

The Open Dentistry Journal

Content list available at: https://opendentistryjournal.com



RESEARCH ARTICLE

Validation of the Jaw and Facial Activities Limitation (JFAL) Questionnaire for Orofacial Pain Patients

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Abstract:

Background:

Orofacial pain remains one of the most complained dental abnormalities that resulted in the limitation of the jaw and facial activities of the sufferer. Therefore, a simple yet effective questionnaire that can be used by dental professionals to evaluate the level of the jaw and facial activity limitation of orofacial patients is needed.

Objective:

The objective of the current study was to test the validity and reliability of the jaw and facial activities limitation questionnaire of orofacial pain patients.

Methods:

One hundred and two(33 male: 69 female) patients aged 18 to 45-year-old (mean: 28.39; standard deviation (SD): 8.23) with orofacial pain(pain in the oral or facial area that was experienced by the participant at the time of data collection) were recruited. The questionnaire consists of seven questions; the first six questions evaluate the patient's jaw activity whilst the seventh question evaluates the patient's facial activity through smiling ability. Each question is accompanied by four Likert-type scale answers, which are "not at all", "a little bit", "moderately", and "a lot". Reliability was measured by calculating the Cronbach's alpha while validity was measured by using the Pearson's correlation.

Results:

Cronbach's alpha measurement revealed a coefficient of 0.80 whilst Pearson correlation analysis showed that the r-value for each question was higher than the r table value (0.230), confirming the validity of all questions. All p-values were < 0.05.

Conclusion:

Validity and reliability testing of the current questionnaire revealed that the questionnaire was proven to be valid and reliable.

Keywords: Orofacial pain, Jaw activity, Questionnaire, Validity, Reliability.

Article History Received: March 07, 2020 Revised: May 08, 2020 Accepted: May 13, 2020

1. INTRODUCTION

Orofacial pain, a term that can be defined as pain that related to the oral and facial region remains one of the most complained dental problems [1 - 3]. At least a quarter of the general population has been affected by orofacial pain [3]. A review study about the prevalence of orofacial pain confirmed that 10% of the adult population experienced facial pain [4].

An epidemiology study conducted by Shetty *et al.*, (2015) in 2200 patients who visited the Oral and Maxillofacial Surgery Departments of Sri Rajiv Gandhi College of Dental Sciences and Hospital in Bangalore, India, from the period of March 2010 to April 2011 revealed that deep somatic oral pain (which were pulpal dental pain and periodontal pain) was the most common type of orofacial pain experienced by orofacial pain patients. It was also reported that orofacial pain is more likely to occur to female than to those of the male population [5, 6]. In another review about orofacial pain conducted by Benoliel *et al.*, (2019), it was revealed that chronic primary orofacial

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pain due to painful Temporomandibular Disorders (TMD) reached 5% of the population (6.3% in women, 2.8% in men) [3].

Aside from the high prevalence, a study about orofacial pain and its impact revealed that orofacial pain interferes with the ability to work as well as the ability to perform daily activities [7]. Another study about orofacial pain and the quality of life of the sufferers in India showed that the occurrence of orofacial pain was strongly associated with poor quality of life [8]. The strong association between orofacial pain and the poor quality of life might be due to the fact that orofacial pain might interfere with mastication as well as swallowing and speaking ability [9 - 11]. In a study about orofacial motor functions on patients with chronic temporomandibular disorders (TMD), it was found that chronic TMD patients had significantly greater difficulty when masticating compared to healthy subjects. It was also revealed that chronic TMD patients demonstrated longer mastication period when performing free mastication [11]. In relation to functions, Sessle (2015) also stated that some chronic orofacial pain patients might experience difficulties when performing mastication and swallowing [12].

Aside from several jaw functions that were mentioned above, facial activities such as smiling and laughing, are the type of activities that manifested simultaneously with those jaw functions. These activities can be limited or impaired by the occurrence of orofacial pain [13]. Based on the functional limitations that might be experienced by orofacial pain patients, a questionnaire that aimed at evaluating the jaw and facial activities limitation on orofacial pain patients was constructed. The current questionnaire is the first questionnaire that evaluates the difficulties of occlusion, speaking, mouth opening and closing, swallowing, lateral movement of the jaw, and facial function on all type of orofacial pain patients, while most previous evaluation tools were designed to evaluate the limitation of the jaw due to a specific orofacial disorder. The current study aimed to test the reliability and validity of the Jaw and Facial Activities Limitation (JFAL) Questionnaire as an evaluation tool for jaw and facial activities limitation on orofacial pain patients.

