

Predictability and Accuracy of the Short-Form Fonseca Anamnestic Index in Relation to the Modified Helkimo Index for the Diagnosis of Temporomandibular Disorders: A Cross-Sectional Study

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ABSTRACT **Aim:** The aim of this study was to evaluate the predictability and accuracy of the Short-Form Fonseca Anamnestic Index (SFAI) in relation to the modified Helkimo Index for the diagnosis of temporomandibular disorders (TMDs). **Materials and Methods:** A cross-sectional, prospective, and analytical predictive study was conducted in 240 students of a public institute of higher technological education in Ica, Peru during the months of February to May 2018. The SFAI of 10 closed questions and the Helkimo Index modified by Maglione (gold standard) were used as instruments to diagnose TMDs. For the analysis of concordance between both instruments, Cohen's Kappa Index was applied. To evaluate the association according to gender and age group, Pearson's chi-square test was used. For validity of the SFAI in relation to accuracy, sensitivity and specificity were calculated, and they were verified by receiver operating characteristics (ROC) to determine the best cutoff points (area under the curve [AUC]) considering a P value < 0.05 . Regarding the predictability of the SFAI, the positive and negative predictive value was calculated by applying Bayes' theorem. **Results:** The SFAI was highly significantly associated with the modified Helkimo Index according to gender ($P < 0.001$), age group ($P < 0.001$), and overall ($P < 0.001$) moderate overall agreement ($k = 0.416$; 95% confidence interval [CI] = 0.287–0.545); better concordance was obtained in individuals older than 20 years ($k = 0.490$, CI = 0.302–0.679) and women ($k = 0.565$, CI = 0.371–0.759). The ROC curve analysis of the SFAI showed good accuracy (0.852, CI = 0.800–0.905) and was highly significant ($P < 0.001$), with an optimal cutoff point of 17.5 and good sensitivity (80.10%) and specificity (74.36%). In addition, a very good positive predictive value (PPV) (94.15%) and a fair negative predictive value (NPV) (42.02%) were obtained. **Conclusions:** Although there was moderate concordance between the SFAI and the modified Helkimo Index for the diagnosis of TMDs, the SFAI obtained good accuracy in the overall analysis of sensitivity and specificity. In addition, it demonstrated a high predictive efficacy for detecting positive TMD cases, whereas its ability to rule out positive cases was fair.

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INTRODUCTION

International epidemiological studies indicated that the prevalence of TMDs affects more than 50% of the world population, where 75% have presented signs at some time, whereas 33% present some symptom and 5% require some type of treatment.^[1,2] It has also been reported that the main origin of this disorder occurs in childhood or adolescence and to a lesser extent in adulthood.^[3] The prevalence of TMDs in Peru is similar to that reported internationally,^[4] so numerous authors in different parts of the world recommend further research to obtain sufficient evidence on this public health problem.^[4-8]

Although approximately 3.58 billion people in the world suffer from oral cavity diseases,^[9] TMDs are no less important for the dentist, since they clinically affect the muscles of mastication and can cause alterations in occlusion and some functional limitation with pain in the facial region.^[5,6]

The affectation of the stomatognathic system can be reflected at a systemic level or vice versa; for example, a headache due to TMDs, or pain reflected at the mandibular level could have a cardiac origin^[7] and therefore its intervention should be multidisciplinary and not individualized, with this being a circumstance that forces the early identification of TMDs by both the physician and the dentist. Therefore, it is necessary to use indexes with a high predictive value and easy application, which allow early identification of this pathology.^[8]

To diagnose the different TMDs, different indexes have been created, with the Helkimo Index being one of the most used and widely accepted, since it has withstood the test of time for being simple and practical, allowing it to quantify the existing dysfunction and also allowing it to correlate the patient's symptoms and the clinical finding, in comparison to other clinical indexes.^[10,11] However, the Helkimo Index was later modified by Maglione^[12,13] in 1982 in order to improve the determination of severity. On the other hand, it should be recognized that this high instrument accuracy requires the application of clinical procedures that require a considerable amount of time, a situation that is not useful for studies in large populations. Subsequently, based on Helkimo's instrument, the SFAI was developed and validated in Brazil in 1992^[14] and in 2017.^[15] This index is an instrument with 10

