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Original articles

Validity and reliability of the neonatal tongue screening test

Validade e confiabilidade da triagem: "teste da linguinha"

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ABSTRACT

Purpose: to verify the psychometric properties – validity and reliability – and the sensitivity, specificity and predictive values of the "Neonatal Tongue Screening Test" from the Lingual Frenulum Protocol for Infants.

Methods: this is an experimental retrospective study using data from 100 newborns. The infants were assessed within the first 48 hours after birth using the Neonatal Tongue Screening Test, and subsequently assessed at 30 days of life using the Lingual Frenulum Protocol for Infants. The assessments were performed by examiner 1, who collected images and data to be analyzed by examiner 2. Newborns with lingual frenulum alterations were referred to frenotomy, reassessed 30 days after surgery and followed until six months of life. Data were used for the validation process, which included the analyses of inter-intra rater agreement, criterion validity, construct validity, sensitivity, specificity, positive predictive value, and negative predictive value. Data were statistically treated. The study was approved by the Ethics Committee under the number CAAE 40784315.9.0000.5538.

Results: the "Neonatal Screening Test" was able to identify newborns with lingual frenulum alteration and the changes after frenotomy; furthermore, the results demonstrated adequate values of sensitivity, specificity, and predictive values. Concerning inter-intra rater agreement, the consistency of results demonstrated reliability and excellent repeatability.

Conclusion: the "Neonatal Tongue Screening Test" has demonstrated to be a valid and reliable assessment tool ensuring accuracy to diagnose lingual frenulum alterations in newborns.

Keywords: Lingual frenum; Breastfeeding; Clinical Protocols; Validation Studies, Surgical Procedures

RESUMO

Objetivo: verificar as propriedades psicométricas de validade e confiabilidade, bem como a sensibilidade, especificidade e valores preditivos da Triagem Neonatal proposta a partir do Protocolo de Avaliação do Frênulo da Língua em Bebês.

Métodos: estudo experimental retrospectivo, utilizando os dados de 100 bebês. Os bebês foram avaliados nas primeiras 48 horas por meio da triagem e com 30 dias utilizando o Protocolo de Avaliação do Frênulo da Língua em Bebês. As imagens e dados de todos os bebês foram coletados pela fonoaudióloga (A1) e analisados pela fonoaudióloga (A2). Os casos com alteração do frênulo foram submetidos à frenotomia, reavaliados 30 dias após o procedimento e acompanhados até o 6º mês. Os dados foram utilizados para as etapas de validação: análise de concordância entre examinadores; análise de concordância intra-examinador; validade de critério; análise da validade de construto; análise de sensibilidade, especificidade, valores preditivos positivo e negativo. Os dados foram submetidos ao tratamento estatístico. O estudo foi aprovado pelo Comitê de Ética em pesquisa sob o número CAAE 40784315.9.0000.5538.

Resultados: a Triagem Neonatal identificou os bebês com alteração do frênulo e as mudanças ocorridas após a frenotomia e apresentou bons índices de sensibilidade, especificidade e valores preditivos. A confiabilidade entre e intra-examinadores permite afirmar que os dados obtidos com a triagem são confiáveis e podem ser reproduzidos.

Conclusão: a Triagem Neonatal do Protocolo de Avaliação do Frênulo da Língua em Bebês mostrou ser um instrumento válido e confiável, assegurando acurácia no diagnóstico das alterações do frênulo lingual em bebês.

Descritores: Freio Lingual; Aleitamento Materno; Protocolos Clínicos; Estudos de Validação; Procedimentos Cirúrgicos

INTRODUCTION

Tongue-tie occurs when a common minor embryologic tissue remnant causes restriction of normal tongue movement. Tissue remnant refers to the persistence of midline sublingual tissue that usually undergoes apoptosis during embryonic development[1].

The interference of lingual frenulum alteration with breastfeeding has been reported by several studies in literature[2-5]. The studies have demonstrated that frenotomy is a simple, safe, fast, and efficient procedure, which improves significantly the breastfeeding ability and maternal nipple pain[4,6].

