frequent	(2.1.2.3.2)	0	14	14
	with referral			(11.8)	(11.8)
	Total		103	16	119
			(86.55)	(13.45)	(100)
Inter-rater reliability for ICOP diagnosis (Cohen's Kappa)		0.973^{*}			

Table 2 Matching diagnostic criteria between ICOP and DC/TMD classifications

*p-value <0.01

Table 3 Validity results for the ICOP criteria with respect to local myalgia according to DC/TMD

	DC/TMD +	DC/TMD -	Total	Sensitivity	Specificity	PPV	NPV
ICOP +	103	0	103	1	1	1	1
ICOP -	0	16	16				
Total	103	16	119				

PPV: Positive predictive value; NPV: Negative predictive value

4.2 Discussion

This study showed that the ICOP criteria is a valid tool to identify all subjects with local myalgia according to DC/TMD criteria, in a Thai academic setting. This study confirms the high sensitivity and specificity of ICOP criteria for local myalgia diagnosis determined that ICOP criteria could be used as an alternative to DC/TMD for diagnosing local myalgia during academic teaching and clinical training at Thai universities. A possible explanation for such high sensitivity and specificity is that both DC/TMD and ICOP use clinical palpation testing on masticatory muscles as the most important criteria. Though in the DC/TMD criteria, the muscle palpation test depends greatly on the experience of clinical examiners; therefore, experts do recommend using algometer as a calibration tool (Iglesias-Peón et al., 2022). Earlier on, The RDC/TMD validation project reported a palpation test with an inter-rater reliability value greater than 0.75 for all diagnostic subtypes (Look, Schiffman, Truelove, & Ahmad, 2010), which indicated that this test had a high satisfactory performance for research and clinical purposes.

In this study, all acute MOP patients were diagnosed with local myalgia, which confirmed that acute MOP has no referred pain. This finding has also been found in another local-myalgia population in Tel Aviv University Orofacial Pain Clinic, Tel Aviv, Israel (Winocur-Arias et al., 2022). Several studies have found that referred muscle pain is associated with increased risk for psychological involvement, different pathogenesis mechanism and different treatment response (Ernberg, Jasim, Wåhlén, & Ghafouri, 2022; Winocur-Arias et al., 2022). Indeed, treatment plans and strategies for local myalgia require less complex follow ups compared with other myalgia subtypes (Montes-Carmona, Gonzalez-Perez, & Infante-Cossio, 2021). Similarly, less medical assistance is needed in acute pain conditions as opposed to chronic ones (Zakrzewska, 2013). In the general comments section of the ICOP report, authors state that referred pain can be present in both acute and chronic patients (International Headache Society, 2020). To our knowledge, there

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are no clear and objective research reports to support this expert opinion. Moreover, while previous studies did not offer a consensus on the definition of "chronic pain", ICOP used a new definition from the International Association for the Study of Pain (Nicholas et al., 2019; Sabsoob et al., 2022). Thus, there is still an ongoing concern on whether 3 months pain duration could be considered as the lower cut-off time for transitioning from localized to refractory, chronic or referred pain.

Because ICOP combines the diagnostic criteria of myalgia, TTH, and headache attributed to TMD, it requires a higher number of diagnostic criteria than the previous individual classification systems to differentiate all clinical orofacial pain subtypes. To illustrate this, for the myalgia diagnostic group for example, ICOP divided it into 6 subcategories of MOP compared to the 3 subcategories of myalgia in the DC/TMD classification system (Figure 1). Hence, for diagnosing myalgia following ICOP criteria, it requires more data on pain parameters such as duration and frequency, which are not deemed necessary for the DC/TMD. Recently, there were clinical experts claiming one should expand the ICOP criteria and create new definitions from ICOP classification for clinical and research purposes involving orofacial pain subjects (Benoliel, 2019; Ziegeler & May, 2020). Despite new ICOP criteria being more complex than DC/TMD, our findings have shown a high agreement between raters and suggest that ICOP criteria are reliable and reproducible to use in academic institutions for training purposes.