2. MATERIAL AND METHODS

In the current study 102 (33 males: 69females) patients that visited the Oral Surgery Outpatient Clinic - Unpad Dental Hospital, Bandung, Indonesia, with a minimum pain score of four [4] due to several orofacial pain conditions were recruited. Orofacial pain was quantified by using a Numeric Rating Scale (NRS). Before the start of the study, ethical clearance was gained from the UniversitasPadjadjaran Research Ethics Committee (ethical clearance number 1303/UN6.KEP/EC/2018). To confirm, every procedure and ethical aspect of the current research has been conducted in full accordance with the World Medical Association Declaration of Helsinki and that all participants gave written consent for their participation in the current study. Therefore, all participants signed informed consent before the start of the study.

2.1. Sample Selection

As there are no standardized rules for sample size calculation for questionnaire validation [14], the authors calculated the sample size based on some references from previous studies [14 - 16]. Previous studies variously employed the 5 to 1 comparison (5 patients should be recruited for each question being validated), the 15 to 1 comparison, and the 30 to 1 comparison. In the current study, the 15 to 1 comparison was implemented. As for the type of patients recruited for the current study, the inclusion criteria were: patients that aged between 18 to 45 years old; the patient was experiencing orofacial pain at the time of data collection (minimum NRS score: 4); the patient had no communication problem(as the data collection was in the form of an interview).

The types of orofacial pain conditions included in the current study were trigeminal neuralgia, atypical odontalgia, myofascial pain of the masticatory muscle, acute irreversible pulpitis pain, orofacial pain due to periapical abscess, orofacial pain due to oromaxillofacial trauma, orofacial pain due to temporomandibular disorders (TMD), and periodontal pain. There were no specific criteria for the type of orofacial pain conditions included in the current study. These are the conditions that were encountered during the period of this study.

2.2. Data Collection

One interviewer (Dentist) interviewed all participants by using the questionnaire. The interview was conducted when the participant was sitting on the dental chair after receiving their final diagnosis and before the start of their treatment. Every dental chair in our outpatient clinic is located in a separate cubicle in order to provide comfort and privacy for our patients. In order to prevent the participants from providing information that might falsely benefit the validation process, prior to the interview, the participants: were given comprehensive information about the aim of the current study including the possible implication of the questionnaire in the treatment planning of orofacial pain patients in the future; were asked to give an honest and accurate response regarding their pain level as well as the amount of limitation of their jaw activity as their response will be used as scientific information for composing the treatment planning for future orofacial pain patients, and therefore, an inaccurate response might have future consequences; were informed that as long as it is relevant there were no "correct" or "incorrect" answer when answering the questions in the questionnaire; were informed that their involvement and response in the study would not affect their current treatment. During data collection, the interviewer was supervised by one of the senior authors to ensure that the interviewer gave the correct information to the participants and did not lead the participants in a certain direction when answering the question.

2.3. Questionnaire

As mentioned above, based on previous studies, there were several specific jaw and facial activities that were limited or impaired on orofacial pain patients. Therefore, to identify as well as evaluate the difficulties experienced by orofacial pain patients in performing those functions, a short questionnaire was constructed. The questionnaire consists of six questions that evaluated several jaw functional activities and one question that evaluated facial activity. The questions of the newly constructed questionnaire can be viewed in Fig. (1). Each question was provided with a Likert-type scale of answers, which were: "not at all", "a little bit", "moderately", and "a lot". An answer of "not at all" was then scored as "0", "a little bit" was scored as 1, "moderately" was scored as 2, and "a lot" was scored as 3. Therefore, a higher score of the questionnaire indicates more jaw and facial activitylimitations.

2.4. Validity Test

Validity is defined as "the extent to which (a test) measures what it is intended to measure" [17, 18]. In the current study,

validity was obtained by performing the face validity (that involved four experts from related fields) and construct validity (the Pearson correlation analysis) [19, 20]. Further elaborations concerning the face validity can be viewed in the Discussion section. As for construct validity, it was obtained by comparing the obtained r-value of each question(from the Pearson correlation analysis) to the r-table product-moment. The determination of the r table (product-moment) value was based on the number of participants (n=102) and the significance of the p-value (p<0.01). The r table value was then set at 0.230. Once the Pearson correlation test was conducted, the r-value for each question was obtained. The authors then compared the obtained r-value for each question to the r table value. If the obtained r-value was higher than the r table value, then the question was considered to be valid.

Name	:
Age	:
Sex	:

Please tick the box that is most appropriate for describing the level of your oral and facial activities limitation due to your orofacial pain!

