



The Validity and Reliability Study of the Turkish Version of the Preterm Oral Feeding Readiness Assessment Scale (T-POFRAS)

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ABSTRACT

Aim: To test the validity and reliability of the Turkish version of the Preterm Oral Feeding Readiness Assessment Scale (T-POFRAS) in order to add this scale to the literature.

Materials and Methods: A methodological study was conducted with 90 pre-terms in a neonatal intensive care unit in a state hospital.

Results: The best cut-off score value was 29 from the receiver operating characteristics analysis. For the 1st observer, 100% sensitivity and 95.7% specificity were seen at a cut-off score of 29, whereas for the 2nd observer, 95.5% sensitivity and 97.8% specificity were seen. The inter-rater agreement was quite high when the two observers were divided into groups according to their cut-off scores (Kappa=0.933; p=0.0001). The inter-rater agreement was 96.7% (in 87 preterms).

Conclusion: This study showed that the validity of the Turkish version of T-POFRAS was acceptable.

Keywords: Preterm infant, reliability and validity, feeding behavior, enteral nutrition

Introduction

Oral feeding of preterm infants is a complex and dynamic process that consists of the interaction of oral-motor, neurological, cardiorespiratory, and gastrointestinal systems (1). However, preterm infants encounter a variety of difficulties in the first weeks of their lives including neuro-developmental retardation as well as physiological and behavioral irregularities (2).

Achievement of oral feeding is explained with the synactive theory. This theory proposes that three subsystems

(autonomic, motor, and behavioral state) of preterm infants are compliant with each other and coordination of these subsystems occurs from behavioral organization by the infant during potential maturation and normal development. These three systems affect each other, and disorganization of any system affects the function of the other systems. Thus, achievement of oral feeding requires the normal functioning of these systems (3,4).

Ensuring normal growth and development of preterm infants is closely related to feeding. Some studies

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have examined the feeding of preterm infants from a multidimensional perspective and reported on the negative effects of feeding problems on the growth and development of infants (5-7). The criteria determined by the American Academy of Pediatrics for the hospital discharge of high-risk neonatal infants include "oral feeding sufficient to support appropriate growth" (8).

Previous studies also report that various factors play a role in a preterm infant's readiness for being fed. These factors include neurological maturation, severity of any disease, and the infant's ability to reorganize the autonomic, motor, and behavioral state systems between two feeding periods (1,3,8). In this context, there are often difficulties regarding a successful start of oral feeding and the achievement of full oral intake. Although there are several universally recognized oral feeding practices for premature infants (for example, feeding is not preferred for extremely premature infants in the first weeks or when intubated orally), individualized oral feeding protocols are required for the majority of premature infants (8).

Studies on preterm infants have also addressed the type of nutrition as a nutrition strategy in three stages: Parenteral Nutrition, Parenteral Nutrition + Enteral Nutrition, and Enteral Nutrition (9-11). National and international guidelines agree (12-16).

A standard method is not followed for every baby in the transition of preterm babies from parenteral nutrition to breastfeeding. It is not always possible to know for certain whether a preterm infant is ready for oral feeding. The infant who is thought to be ready sometimes fails and oral feeding is delayed (17-19). However, there are cue-based feeding models and scales in the literature evaluating an infant's readiness for oral feeding that assess all physiological systems during their development (17-19). In the cue-based feeding model, oral feeding of the baby should be started and feeding should be terminated if the baby shows signs of stress (20). These cues; responding to the gentle touches on the baby's face, tolerating full enteral feeding, licking their lips with their tongue, opening their mouth, turning to a stimulus close to their mouth, showing sucking behavior, bringing their hand to their mouth, oxygen saturation at normal values during feeding, the baby maintaining a state of alertness during the feeding process, keeping their body in a flexed posture, lowering their tongue to take the pacifier and licking the bottle teat (20-22).