questionnaire-type items and it evaluates the frequency of pain, psychological distress, limitation of jaw function, and parafunctional behaviors associated with TMDs, having the advantage of evaluating large populations in a shorter time,^[15,16] making it suitable for epidemiological evaluations and as a clinical screening method in daily dental practice.^[17,18] Taking into account that a diagnostic test basically depends on its validity, reliability, clinical performance, and cost,^[18-20] the SFAI has proven to possess these attributes and has also been psychometrically validated and applied in numerous countries with different languages.^[14-18,21-23]

Therefore, the aim was to evaluate the predictability and accuracy of the SFAI in relation to the modified Helkimo Index for the diagnosis of TMDs.

MATERIALS AND METHODS

TYPE OF STUDY

A cross-sectional, prospective, and analytical predictive study was performed following the recommendations of the Standards for Reporting Diagnostic Accuracy Studies (STARD).^[19,20]

CALCULATION OF SAMPLE SIZE AND SELECTION OF PARTICIPANTS

The population from the Catalina Buendia de Pecho Technological Institute comprised 800 students. The sample size was 240 students and it was calculated from a formula for the proportion of a finite population, considering an $\alpha = 0.05$ and a margin of error of 5%. To determine the occurrence probability of the event (TMDs), findings obtained by Lázaro and Alvarado in Peru^[23] were taken into account, with a $P = 0.667$ and $q = 0.333$.

The study was conducted during the months of February to May 2018. The selection of participants was made by simple random sampling without replacement, taking into account the following criteria [Figure 1].

Inclusion criteria

1. Students of legal age;
2. Students who accepted informed consent;
3. Students who completed the questionnaire.

Exclusion criteria

1. Students with systemic diseases such as rheumatoid arthritis, fibromyalgia, osteoarthritis, migraine, otitis, sinusitis, trigeminal neuralgia, Tagle's syndrome, and temporalis tendinitis;