This study was unique as it was the first to characterize patients with local myalgia using the new ICOP criteria. In addition, it was first study to our knowledge to validate ICOP criteria for local myalgia while comparing with the reference standard DC/TMD. The current study was not able to answer the question whether the effectiveness of ICOP is better than the previous classifications for the diagnosis of myalgia, headache attributed TMD and TTH. However, it will be useful for strengthen ICOP criteria and for further ICOP revisions of the ICOP. Confusing synonyms for myalgia conditions from previous orofacial pain classification systems have been unified and presented in this study. To manage big data in healthcare, it would be relevant to avoid using overlapping terms during the diagnostic process for orofacial pain conditions, and improve the academic learning and training towards the clarity of such processes and to offer better treatment outcomes for pain patients.

We should acknowledge that this study has its own limitations. Firstly, the number of individuals in the "non-local myalgia" group was limited and not matched with the "local myalgia" group due to the study retrospective design. Secondly, the reliability testing was performed according to raters recently graduated in TMD, therefore, further investigations are needed to determine if these findings are reproducible at the undergraduate teaching levels or if experience after TMD graduation would change our outcomes. Thirdly, the influence of the heterogeneity in palpation techniques could be source of bias in DC/TMD and could have influenced our results. Finally, the psychological aspects could influence in pain diagnosis did not exclude in this study.

This study demonstrates that the ICOP criteria could be used for diagnosis local myalgia condition. Further studies are needed for validating ICOP criteria for other myalgia subgroups. Moreover, the possibility of unifying ICOP criteria for diagnosing myalgia, TTH and headache attributed to TMD may need to be investigated further. There are some overlapping signs and symptoms and also common responses to treatment among these conditions. Notably, myalgia and headaches frequently co-occur as comorbid conditions and could commonly cause misdiagnosis (Ashraf, Narhi, Suominen, & Saxlin, 2022). However, according to pain field experts like Dr. Jeffrey Okeson (Okeson, 2008), musculoskeletal pain originates from deep somatic tissue while TTH are neurovascular in origin. Clinical features of myalgia may not be present together with spontaneous pain symptom patterns. Additionally, according to several epidemiological studies, not all myalgia cases report headache symptoms or vice-versa (Memmedova, Emre, Yalın, & Doğan, 2021; Yakkaphan, Smith, Chana, Renton, & Lambru, 2022). Hence, once these 3 separate entities merged into one, that might create a convergence of treatment strategies for muscle pain and headache. In the current state-of-the-art management of orofacial pains, treatment of TTH has more similarities to the one for MFP but not for local myalgia, which can lead to over-treatment on individuals with local myalgia (Ashina et al., 2021).

Presently, for research purposes, the separation in the validation project of myalgia subtypes may be justified. This study is feasible to use the available data because DC/TMD and ICOP share the same palpation

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procedure on the masseter and temporalis muscles to diagnose local myalgia. However, for future studies determining the diagnostic efficacy of ICOP in clinical and research settings, a broader population combining both myalgia and headache participants is necessary. Secondly, examination procedure should confirm trigger points in neck region such as sternocleidomastoid, splenius, and trapezius muscles for screening tension type headache individuals (International Headache Society, 2018). Previously, the RDC/TMD examination recommended 20 palpation points on muscles (Dworkin et al, 1992), but the current DC/TMD was revised and reduced to 12 palpation points due to the low accuracy of intraoral muscle palpation (Schiffman et al., 2014). Since ICOP is a comprehensive classification containing TTH into MOP diagnosis, defining the location of trigger points with the palpation test is essential to avoid misdiagnosis. Thus, the cooperation between orofacial pain and headache experts in future ICOP or DC/TMD revisions and updates is required.

In summary, the ICOP criteria had a high sensitivity, specificity, and reliability for diagnosing local myalgia when the DC/TMD was used as a standard at an academic setting.

5. Conclusion

The 2020 ICOP criteria was found to possess high sensitivity, specificity and inter-rater reliability for screening and diagnosing masticatory local myalgia for educational and training purposes in an academic clinical setting. These outcomes were comparable to the reference standard DC/TMD, hence ICOP criteria can be a feasible alternative to the latter. To our knowledge, this is the first study to assess the sensitivity and specificity of the newly reported 2020 ICOP criteria for local masticatory myalgia.

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