A study on the histology of lingual frenulum has demonstrated that lingual frenulum does not undergo spontaneous rupture and cannot be elongated[7]. Additionally, another study reported that the frenulum attachment to the tongue and to the floor of the mouth does not change during life[8].

Since studies have reported the efficiency of frenotomy for breastfeeding, standardized assessment tools to diagnose ankyloglossia may provide parameters for assessment, diagnosis, and frenotomy referral.

The literature reports the existence of three tools for the assessment of infant's lingual frenulum. In 1993, the *Hazelbaker Assessment Tool for Lingual Frenulum Function* (HATLFF) was designed, and re-designed in 2010[9,10]. Although the HATLFF proposed the assessment of the anatomic and functional aspects of the lingual frenulum, it was partially validated. In 2013, the Lingual Frenulum Protocol for Infants (LFPI) was published[11,12]. LFPI consists of clinical history, anatomo-functional evaluation, nutritive and non-nutritive suction evaluations. Content Validity of the LFPI was determined and subsequently the validation process was concluded[13].

In 2015, the *Bristol Tongue Assessment Tool* (BTAT), a four-item protocol, was published. BTAT has partially fulfilled the international requirements for the validation process[14].

In Brazil, the law 13.002 passed in 2014 states that all newborns in the country must undergo lingual frenulum assessment using the LFPI -"Neonatal Tongue Screening Test" before hospital discharge[15].

The Neonatal Tongue Screening Test consists of the anatomo-functional evaluation, which should be administered within 48 hours after birth. Through the early assessment, severe cases can be diagnosed and referred to frenotomy. In case of doubt (score 5-6), or when lingual frenulum is not visible, re-assessment is recommended at 30 days of life. The re-assessment consists of the administration of the full protocol (LFPI). In order to avoid early weaning during this period, the parents should be warned about possible breastfeeding difficulties, such as poor latch and short intervals between feedings, resulting from lingual frenulum alteration[16].

The aim of the study was to verify the psychometric properties – validity and reliability – and the sensitivity, specificity and predictive values of the "Neonatal Tongue Screening Test".

METHODS

The study was approved by the Ethics Committee of Bauru School of Dentistry - University of São Paulo under the number 40784315.9.0000.5538.

The experimental retrospective study used data from infants assessed at the Neonatal Tongue Screening Test department at Santa Therezinha Hospital, in Brotas – São Paulo. All assessments and follow-up care were registered in patient's records and videotaped.

Based on the analysis of the total score of the LFPI and the minimum difference of 3 between groups (normal and altered), at 5% level of significance and 80% strength of study designed, a standard deviation of 6 was considered to calculate the sample size.

64 infants were required for the t-Test, and additional 25% were required for the Mann-Whitney test. Sample loss was considered; thus, 100 infants were determined as the optimal sample size to validate the Neonatal Tongue Screening Test.

The inclusion criteria were: a) sharp images and videotapes of the assessments of the healthy full-term infants of both genders, regardless of the methods of childbirth, and b) full administration of the Neonatal Tongue Screening Test (Appendix 1). Prematurity, perinatal complications, craniofacial anomalies, neurological disorders, and visible genetics syndromes were the exclusion criteria.

Sharp imagens and data from each assessment were collected by one Examiner – a Speech Language Pathologist (SLP) – with breastfeeding and lingual frenulum assessment expertise (E1), who was trained to administer the Neonatal Tongue Screening Test. Subsequently, another experienced SLP, Examiner 2 (E2), analyzed the images and data provided by E1. The calibration between E1 and E2 was performed by using live exam, analysis of the data collected during the LFPI administration, and clinical case discussion.