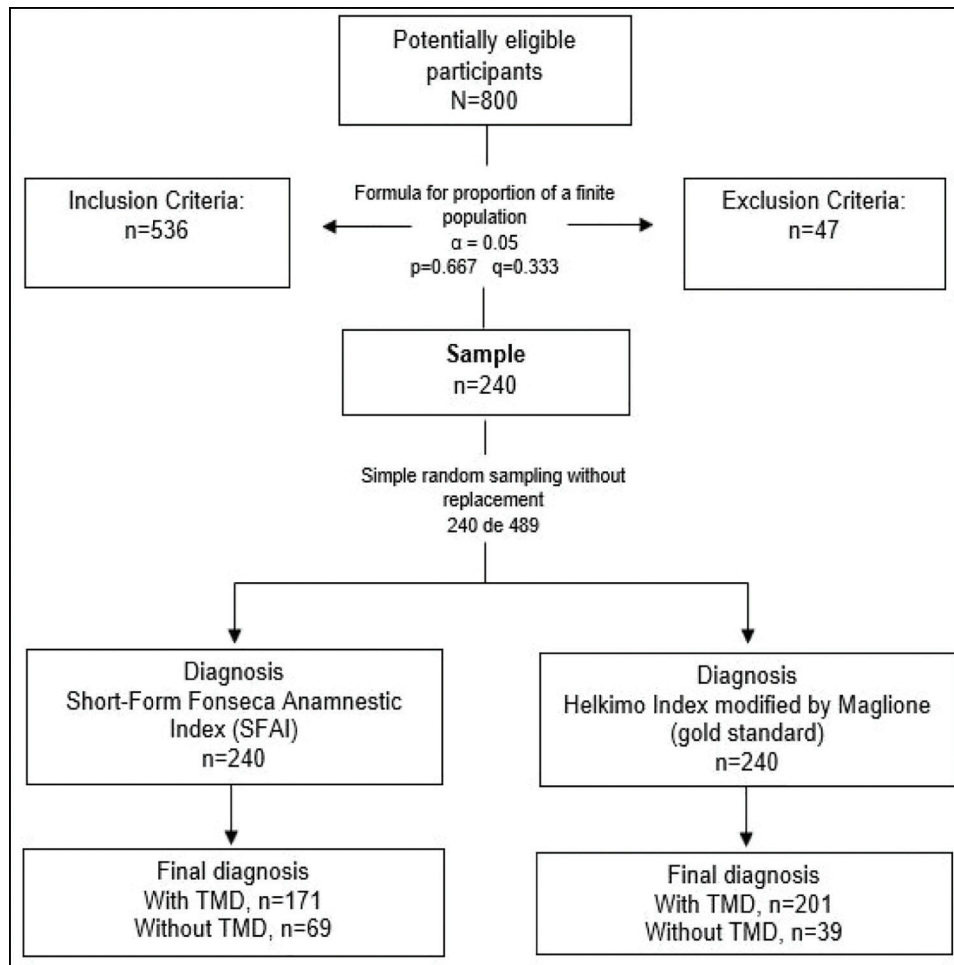


Figure 1: Sample selection and final diagnosis flow chart

- Students with pericoronitis of the third molar, anterior guide edentulous, severe crowding in the anterior zone, Angle class II or class III;
- Students with orthodontic treatment;
- Students with TMJ degenerative diseases;
- Students with incomplete studies.

PROCEDURE AND CALIBRATION

First, permission was requested from the director of the institution, and then the study was explained to the participants. After providing them with informed consent, a heteroadministered questionnaire (SFAI) was physically shared by groups of 15–20 participants, who usually completed the answers in 5–7 min, being supervised at all times by two calibrated researchers. Once all participants had completed the SFAI questionnaire, the presence of TMDs was assessed using the modified Helkimo Index. The results were collected on a data collection form and then transferred to a Microsoft Excel 2016 spreadsheet.

The clinical examination was performed in the same educational center by a dental professor specialized in oral rehabilitation (EYB) [Figures 2 and 3]. To reduce diagnostic biases, an intraexaminer calibration (intraclass correlation coefficient [ICC] = 0.91, 95% confidence interval [CI] = 0.65–0.93) and interexaminer calibration with another specialist (EYB and JHE) (ICC = 0.87, CI = 0.72–0.91) was performed, based on the total score of the modified Helkimo Index in a previous pilot study, with very good results. The same was done with the total score of the SFAI, obtaining very good intraexaminer (ICC = 0.92, CI = 0.67–0.94) and interexaminer (ICC = 0.88, CI = 0.53–0.91) calibration.

MODIFIED HELKIMO INDEX (GOLD STANDARD)

An internal consistency test (Cronbach's alpha) was performed to evaluate the reliability of this instrument in all the subjects sampled, obtaining an alpha of 0.84, CI = 0.75–0.93, being considered as very good.^[24]



Figure 2: Clinical evaluation at the educational center



Figure 3: Material and instruments used during the clinical evaluation

The index consists of the following criteria for its execution (use of a millimeter ruler):

A. Limitation in the mandibular range of motion

a. **Maximum opening:** It was measured from the upper incisal edge to the lower incisal edge on the midline, considering:

- 40 mm or more: no limitation or normal opening (0 points)
- 30–39 mm: mild limitation (1 point)
- Less than 30 mm: severe limitation (5 points)

b. **Maximum sliding to the right:** With the mandible at rest, the maximum laterality was measured while taking the upper incisor line as a reference, considering:

- 7 mm or more: normal sliding (0 points)
- 4–6 mm: mild sliding limitation (1 point)
- 0–3 mm: severe sliding limitation (5 points)

c. Maximum sliding to the left: Same consideration as item b

d. **Maximum protrusion:** It was measured from the upper to the lower incisal edge in the midline,

when the mandible performed the maximum protrusive movement.