In Cochrane Review (Instruments for assessing readiness to commence suck feeds in preterm infants: effects on time to establish full oral feeding and duration of hospitalization),

a preliminary search revealed three instruments designed to aid neonatal care providers in determining preterm infants' readiness to commence feeding (23).

The Preterm Infant Nipple Feeding Readiness scale is a 10-item scale that scored variables such as gestational age, post-conceptual age, color and activity, state regulation, hunger cues and tone. Subsequently, this instrument was renamed the Feeding Readiness and Progression in Preterms scale (24). The second instrument found was the Early Feeding Skill (EFS) assessment tool, which not only aims to assess feeding readiness but also feeding skill and feeding recovery. The feeding readiness section of the EFS consists of five items that assess an infant's readiness to commence oral feeds by observing their tone, energy level, state of arousal and oxygen saturation (25). The Neonatal Oral Motor Assessment scale (NOMAS) measures infants' nutritive sucking behaviors. Some studies have investigated the NOMAS psychometric characteristics within a healthy preterm population (26).

Lastly, the Preterm Oral Feeding Readiness Assessment scale (POFRAS) was developed and tested. POFRAS is an 18-item preterm infant oral feeding readiness instrument consisting of items in relation to corrected gestational age, behavioral state, global posture and tone, gag reflex, tongue movement and cupping, jaw movements and maintenance of an alert state. Each item was scored from 0 to 2 with a possible maximum score of 36 (27,28).

As stated in the POFRAS study, health care professionals have difficulty determining the appropriate and safe time to start oral feeding in preterm infants (27-29). Moreover, when preterm infants switch from gastric tube feeding to oral feeding, it is one of the biggest concerns of health care professionals, and therefore these professionals require an objective criterion to support the start of this process (22,27,29). The POFRAS scale is an objective scale that can be easily used by healthcare professionals. Scoring requires as little as a few minutes. Preterm babies whose physiological stability is considered to be suitable for oral feeding are determined to be ready to be fed orally by use of this scale.

The scale ensures an objective assessment of readiness for oral feeding and can have a positive effect on recognition of and support for oral feeding readiness, shorter hospitalization, and a reduction in health expenses. Supporting evidence-based oral feeding through a meticulous assessment or using evidence-based guidelines maximizes the infants' and caregivers' hospital experience, and can increase parent-infant bonding and parent satisfaction (29).

No measurement tool is known to be available in Turkey to assess the readiness of preterm infants for oral feeding. This study tested the validity and reliability of the Turkish version of POFRAS in order to add this scale to the literature.

Materials and Methods

Participants

This methodological study was conducted in a neonatal intensive care unit of a state hospital in a province located in western Turkey. The population of the study included preterm infants who were admitted to the neonatal intensive care unit, whose corrected gestational age was ≤ 36 weeks + 6 days, and who could not be fed orally. The infants had no face deformity and no respiratory, cardiovascular, gastrointestinal, or neurological disorders or syndromes that would prevent or aggravate oral intake.

The sample of the study included 90 preterm infants who matched these criteria, which was five times higher than the 18 items included in the scale. The sample size was determined based on the number of items included in the scale (30).

Instruments

The study data were collected using a "Preterm Infant Introductory Information Form" and the "POFRAS". The introductory information form for preterm infants had seven questions including the infant's age, gestational age, corrected gestational age, age in days, birth weight, current weight, and problems experienced during labor. POFRAS is an observational scale developed by Fujinaga et al. (28) and a pilot study of this scale with 10 preterm infants and the original study with 30 preterm infants were conducted with individuals who fitted the following inclusion criteria: Corrected gestational age <36 weeks and 6 days; clinically stable; absence of facial deformities; an absence of respiratory, cardiovascular, gastrointestinal and neurological disorders or syndromes that prevent or make oral feeding difficult; and not having received oral feeding of milk. The scale includes five categories (corrected gestational age, behavioral organization, oral posture, oral reflexes, and non-nutritive sucking) with a total of 18 items and it assesses preterm infants' readiness for oral feeding. Each item is scored from 0 to 2, and the maximum score of the scale is 36. The cut-off score to switch a preterm infant to oral feeding is 30 (28). The Kappa coefficient calculated to evaluate the inter-rater agreement was very good (>0.85).