Due to your orofacial pain:

1.	. How difficult it is contact?	for you to	bring your u	pper teeth and yo	our lower teeth in
	\Box not at all \Box a l	little bit	moderately	□ a lot	
2.	. How difficult it is f	or you to sp	eak?		
	\square not at all \square a l	little bit	moderately	□ a lot	
3.	. How difficult it is f	or you to op	en your mout	h?	
	\Box not at all \Box a l	little bit	moderately	□ a lot	
4.	. How difficult it is f	or you to cl	ose your mou	th after you open y	our mouth?
	\square not at all \square a l	little bit	moderately	□ a lot	
5.	. How difficult it is f	or you to sv	vallow (saliva	or food)?	
	\square not at all \square a l	little bit	moderately	□ a lot	
6.	. How difficult it is f	or you to m	ove your jaw	laterally?	
	\square not at all \square a l	little bit	moderately	□ a lot	
7.	. How difficult it is f	or you to sr	nile?		
	□ not at all □ a l	•		□ a lot	

Fig. (1). Jaw and facial activities limitation questionnaire for orofacial pain patients.

2.5. Reliability Test

Internal consistency (which is one of the variables of reliability), is defined as the ability of an instrument to measure consistently [21]. In this study, internal consistency was measured by calculating the Cronbach's alpha coefficient, which has been used in many previous studies and has been well-acknowledged as a valid measurement to measure internal consistency [22 - 24]. Cronbach's alpha was first introduced by Lee Cronbach (1951) in an attempt to provide a valid measurement method to measure internal consistency. The value of Cronbach's alpha ranged from 0 to 1. The result is a description of the extent to which all items in the questionnaire measure the same concept [21]. In the current study, once the data was tabulated, Cronbach's alpha was measured by analyzing question 1 to question 7 by using the inter-item correlation analysis. The description of each item, as well as the scale was included in the analysis. Once the Cronbach's alpha value was obtained, it was interpreted. The closer the value to 1, the greater the reliability is.

2.6. Additional Measurements

The current study also measured the participant's pain level by using the Numeric Rating Scale (NRS) for pain measurement. This NRS for pain measurement is a scale that consists of numbers between 0 (no pain) to 10 (worst pain possible). Participants were asked to mention a certain number (between 0 to 10) that represented their pain level at the time of the interview. Measurement of the mouth opening was also conducted by using the Alma bite gauge. The participant was asked to open their mouth to a certain position where no pain was experienced, and a vertical distance between the upper incisor and the lower incisor was measured.

3. RESULTS

Participants recruited in the current study aged between 18 to 45 years old (mean age: 28.39; SD: 8.23) that consisted of 33 male participants and 69 female participants. The evaluation of the current questionnaire involved 102 participants with different orofacial pain conditions. The pain level, as well as the mouth opening level of the participants, were also recorded. The demographical, as well as clinical characteristics, are displayed in Table 1.

All participants responded to the questions in the questionnaire. The data of the participants' responses can be viewed in Fig. (2).

The validity testing of the current questionnaire revealed that all questions were proven to be valid Table 2 and significantly correlated (p< 0.01).

It was also revealed that question number 3 showed the highest average score, indicating that for patients with pain due to periapical abscess, the difficulty level to open the mouth was higher compared to other jaw functional activities. As for internal consistency, the reliability test of the questionnaire gave a Cronbach's alpha coefficient of 0.80, indicating the high reliability of the questionnaire. Additional descriptive analysis to see the mean score for each question Table 2 as well as the distribution of participants based on the answers provided, can be viewed in Table 3. From the last table, it can be concluded that the activities that were most likely to be highly limited based on the participants' answer was mouth opening (39.2% participant answered their limitation level was moderate to a lot) and smiling (30.3% participant answered their limitation level was moderate to a lot).

Table 1. Distribution of participants based on its demographical and clinical characteristics.

Variable	Categories and Number of participants							
Sex		N	Male			Femal	e	
	3	33 participants 69 participants						
Age	18	3 – 3	0 year old	i	31	– 45 ye	ar old	
	6	5 pa	rticipants		37	particip	oants	
Type of orofacial pain condition*	TN	ΑO	MPMM	AIPP	PPA	POMT	TMD	PP
	9	8	10	26	15	10	12	12
NRS** score			4 to 7			>7		
	59 participants 43 participan		oants					
Mouth opening	≤35 mm			>35 mm				
	2	5 pa	rticipants		77	particip	oants	

^{*} TN: trigeminal neuralgia; AO: atypical odontalgia; MPMM: myofascial pain of the masticatory muscle; AIPP: acute irreversible pulpitis pain; PPA: pain due to periapical abscess; POMT: pain due to oral and maxillofacial trauma; TMD: pain due to TMD; PP: periodontal pain.