- 7 mm or more: normal protrusive movement (0 points)
- 4–6 mm: mild protrusive movement limitation (1 point)
- 0–3 mm: severe protrusive movement limitation (5 points)

Dimension score

From the final sum, it was considered:

- Normal mobility (0 points) = 0 points
- Mild impairment of mobility (1–4 points) = 1 point
- Severe impairment of mobility (5–20 points) = 5 points

B. Alterations in joint function

By digital palpation and auscultation, it was considered:

- **Joint noise:** Crackling or popping
- **Locking:** Occasional blockage of short duration

- **Dislocation:** Displacement of the condyle with fixation outside the fossa

Dimension score

- Opening and closing without mandibular deviation or sound = 0 points
- Articular sounds or mandibular deviation during opening movement, or both = 1 point
- Locking or dislocation, with or without sound = 5 points

C. Pain on movement

According to the participant’s statement:

Dimension score

- Mandibular movement without pain = 0 points
- Pain referred to a single movement = 1 point
- Pain referred to two or more movements = 5 points

D. Muscle pain

In the resting position, the masticatory muscles were palpated as follows:

The anterior, middle, and posterior fibers of the **temporalis muscle** were palpated bimanually. With light pressure, the index finger was placed on the temple, the middle finger on the upper pole of the temporal fossa, and the ring finger behind the pinna. Palpation of the **masseter muscle** was performed bimanually by placing the index finger of the hand opposite to the muscle to be palpated, extrabuccally and intrabuccally, performing a light palpation of the entire muscle, considering its insertions and the anterior and posterior border. The student was requested not to open his mouth during the rest of the examination. The deep fascicle of this muscle was pressed firmly and then the fingers were slid toward the angle (superficial fascicle). For the **medial or internal pterygoid muscle**, a tongue depressor was placed between the posterior teeth, indicating the student to bite on it, as well as instructing him/her to perform the maximum mouth opening. For the **inferior lateral pterygoid**, the student was instructed to perform a protrusion movement against a resistance applied by the examiner. For the **upper lateral pterygoid**, the subject was instructed to clench the teeth and then to open the mouth, while the muscle was palpated.

Dimension score

- Pain on palpation and/or functional manipulation = 0 points
- Pain on palpation and/or functional manipulation in 3 zones = 1 point
- Pain on palpation and/or functional manipulation in 4 or more zones = 5 points

E. Temporomandibular joint pain

By placing the index fingers in front of the tragus and applying bimanual pressure, the presence or absence of pain on palpation was checked. Subsequently, pressure was applied to the external auditory canals.

Dimension score

- No spontaneous pain or pain on palpation = 0 points
- Pain on unilateral or bilateral periauricular palpation of the joint = 1 point
- Pain on palpation in the external auditory canal and periauricular = 5 points.

Finally, the scores of the five dimensions were added up and interpreted [Table 1].

SHORT-FORM FONSECA ANAMNESTIC INDEX (SFAI) (INSTRUMENT TO BE EVALUATED)

An internal consistency test (Cronbach’s alpha) was conducted to assess the reliability of this instrument in all sampled students, obtaining an alpha of 0.68, CI = 0.62–0.74, considering it acceptable.^[24]

The SFAI questionnaire consists of 10 questions:

1. Is it difficult for you to open your mouth?
2. Is it difficult for you to move your jaw sideways?
3. Do you feel fatigue or muscle pain when chewing?
4. Do you have frequent headaches?
5. Do you have neck pain or stiff pain (torticollis)?
6. Do you suffer from earaches or pain in your temporomandibular joints?
7. Have you noticed noises in your temporomandibular joints when you chew or open your mouth?
8. Do you clench or grind your teeth?
9. Do you feel that when you close your mouth your teeth do not fit together properly?
10. Do you consider yourself a tense or nervous person?

The alternatives to these questions are: “yes,” “sometimes,” and “no” with values of 10 points, 5 points, and 0 points, respectively. The scores of the 10 questions are added up and the results are interpreted [Table 2].

Table 1: Classification of the severity of TMD, according to modified Helkimo Index

Score	Interpretation
0	No TMD
1–9	Mild TMD
10–19	Moderate TMD
20–25	Severe TMD

TMD = temporomandibular disorder

STATISTICAL ANALYSIS

Data analysis was performed with the Statistical Package for the Social Sciences (SPSS) version 24.0, using descriptive statistics to obtain percentages for categorical variables and measures of central tendency and dispersion for numerical variables. For the concordance analysis between the instruments, Cohen's Kappa Index was applied at 95% reliability, considering ≤ 0.20 (slight), 0.21–0.40 (fair), 0.41–0.60 (moderate), 0.61–0.80 (satisfactory), and 0.81–1.00 (excellent)^[24]; and to evaluate the association according to gender and age group, Pearson's chi-square test was used. The validity of the diagnostic test in relation to accuracy was calculated with sensitivity and specificity analysis; with respect to predictability, Bayes' theorem was applied to calculate the probability of PPV and NPV. Accuracy was verified using ROC to determine the best cutoff points (AUC).