The anatomo-functional evaluation from the LFPI – Neonatal Tongue Screening Test – was administered

within the first 48 hours in order to indicate whether there was any lingual frenulum alteration. When the sum of the scores from the anatomo-functional evaluation was equal or greater than 7, the interference of the lingual frenulum with the movements of the tongue was diagnosed[16]. At 30 days of life, the infants were re-assessed by E1. Infants with lingual frenulum alteration were referred to frenotomy, which was performed by an Otorhinolaringologist. All infants were re-assessed at 30 days after the surgery by E1. Follow-up care of each infant was performed monthly until the 6th month of life. Images and data from the surgery, re-assessments, and follow-up care were registered in patient's records. At each re-assessment, the mothers of the infants answered the following questions: a) Are you breastfeeding your baby? b) Have you combined breastfeeding and bottle-feeding? If so, what formula have you used and when? c) Why have you complemented breastfeeding?

Data from assessments and re-assessments were considered for the process of validation of the Neonatal Tongue Screening Test. The results of the assessments and re-assessments performed by E1 and E2 were compared. To indicate reliability, inter-rater agreement analysis was performed by comparing data from the anatomo-functional evaluation of the 100 infants within 48 hours after birth and 30 days of life.

Intra-rater agreement analysis was performed by comparing data from the anatomo-functional evaluation of 20% sample (randomly selected) conducted by E2. 15 to 30 days after the first assessment, the re-assessment of data was performed in order to avoid the interference of memory.

The criterion validity was measured by comparing the results from the Neonatal Tongue Screening Test administered within 48 hours after birth and the results from the administration of the LFPI at 30 days of life in order to verify whether the results from the administration of the Neonatal Tongue Screening Test were the same of the LFPI.

The construct validity was performed by comparing the scores of the screening before and 30 days after frenotomy in order to demonstrate the anatomo-functional changes after the surgery.

The sensitivity (S), specificity (SPC), positive predictive value (PPV), and negative predictive value (NPV) were calculated by considering the total scores of the Neonatal Screening Test administered to 100 infants within 48 hours after birth and the scores of the LFPI administered to the same infants at 30 days.

Statistical treatment of data was performed. For the intra-inter rater agreement analysis, concerning the quantitative aspects, the Intraclass Correlation Coefficient (ICC) and the Cronbach's alpha were used. Concerning the qualitative aspects, the Kappa statistic was used. For the criterion validity analysis, the results of the administration of the Neonatal Tongue Screening Test and the LFPI were compared using the Kappa statistics. The Wilcoxon test was used for the analysis of the comparison of the results from the total score of the screening within 48 hours after birth and the results from the screening at 30 days after frenotomy.

The significance level adopted was 5% ($p < 0,05$).

RESULTS

For the inter-rater agreement analysis, the anatomo-functional evaluations of all infants performed by E1 and E2 were compared, as demonstrated in Tables 1 and 2.

Table 1. The intraclass correlation coefficient (ICC) obtained through quantitative measurements performed by E1 and E2

Measurement	Average	SD	ICC
E1 screening score within 48 hours	2,81	3,13	1,00
E2 screening score within 48 hours	2,81	3,13	
E1 score at 30 days	2,81	3.13	1,00
E2 score at 30 days	2,81	3.13	

Table 2. Agreement between screening (administered within the first 48 hours of life) and screening (administered at 30 days) performed by E1 and E2 – Kappa statistic

Screening (48 hours)	Anatomo-functional evaluation (30 days)			Total
	Altered	Doubt	Normal	
Altered	21 (21,0%)	0 (0,0%)	0 (0,0%)	21 (21,0%)
Doubt	0 (0,0%)	9 (9,0%)	0 (0,0%)	9 (9,0%)
Normal	0 (0,0%)	0 (0,0%)	70 (70,0%)	70 (70,0%)
Total	21 (21,0%)	9 (9,0%)	70 (70,0%)	100 (100.0%)

Agreement: 100 (100%)
Kappa = 1,00 ($p < 0,001$)

For the intra-rater agreement analysis, data from the anatomo-functional evaluation of all infants performed within 48 hours (screening) and from the anatomo-functional evaluation of 20% sample (assessment and re-assessment) conducted by E2 were compared, as demonstrated in Tables 3 and 4.