Data Collection

The data were collected by two neonatal intensive care unit nurses who were the observers. The preterm infants were evaluated using POFRAS 15 minutes before feeding time. The observers did not orally communicate with each other. First, one of the observers placed the infant in an incubator in a lateral decubitus position and awakened the infant through gentle tactile touching or calling the infant by their name. Following this, both of the researchers simultaneously observed the behaviors of the infant. Biting, sucking reflex, and non-nutritive sucking included in the scale items were evaluated twice by the observers who were wearing gloves and using the second finger. Non-nutritive sucking was evaluated over a one-minute period. After both observers gave scores using the scale, the researcher fed the infant via the finger feeding method. Finger feeding is an alternative feeding method and provides a temporary feeding method for preterm infants (31,32). The researcher allowed the preterm infant to suck 5ml of breast milk using a 5ml non-piston injector by fixing a 6 French feeding tube which was 40 cm long to the second finger of the gloved hand with medical tape. Milk flow was maintained from the injector which was at the same level as the infant during feeding by the help of the preterm infant's sucking pressure; therefore, milk flowed into the oral cavity when the infant sucked.

Breastfeeding should be stopped if the presence of sucking does not occur within five minutes or symptoms that damage the stability of the preterm infant emerge (apnea, bradycardia, cough, saturation decrease, change in skin color, nasal flaring, hiccup, gagging, etc.) (25,33,34). Studies regard an infant's ability to be fed with 5ml of breast milk as the "gold standard" (28,35).

Data Analysis

The data obtained from the study were analyzed using the statistical package for the social sciences version 17 software package. The significance level was $p < 0.05$. The data were analyzed to test validity including linguistic validity, content validity, and criterion validity. For criterion validity, the cut-off score of the POFRAS was compared with global accuracy, sensitivity, and specificity using the gold standard, the receiver operating characteristics (ROC) curve. The Kappa coefficient for inter-rater reliability, intra class correlation (ICC), and Kappa agreement for each scale item were calculated within the scope.

Ethical Considerations

To test the validity and reliability of the POFRAS in Turkish, permission was obtained via e-mail from the

authors who developed the scale. Following this, approval was obtained from the ethics committee of non-invasive clinical trials of the Pamukkale University (January 16th, 2018), and then legal permission was obtained from the state hospital where the study was conducted. Written informed consent was obtained from the parents of the preterm infants within the study after informing them about the study aims.

Results

Descriptive Characteristics of Preterm Infants

The study found that 58.9% of the infants included in the study were female and 41.1% were male. Of the problems experienced during birth, 84.4% were respiratory distress (RD) and 15.6% were RD + small for gestational age. The mean gestational age was 33.70 (± 1.80) weeks, the mean corrected gestational age was 34.49 (± 1.56) weeks, the mean age of the infants was 5.86 (± 5.47) days, their mean birth weight was 2,061.25 (± 404.51) grams, and their mean current weight was 2,024.90 (± 370.93) grams (Table I).

Validity

Language and Content Validity

The linguistic validity was tested firstly for the validity practices of the scale. The scale was translated from English to Turkish by a pediatrician, a nurse academic, and a translator, all of whom have an advanced command of English. These three versions of translation were combined into one and finalized by the researchers. Following this, the resulting form was translated back from Turkish to English by a neonatologist, a translator, and a pediatrician, all of whom write and speak both languages very well

and who had never seen the scale before. Following this, the translation was compared with the original scale by the researchers and it was finalized. Regarding content validity, eight specialists including three nurse academics in pediatric nursing, one neonatologist, and four pediatricians were asked to score from 1 to 3 using a triple scoring system (1=essential, 3=not necessary) to assess the applicability of the scale items.