BIOETHICAL CONSIDERATIONS

The present study respected the bioethical principles for medical research on human subjects from the Declaration of Helsinki^[25] related to confidentiality, freedom, respect, and nonmaleficence; and it was approved by a research committee of Alas Peruanas University, which evaluated the ethical and methodological aspects of the study, with resolution No. 1459-2017-EPG-UAP. In addition, all participants understood and signed an informed consent form.

RESULTS

Both instruments had a highly significant association by gender, age group, and overall ($P < 0.001$). Regarding the analysis of concordance between the SFAI and the modified Helkimo Index, according to age group, moderate concordance was observed ($k = 0.490$, $CI = 0.302$ – 0.679) in students older than 20 years of age. Likewise, in relation to gender, a moderate concordance could be observed in women ($k = 0.565$, $CI = 0.371$ – 0.759) [Table 3].

Further, in relation to the concordance analysis between the SFAI and the modified Helkimo Index, including all participants, a moderate concordance was obtained ($k = 0.416$, $CI = 0.287$ – 0.545) [Table 3].

Table 2: Severity classification of TMD, proposed by Fonseca

Score	Interpretation
0–15	No TMD
20–40	Mild TMD
45–65	Moderate TMD
70–100	Severe TMD

TMD = temporomandibular disorder

When using the SFAI, 71.3% ($CI = 65.5\%$ – 77.0%) of the sample had TMD; when using the modified Helkimo Index in the same sample, 83.8% ($CI = 79.1\%$ – 88.4%) had TMD. Positive concordance for TTMs was 67.1% and negative concordance was 12.1%. The discordances determined a false positive of 4.2% and a false negative of 16.7% [Table 4 and Figure 4].

Regarding the validity of the SFAI in relation to the diagnosis using the gold standard test (modified Helkimo Index), a good sensitivity (80.10%) was observed, showing good accuracy to diagnose a patient with TMD who really has the disorder. In addition, good specificity (74.36%) was also observed, showing good accuracy to diagnose a patient without TMD who really does not have the disorder [Table 5]. Overall, the ROC curve analysis showed good accuracy (0.852, $CI = 0.800$ without TMD 0.905) ($P < 0.001$), with the coordinates of sensitivity and the complement of the optimal specificity closer to the coordinates 0.801 and 0.256, respectively, resulting in an optimal cutoff point of 17.5 of the SFAI score [Table 6 and Figure 5].

The predictive ability of the SFAI to detect a patient actually suffering from TMD among all those who presented positive TMD was almost perfect with 94.15%, whereas its predictive ability to diagnose a patient without TMD among all those who presented negative TMD was regular with 42.02% [Table 7].

DISCUSSION

The present study tested the predictability and accuracy of the SFAI with respect to the modified Helkimo Index for the diagnosis of TMD. It was found that both indexes were highly significantly associated by gender, age group, and overall; and in relation to the concordance analysis between them, a better concordance (kappa) was observed in students older than 20 years and in females. It should be noted that the overall concordance of the participants was moderate. These results corroborate those reported by Mendiburu *et al.*, de Paiva *et al.*, and Solís *et al.*,^[1,3,16] who stated that the TMDs detected with the SFAI showed a greater predilection for the female sex. In addition, our results also coincided with those of Mendiburu *et al.* in relation to the significant association of TMDs with young people older than 20 years of age.^[1]

In the present study, the modified Helkimo Index was considered as the gold standard test, since several studies support its consistency in withstanding the passage of time due to its simplicity and practicality in quantifying dysfunction and correlating the patient's symptoms with the clinical finding, being able to compare it with other clinical indexes.^[10,11,26-28] Related to the latter, in