**NRS = Numeric Rating Scale for pain.

Table 2. r values and p values for the Pearson correlation and mean score for every question of the questionnaire.

Item	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7
r value	0.675	0.888	0.594	0.614	0.767	0.383	0.781
p value (two tailed)	< 0.01*	< 0.01*	< 0.01*	< 0.01*	< 0.01*	< 0.01*	< 0.01*
Mean score	0.74	0.94	1.26	0.44	0.94	0.97	0.90

^{*}significant

Item	Number of participants							
	Not at all	A little bit	Moderately	A lot				
Question 1	41 (40.2%)	47 (46.1)	14 (13.7%)	0 (0%)				
Question 2	40 (39.2%)	37 (36.3%)	16 (15.7%)	9 (8.8%)				
Question 3	23 (22.5%)	39 (38.2%)	30 (29.4%)	10 (9.8%)				
Question 4	62 (60.8%)	35 (34.3%)	5 (4.9%)	0 (0%)				
Question 5	39 (38.2%)	33 (32.4%)	27 (26.5%)	3 (2.9%)				
Question 6	30 (29.4%)	50 (49.0%)	17 (16.7%)	5 (4.9%)				
Question 7	49 (48.0%)	22 (21.6%)	23 (22.5%)	8 (7.8%)				

Table 3. Distribution of participant answers based on the Likert-type scale of the questionnaire.

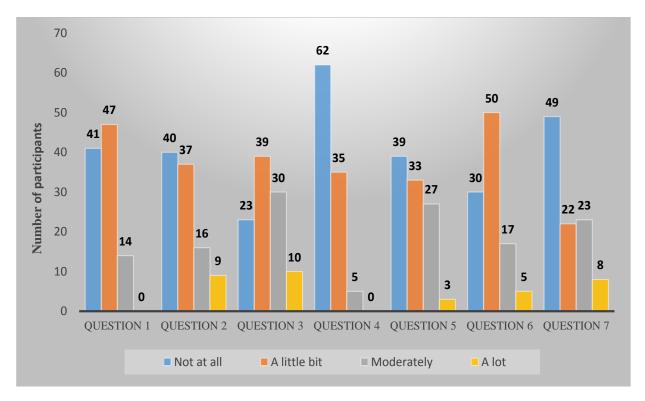


Fig. (2). Distribution of participants based on the response to thequestions in the questionnaire.

4. DISCUSSION

As previously mentioned, orofacial pain is known for its impact on several jaw activities as well as facial activity, namely smiling. It is, therefore, an evaluation of the impact that it has on these functions has become an important part of the management of orofacial pain. Aside from the current questionnaire, there are several evaluation toolsthat have been used the most,to evaluate the limitation of the jaw due to oral disorder, namely the Jaw Function Limitation Scale (JFLS), the Mandibular Function Impairment Questionnaire (MFIQ), the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) functional limitation checklist, and the

Oral Health Impact Profile (OHIP) [13, 25 - 27]. Yet, none of these evaluation tools evaluate the difficulties of occlusion as well as the lateral movement of the jaw along with the other jaw basic functions. It is also important to note that most of the evaluation tools mentioned above (aside from the JFLS) are intended to evaluate the limitation of the jaw due to a specific orofacial disorder [13]. It is, therefore, in our opinion, would be of benefit to compose a simple-yet representative self-reported questionnaire that can be used generally for all types of orofacial pain.

In the current study, the validity and reliability of the

questionnaire that was composed to evaluate the difficulty experienced by orofacial pain patients when performing several jaw functions and one facial function namely smiling due to the pain experienced by the patient, were tested. As known, there are several types of validity, which are face validity, content validity, construct validity, and criterion validity [23, 28] Concerningface validity, several methods can be used to measure face validity, one of which, is expert evaluation [29]. In the current study, the face validity of the questionnaire was evaluated by four experts. The first expert was a specialist in the field of prosthodontics (TS), the second expert was a certified psychologist and researcher (ST), the third expert was a certified oral physiologist (RW), and the last one is an expert in the field of orofacial pain (TM). All experts discussed, selected, and evaluated every question contained in the questionnaire.