Lawshe's (36) technique ranks the opinions of the specialists as (a) "Essential," (b) "Useful, but not essential," and (c) "Not necessary." In the present study, the content validity ratio (CVR) was 0.75 and the content validity index (CVI) was 1. Since CVI was higher than CVR, the content validity of the scale was statistically significant. This result indicates the comprehensibility of the scale items (36).

Criterion Validity

Figure 1 shows the area under curve (AUC) values calculated on the ROC curve for each observer.

The best cut-off score based on "Youden index" values was 29 from the ROC analysis. For the 1st observer, 100% sensitivity and 95.7% specificity were seen at a cut-off score of 29, whereas for the 2nd observer, 95.5% sensitivity and 97.8% specificity were seen (Table II).

The inter-rater agreement was quite high when the two observers were divided into groups according to their cut-off scores (Kappa=0.933; p=0.0001). The inter-rater agreement rate was 96.7% (in 87 people) (Table III).

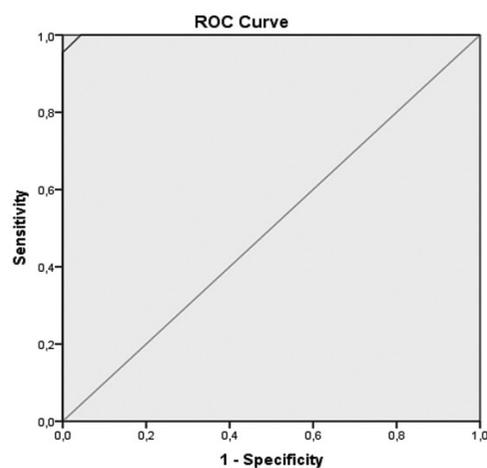
Reliability

The Kappa agreement of the scale items was fair only for three items (16.6%), whereas it was very good for fourteen items (83.3%) (Table IV).

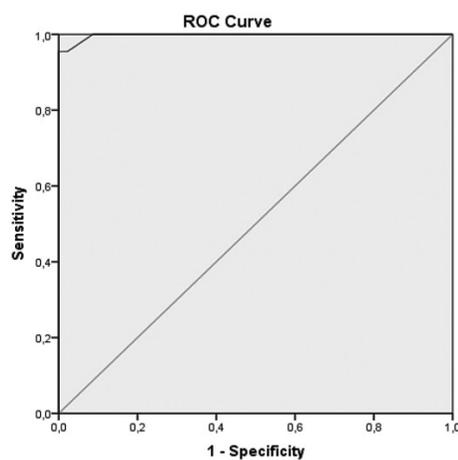
Table I. Descriptive characteristics of neonatal preterm infants

| Descriptive characteristics | | Mean \pm SD | Min. - max. |
|-----------------------------------|--------|----------------------|----------------|
| Gestational age (weeks) | | 33.70 \pm 1.80 | (29-36) |
| Corrected gestational age (weeks) | | 34.49 \pm 1.56 | (29.4-36.6) |
| Days of life | | 5.86 \pm 5.47 | (1-35) |
| Birth weight (grams) | | 2061.25 \pm 404.51 | (1,290-2,950) |
| Current weight (grams) | | 2024.90 \pm 370.93 | (1,230-2,830) |
| | | Number | Percentage (%) |
| Gender | Female | 53 | 58.9 |
| | Male | 37 | 41.1 |
| Problems at birth | RD | 76 | 84.4 |
| | RD/SGA | 14 | 15.6 |

SD: Standard deviation, Min: Minimum, Max: Maximum, RD: Respiratory distress, SGA: Small for gestational age



1st Observer AUC=0.999 (95% CI=0.996-1)



2nd Observer AUC=0.998 (95% CI=0.993-1)

Figure 1. Receiver operating characteristics curve (Global accuracy)