Table 3: Analysis of concordance between SFAI and modified Helkimo Index for the diagnosis of TMD according to age group, gender, and total

Variable	Category	n	KI	SE	95% CI		P value*
Age group	≤20 years	135	0.358	0.089	0.184	0.532	<0.001
	>20 years	105	0.490	0.096	0.302	0.679	<0.001
Gender	Male	115	0.297	0.085	0.131	0.463	<0.001
	Female	125	0.565	0.099	0.371	0.759	<0.001
Total		240	0.416	0.066	0.287	0.545	<0.001

95% CI = 95% confidence interval, KI = Kappa Index, n = sample, SE = standard error

*Pearson's Chi-square, $P < 0.001$ (highly significant association)

Table 4: Overview of the concordance between SFAI and modified Helkimo Index for the diagnosis of TMD

SFAI	Modified Helkimo Index				Total	
	With TMD		Without TMD		N	%
	N	%	N	%		
With TMD	161	67.08	10	4.17	171	71.25
Without TMD	40	16.67	29	12.08	69	28.75
Total	201	83.75	39	16.25	240	100.00

TMD = temporomandibular disorder

a validation study of the Helkimo Index by Alonso *et al.*,^[26] a significantly good concordance ($k = 0.626$) was obtained with the SFAI; however, in the present study, the concordance was different but not negligible, since a significantly moderate concordance ($k = 0.416$) was obtained. These differences may be due to the fact that the population evaluated in both studies was located in different geographical areas and in different social contexts. In addition, the sample used by Alonso *et al.*^[26] was less than half of the sample used in the present study.

Regarding the diagnostic accuracy of SFAI, taking the gold standard test as a reference, a good sensitivity (80.1%) and good specificity (74.4%) were observed, being similar to the results obtained by Sánchez *et al.*,^[22] who obtained 83.3% and 77.9%, respectively. However, Zhang *et al.* obtained better sensitivity (95.9%) and similar specificity (71.9%),^[24] and Stasiak *et al.* reported high sensitivity (97.2%) and low specificity (26.0%).^[29] In light of these results, it could be stated that the SFAI has a higher diagnostic accuracy for detecting patients with TMD than for detecting healthy patients, with this statement being also supported by the findings obtained by Yap *et al.*^[30]

Regarding the ROC curve analysis performed in the present study, a good precision was obtained with an AUC of 0.852 and with an optimal cutoff point equal to 17.5 of the SFAI score, which determined that, below that value, the patient is diagnosed with positive TMD. This is similar to that reported by Pires *et al.* and Yap *et al.* in a study performed in Brazil and China, respectively.^[31,32] However, this was different from the

SFAI cutoff point obtained by Berni *et al.*,^[33] probably because they conducted their study only in female patients, although with a similar sample size to the one used in the present study.^[33]

Regarding predictability analysis, the predictive ability of the SFAI to detect a patient with TMD among all those who presented positive TMD was very good (94.15%), whereas the predictive ability to diagnose as healthy among all those who presented negative TMD was fair (42.02%). These results agree with those obtained by Yap *et al.*,^[32] who reported a PPV and NPV of 99.4% and 41.7%, respectively; however, Stasiak *et al.*^[29] reported a PPV and NPV of 84.96% and 68.42%, respectively. These differences may be due to the fact that the latter applied the SFAI in a predominantly female sample, whereas in the present study, the number of men and women was balanced. It should be noted that in both studies, the SFAI showed a better PPV than NPV.

The importance of this study lies in the fact that by calculating the predictive value of the SFAI, it was possible to identify its good positive predictability in a Peruvian area never studied earlier; in other words, it allowed the detection of a patient with TMD among all those who presented positive TMD in 94.15% of the cases, which is similar to the findings obtained by Lázaro and Alvarado in other areas of Peru.^[23] Further, the results obtained in this study corroborate the high efficacy of the SFAI for detecting positive TMDs, since similar results have been obtained in other investigations carried out in countries such as Mexico, Turkey, Spain, China, and Brazil.^[16,18,22,24,31]