With regard to construct validity, as it is the only validity that can be tested statistically, we tested the construct validity of the questionnaire by using the Pearson correlation. The usage of the Pearson correlation for measuring the construct validity of a Likert scale questionnaire has been well documented in previous studies [20, 30, 31]. In a literature study by Norman (2010) about the selection of the appropriate statistical measure for a questionnaire or another evaluation tool that has a Likert scale type of answer, the reasoning for using Pearson correlation as a measurement method for Likert scale type of questionnaire was fairly discussed. It was concluded and stated that there was no significant difference found between the Pearson correlation and the Spearman correlation when it comes to validity measurement and that the two measurements yielded identical values. The Pearson correlation is considered to be extremely robust, regarding assumption violation [32]. Concerning the usage of the Likert scale in the current study, the usage of this particular scale in the questionnaire is considered to be appropriate as the Likert scale is considered to be more reliable when used in literate subjects. According to the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the adult literacy rate in Indonesia as per 2018 is 95.7% [33], which means, the usage of the Likert scale in the current questionnaire is of appropriate.

As for internal consistency, the results of the current study showed a high Cronbach's alpha value. In internal consistency, the higher the score, the more related the items contained in the evaluation tool. Yet, it is important to note that a high Cronbach's alpha value is not necessarily an indication of high internal consistency. This is because Cronbach's alpha value is also affected by the length of the questionnaire. If the questionnaire is short or not long enough, then Cronbach's alpha value will decrease [21]. In regards to Cronbach's alpha value, it is worthy to note that for a newly developed scale or questionnaire, the minimum value of Cronbach's alpha that can be considered as acceptable is 0.70, while a value that lies between 0.70 and 0.90 is considered as good [34].

The usage of Cronbach's alpha as an indicator of the internal consistency or reliability of an evaluation tool has also been documented in previous studies, including those of pain studies [23, 35, 36]. In a study about the pain experienced by

oral cancer patients by using a custom made oral cancer pain questionnaire, internal consistency was also calculated by measuring the Cronbach's alpha coefficient [23], indicating its common usage for describing internal consistency. Concerning the current questionnaire, the selection of Cronbach's alpha as a reliability indicator is becausethe Cronbach's alpha determines how all the questions or items in the evaluation tool relate to the other questions or items as well as to the total of the questions or items. Additionally, it is important to note that whenever a Likert-type scale is used, it is essential for the researcher to calculate internal consistency by using Cronbach's alpha coefficient [37]. Therefore, the usage of the Cronbach's alpha value as the indicator of the reliability of the current questionnaire is considered to be appropriate and that internal consistency has been well-measured.

The next important aspect concerning questionnaire development as well as questionnaire validity and reliability testing is its applicability in daily practice. The current questionnaire, due to its simplicity, can be used by a general dental practitioner as well as an orofacial pain specialist to evaluate the degree of several jaw and facial functions in orofacial pain patients. This simplicity aspect is also considered to be an advantage for orofacial pain patients as it will be more convenient for patients to complete the questionnaire. And due to its generality, it can be used to evaluate functions limitation in all kinds of orofacial patients. It is hoped that by revealing the degree of these functions' limitation, treatment planning will no longer focus on pain elimination alone, but also the restoration of those jaw and facial functions. In the future, a treatment plan that consists of a pharmacological approach, invasive procedure, as well asjaw and facial functions restoration, can be proposed. This more comprehensive treatment plan is expected to increase orofacial pain patients' quality of life more immediately.

CONCLUSION

The validity, as well as reliability test performed on the jaw and facial activities questionnaire, confirmed its validity as well as reliability to be used as jaw and facial function's evaluation tool of orofacial pain condition. This questionnaire is, therefore, can serve its role as an evaluation tool. Yet, as the questionnaire is intended to measure the difficulty in performing jaw functional activities as well as facial activities experienced by those who suffer from all types of orofacial pain, it is of importance to conduct further study in the future that evaluates these difficulties in other orofacial pain condition.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethics approval was gained from the Universitas Padjadjaran Research Ethics Committee (ethical clearance number 1303/UN6.KEP/EC/2018). All participants signed informed consent prior to the start of the study.

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All research procedures on humans were followed in accordance with the ethical standards of the committee responsible for human

experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2008 (http://www.wma.net/en/20activities/10ethics/10helsinki/).

CONSENT FOR PUBLICATION

All participants signed an informed consent regarding their participation in the study and their agreement regarding the publication of the data gained in the current study.

AVAILABILITY OF DATA AND MATERIALS

The data supporting the findings of the current study are available from the corresponding author on reasonable request.

FUNDING

The current study was funded by Universitas Padjadjaran through the Riset Fundamental Unpad (RFU) research scheme.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

ACKNOWLEDGEMENTS

The authors would like to express our sincere gratitude to the experts who were involved in the process of evaluating the face validity, Dr. TaufikSumarsongko, Dr. RosilawatiWihardja, and Dr.SunggoroTrihardjo for their valuable contribution.

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