ROC: Receiver operating characteristics, AUC: Area under curve, CI: Confidence interval

Table II. Youden index values and Kappa coefficients for both observers

| | Sensitivity (%) | Specificity (%) | Kappa | p-value |
|--------------------------|-----------------|-----------------|-------|---------|
| 1 st observer | 100 | 95.7 | 0.956 | 0.0001* |
| 2 nd observer | 95.5 | 97.8 | 0.933 | 0.0001* |

Table III. Distribution by the inter-rater cut-off scores

| Cut-off score | 1 st observer (n) | 2 nd observer (n) |
|---------------|------------------------------|------------------------------|
| ≤29 | 44 | 47 |
| ≥28 | 46 | 43 |
| Total | 90 | 90 |

The ICC value was ICC=0.997 [95% confidence interval (CI)=0.996-0.998] and statistically significant.

Discussion

In this study, highly significant values as a result of the reliability and validity analysis of the Turkish version of the scale were found, in parallel with the original version of the POFRAS. The CVR was 0.75 using Lawshe's (36) technique. This result indicates the comprehensibility of the scale items in terms of linguistic validity.

The most commonly used method to determine the appropriate cut-off score with the highest accuracy is the ROC curve method. To use this method, a reference reported as the "gold standard" is required. The area below the curve is the AUC (AUC; 0.5<AUC<1) (37,38). The reference determined as the "gold standard" in the present study was the "Finger Feeding" nutrition method.

In this study, the cut-off score was 29 from the ROC analysis. Of the three cut-off scores (28, 29, and 30) specified in the original scale, the highest (30) was taken. It is compatible with the cut-off score specified in the present study. Having a cut-off score makes a scale objective, which makes the scale user-friendly, fast, and practical for health care professionals to determine readiness for oral feeding. The AUC score in the original scale was significant with a value of 0.5<AUC, as it was in the present study.

Regarding reliability, inter-rater agreement was calculated using the Kappa coefficient. Fleiss classified the agreement levels of a Kappa score of 0.75 or higher as very good, 0.40-0.75 as fair, and lower than 0.40 as poor (39). The inter-rater Kappa coefficient of agreement in the present study (0.93) showed a very good agreement as in the original version of the scale (0.85). Furthermore, the majority of the scale items (82.3%) showed a very good

Table IV. Inter-rater Agreement-Kappa (K) on POFRAS items for 90 infants

| Scale items | Kappa | Qualitative Assessment |
|---|-------|------------------------|
| Corrected gestational age | 1.00 | Very good |
| Behavioral state | 0.96 | Very good |
| Global posture | 0.97 | Very good |
| Global tonus | 1.00 | Very good |
| Lips posture | 0.95 | Very good |
| Tongue posture | 1.00 | Very good |
| Rooting reflex | 1.00 | Very good |
| Sucking reflex | 0.95 | Very good |
| Biting reflex | 0.74 | Fair |
| Gag reflex | 0.75 | Very good |
| Tongue movement | 0.95 | Very good |
| Tongue cupping | 1.00 | Very good |
| Jaw movement | 0.97 | Very good |
| Sucking strain | 0.87 | Very good |
| Sucking and pause | 0.70 | Fair |
| Maintenance of sucking/pause | 0.90 | Very good |
| Maintenance of alert state | 0.86 | Very good |
| Stress signs | 0.70 | Fair |
| POFRAS: The Preterm Oral Feeding Readiness Assessment scale | | |

Kappa agreement. In addition, the inter-class ICC score was highly significant at the 95% CI.

The POFRAS scale can be used in Turkish culture by health care professionals (physicians, nurses, etc.) who work in neonatal intensive care units. It can be used to determine the readiness of preterm infants who do not have a feeding barrier for oral feeding.