One of the limitations of the present study was that multiple comparisons of predictability with various diagnostic tests were not performed. Further, due to the study design, it was not possible to extrapolate the results of TMD prevalence to the entire Peruvian population, so more epidemiological studies are needed in Peru, with a large scope, that apply the SFAI for the identification of TMD. However, apart from the constant monitoring of the temporomandibular joint in

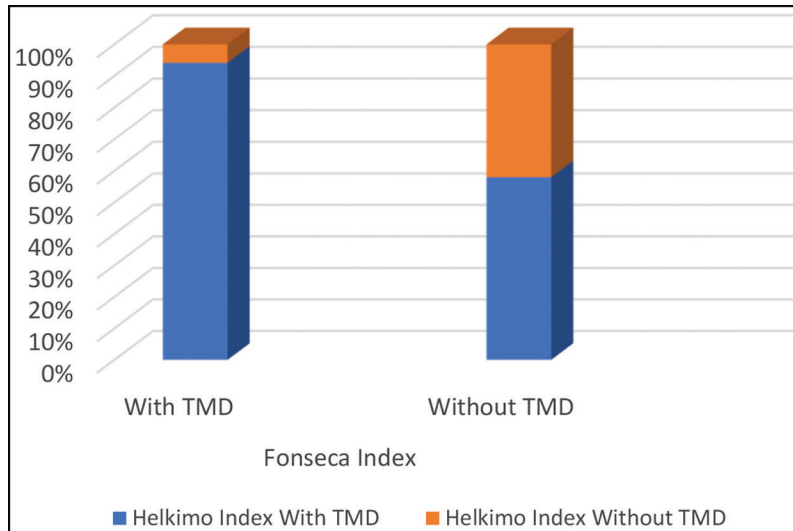


Figure 4: Concordance and discordance of the SFAI in relation to the Gold Standard test (modified Helkimo Index). TMD = temporomandibular disorder

Table 5: Analysis of the accuracy between the SFAI and the modified Helkimo Index for the diagnosis of TMD

SFAI	Modified Helkimo Index				Total		SE%	SP%	AUC (95% CI)
	With TMD		Without TMD		N	%			
	N	%	N	%					
With TMD	161	80.10	10	25.64	171	71.25	80.10	74.36	0.852 (0.800–0.905)
Without TMD	40	19.90	29	74.36	69	28.75			
Total	201	100.00	39	100.00	240	100.00			

AUC = area under the curve, 95% CI = 95% confidence interval, SE = sensitivity, SFAI = Short-Form Fonseca Anamnestic Index, SP = specificity, TMD = temporomandibular disorder

Table 6: Coordinates of the ROC curve to determine the optimal cutoff point

Optimal cutoff point	Coordinates of the ROC curve	
	Sensitivity	1-Specificity
12.50	0.886	0.462
17.50*	0.801	0.256
22.50	0.731	0.128

*Optimal cutoff point = higher values indicate TMD positivity

patients with related symptomatology due to anxiety or stress disorders,^[5,12,34] bruxism, and partial edentulism, among others,^[10,32] being necessary, it would be very useful to use the SFAI as a rapid diagnostic test to detect TMD in large populations where it is required to evaluate the largest number of people in a relatively short time and at low cost. It is recommended that more studies of predictability and precision of the SFAI be carried out in different regions of Peru and Latin America, in order to evaluate possible exogenous variables that affect its predictive efficacy. In addition, we recommend the use of the SFAI, since it is a simple instrument that does not require prior training of the examiner or long evaluation time. We also suggest that this instrument be used to monitor the effects of

different therapeutic procedures, especially in the field of physiotherapy of the stomatognathic system.

CONCLUSIONS

Recognizing the limitations of the present study, we can conclude that there was moderate agreement between the SFAI and the modified Helkimo Index for the diagnosis of TMDs. The SFAI showed good accuracy (85.2%) in the global analysis of sensitivity and specificity under the area of the ROC curve, demonstrating also a very good PPV, having the ability to detect an individual who really suffers from TMD among all those who presented positive TMD, in 94.15% of the cases. However, its capacity to rule out positive cases was regular with 42.02%. Therefore, it is recommended to use this instrument for epidemiological studies in which it is necessary to diagnose positive cases of TMD in the largest number of people, in a short period of time and at low cost.