Table 3. ICC obtained through the analysis of the quantitative data from assessment and re-assessement performed by E2

Measurement	Average	SD	ICC
Screening score	2,60	3,22	1,00
Screening score - 20%	2,60	3,22	

Table 4. Agreement between screening (administered within the first 48 hours of life) and re-assessment of 20% sample conducted by E2 – Kappa statistic

Screening (48 hours)	Reavaliação 20% Triagem			Total
	Altered	Doubt	Normal	
Altered	4 (20,0%)	0 (0,0%)	0 (0,0%)	4 (20,0%)
Altered	0 (0,0%)	1 (5,0%)	0 (0,0%)	1 (5,0%)
Normal	0 (0,0%)	0 (0,0%)	15 (75,0%)	15 (75,0%)
Total	4 (20,0%)	1 (5,0%)	15 (75,0%)	20 (100,0%)

Agreement: 20 (100%)
Kappa = 1,00 ($p < 0,001$)

Moreover, to indicate reliability, data obtained through the Cronbach's Alpha coefficient were analyzed and demonstrated excellent internal consistency (0,967).

For the criterion validity analysis, the results of the administration of the Neonatal Tongue Screening Test and the LFPI were compared and demonstrated to be congruent, as shown in Table 5.

Table 5. Agreement between screening (48 hours) and the LFPI administered by E1 – Kappa statistic

Screening (48 hours)	LFPI (30 days)		Total
	Altered	Normal	
Altered	21 (21,0%)	0 (0,0%)	21 (21,0%)
Doubt	1 (1,0%)	8 (8,0%)	9 (9,0%)
Normal	0 (0,0%)	70 (70,0%)	70 (70,0%)
Total	22% (22,0%)	78% (78,0%)	100 (100,0%)

Agreement: 91 (91%)
Kappa = 0,78

The construct validity was performed by comparing the scores of the Neonatal Tongue Screening Test before and 30 days after frenotomy in order to demonstrate the anatomo-functional changes after the surgery. The Wilcoxon test was used for the analysis and demonstrated that there were changes after frenotomy (Table 6).

Table 6. Comparison between scores of the screening (administered within 48 hours) and re-assessment performed 30 days after frenotomy

Measurement	Average	SD	p
Screening score	7,86	0,83	<0,001*
30 days after frenotomy	1,27	1,35	

*statistically significant (p<0,05)

Concerning sensitivity and specificity, the results from the Neonatal Tongue Screening Test and the LFPI had 100% of agreement; therefore, the positive and negative predictive values were 100%

The Neonatal Tongue Screening Test indicated 21% of lingual frenulum alteration occurrence while the LFPI indicated 22%.

Of the infants who had frenulum alteration, 10 (45,46%) were being exclusively breastfed despite maternal complaints about breastfeeding difficulties. 8 infants (36,36%) were being breastfed and supplemented with formula. 4 infants (18,18%) were being exclusively bottle fed before frenotomy.

After frenotomy 16 infants (72,72%) started being exclusively breastfed until the 6th month of life without maternal complaints. 1 infant (4,55%) continued with breastfeeding combined with formula feeding. 5 infants continued with formula feeding exclusively and 1 infant started being bottle fed due to the return of the mother to work (22,73%).

DISCUSSION

The current study aimed to validate the "Neonatal Tongue Screening Test" from the LFPI. Criterion validity, construct validity, inter-intra rater agreement for

tool administration, sensitivity, specificity, positive and negative values were included in the study. The content validity was defined in a previous study[13].

Besides allowing standardized assessment by health professionals and assisting the comparison of findings among researches centers[17], specific protocols are also recommended by the Orofacial Motricity department of the Brazilian Society of Speech-Language Pathology and Audiology[18], by the *American Speech-Language-Hearing Association[19], and by the International Association of Orofacial Myology*[20].

The Neonatal Tongue Screening Test demonstrated to be a reliable tool, ensuring accuracy to diagnose lingual frenulum alterations within the investigated parameters and to identify changes after frenotomy. The excellent inter-intra rater reliability demonstrated that data from the screening are reliable and repeatable since there are training and calibration between examiners. The results demonstrated that the Neonatal Tongue Screening Test fulfilled all requirements for validation[21-26].