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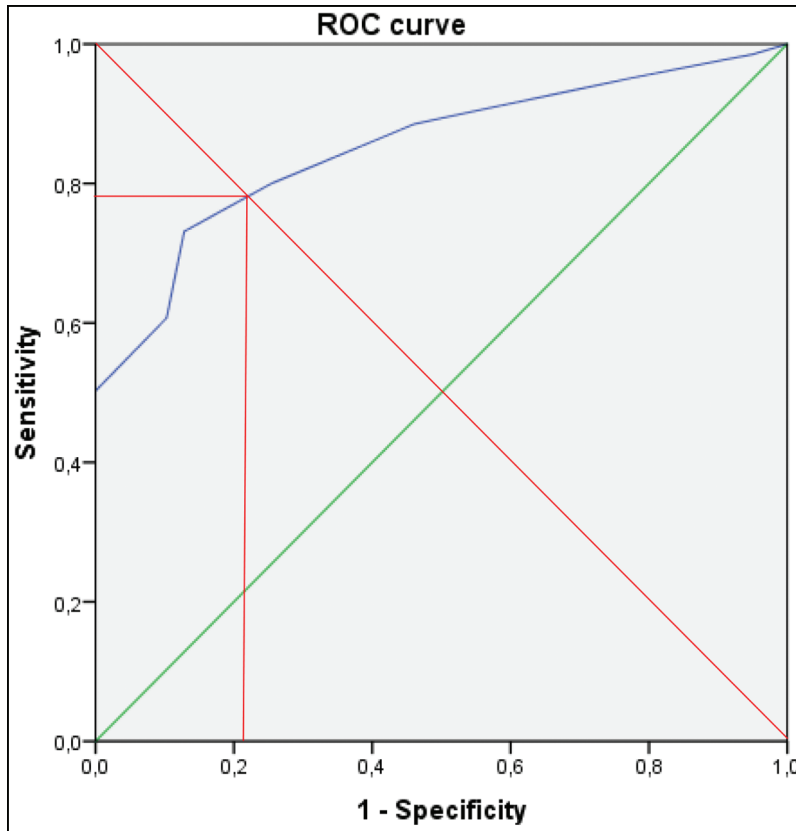


Figure 5: ROC curve for the SFAI, in the upper left quadrant of the graph (blue line)

Table 7: Analysis of the prediction between the SFAI and the Helkimo Index modified by Maglione, for the diagnosis of TMD

SFAI	Helkimo Index modified by Maglione				Total		PPV%	NPV%
	With TMD		Without TMD		N	%		
	N	%	N	%				
With TMD	161	94.15	10	5.85	171	100.00	94.15	42.03
Without TMD	40	57.97	29	42.03	69	100.00		
Total	201	83.75	39	16.25	240	100.00		

NPV = negative predictive value, PPV = positive predictive value, SFAI = Short-Form Fonseca Anamnestic Index, TMD = temporomandibular disorder

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Nil.

CONFLICTS OF INTEREST

There are not conflicts of interest.

AUTHORS' CONTRIBUTIONS

They conceived the research idea (EYB, JHE), carried out the field work (EYB, JHE, RTV, LTR), elaborated the article (EYB, CFCR, JHE), collected and tabulated the information (CFCR, JHE), carried out the

bibliographic search (RTV, CLG, LTR), interpreted the statistical results, helped in the development from the discussion (CFCR, LCG), and performed the critical revision of the article (CFCR, LCG, CLG). All authors approved the final version of the article.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

The present study respected the bioethical principles for medical research on human subjects from the Declaration of Helsinki related to confidentiality, freedom, respect, and nonmaleficence; and it was approved by a research committee of Alas Peruanas University, which evaluated the ethical and methodological aspects of the study, with resolution No. 1459-2017-EPG-UAP.

PATIENT DECLARATION OF CONSENT

All participants understood and signed an informed consent form.

DATA AVAILABILITY STATEMENT

The data that support the study results are available from the author (Prof. Enrique Yarasca Berrocal, e-mail: enrique.yarasca@upsjb.edu.pe) on request.

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