The infants referred to frenotomy did not undergo the procedure before 30 days of life; therefore, comparison between the screening performed within the first 48 hours and the administration of the LFPI performed at 30 days of life was made and demonstrated that the anatomo-functional aspects of all infants included in the study did not change over the first 30 days. The results of this study contradict what had been cited in literature about possible changes of lingual frenulum, such as spontaneous rupture or new attachment positioning to the tongue[27,28].

The sensitivity, specificity, positive and negative predictive values of the Neonatal Tongue Screening Test were 100%, demonstrating its accuracy to diagnose subjects with and without lingual frenulum alteration. The higher the sensitivity the higher the negative predictive value (higher probability of true negative results). The higher the specificity the higher the positive predictive value (higher probability of true positive results).

The occurrence of lingual frenulum alteration in this study was 21% (Neonatal Tongue Screening Test) and 22% (LFPI), being less than the percentage of 37,11% reported by a study in Brazil[29,30] and greater than the percentage reported by previous studies from other countries (4,8% to 12,8%)[31-33].

The high occurrence of lingual frenulum alteration reported in this study may be explained by the criteria for assessments, which, differently from other methodologies, considered the anatomo functional aspects[31-33].

As there were doubts concerning the presence of lingual frenulum alteration in 9% of infants who were assessed within the first 48 hours (screening), the administration of the LFPI, performed at 30 days, assisted the final diagnosis to indicate surgery. Of the 9 subjects, only one infant was referred to surgery. Data demonstrated that in case of doubt re-assessment at 30 days using the LFPI is required.

Breastfeeding percentages increased after frenotomy (from 45,56% to 72,72%). The results agree with the literature, which reports that frenotomy contributes to the maintenance of breastfeeding and absence of maternal complaints[3-5].

The Neonatal Tongue Screening Test was validated and has demonstrated to be an effective tool for the diagnosis of lingual frenulum alteration; nevertheless, training and calibration of professionals is required for its administration.

CONCLUSION

The Neonatal Tongue Screening Test has demonstrated to be a valid and reliable assessment tool ensuring accuracy to diagnose lingual frenulum alterations in newborns.

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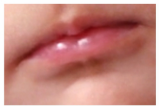
APPENDIX 1 – Neonatal tongue screening test

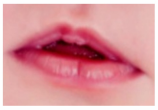
NEONATAL TONGUE SCREENING TEST
Lingual Frenulum Protocol for Infants

Name: _____

Birthdate: _____ / _____ / _____ **Examination Date:** _____ / _____ / _____

1. Lip posture at rest

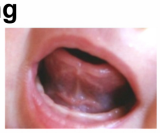

( ) closed (0)


( ) half-open (1)

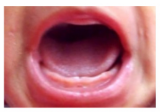

( ) open (1)

2. Tongue posture during crying


( ) midline (0)


( ) elevated (0)


( ) midline with lateral elevation (2)


( ) apex of the tongue down with tongue lateral elevation (2)

3. Shape of the tongue apex when elevated during crying or elevation maneuver


( ) round (0)


( ) V-shaped (2)


( ) heart-shaped (3)

4. Lingual Frenulum


( ) visible


( ) not visible


( ) visible with maneuver*

*Maneuver: elevate and push back the tongue. If the frenulum is not visible, re-assessment is required at 30 days of life.

4.1. Frenulum thickness


( ) thin (0)


( ) thick (2)

4.2. Frenulum attachment to the tongue

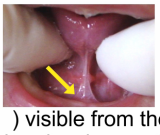

( ) midline (0)


( ) between midline and apex (2)


( ) apex (3)

4.3. Frenulum attachment to the floor of the mouth


( ) visible from the sublingual caruncles (0)


( ) visible from the inferior alveolar crest (1)

Score 0 to 4: normal ( )

Score 5 to 6: doubt ( ) **Re-assessment required in** _____ / _____ / _____

Score 7 or more: altered ( ) **Release of lingual frenulum is indicated.**