Preterm infants' readiness for oral feeding is a longer and more complex process compared to those who are full-term. This process is dependent on the physiological development of the infant. If a full-term infant does not have any pathology to prevent it, it can be fed orally immediately after delivery because it has completed its developmental processes and its body systems are coordinated. However, this situation is more complex for preterm infants. The infant needs a suitable period of time to be ready for oral feeding and to strengthen its physiological stability. The coordination of all the body systems prior to the transition to oral feeding makes the feeding process faster and easier. Therefore, cardiorespiratory and neurological

(motor, autonomic, and behavioral) systems, not just a single system, should work in harmony prior to oral feeding.

To improve physiological stability, some interventions are required for preterm infants. These include feeding the infant either with a parenteral or a gastric tube or providing a mixed diet (parenteral and gastric feeding together) until the infant gains spontaneous breathing ability. As the infants' body systems are developing and improving, their abilities are expected to change over time. The change in the infant's skills over time should be evaluated so the interventions meet the infant's needs. The suction reflex of the infant who can achieve spontaneous breathing can be strengthened by non-nutritive suction methods. During this time, the preterm infant improves their suction reflex and learns to regulate their suction pressure and rhythm.

Those scales that evaluate readiness for oral feeding are guidelines that provide a reliable and valid way to systematically monitor and assess the development of skills for feeding. They function as a guide in the selection of interventions to best support the skills required for oral feeding. After individualized interventions for specified goals are determined, ensuring the infant's ability for spontaneous nutrition, coordinating breathing, coordinating breathing and swallowing, regulating and managing milk flow, and maintaining stable physiological interactions during feeding must be assessed continually.

For example, a score less than 29 in POFRAS shows that the infant is not ready for oral feeding. If an infant has a score greater than 29, oral feeding methods may be applied.

Study Limitations

The scale is only suitable for healthy preterms. It is not to be used for term babies and those preterm babies who have pathologies that can prevent feeding.

Conclusion

The Turkish Version of the Preterm Oral Feeding Readiness Assessment scale [T-POFRAS (Appendix 1)] was analyzed for reliability and validity, and the study concluded that the validity of the inter-rater agreement was high, the inter-rater coefficients of consistence were fair, and the Kappa agreement of the scale items was very good in general. Health care professionals who work in neonatal intensive care units are recommended to use the T-POFRAS to determine neonatal preterm infants' readiness for oral feeding. This version will enable health care professionals to assess preterm neonatal infants' readiness for oral feeding, and then objectively determine the process of determining when to switch to oral feeding.

Ethics

Ethics Committee Approval: The study approval was obtained from the ethics committee of non-invasive clinical trials of the Pamukkale University. Research ethics committee (approval no: 60116787-020/4304, date: 16.01.2018).

Informed Consent: Written informed consent was obtained from the parents of the preterm infants within the study after informing them about the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: Z.Ç., B.Ç., Data Collection or Processing: Z.Ç., B.Ç., Analysis or Interpretation: Z.Ç., B.Ç., Literature Search: Z.Ç., B.Ç., Writing: Z.Ç., B.Ç.

Conflict of Interest: No conflict of interest was declared by the authors.

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| Appendix 1. Turkish version of the Preterm Oral Feeding Readiness Assessment Scale (T-POFRAS) | | | |
|--|----------------------|------------------------------------|-----------------------------|
| Corrected gestational age | (2) ≥34 weeks | (1) Between 32 and 34 weeks | (0) ≤32 weeks |
| Behavioral organization | | | |
| Behavioral state | (2) Alert | (1) Drowsy | (0) Sleep |
| Global posture | (2) Flexed | (1) Partly flexed | (0) Extended |
| Global tonus | (2) Normotonia | (0) Hypertonia | (0) Hypotonia |
| Oral posture | | | |
| Lips posture | (2) Closed | (1) Half-open | (0) Open |
| Tongue posture | (2) Flat | (0) Elevated | (0) Retracted (0) Protruded |
| Oral reflexes | | | |
| Rooting reflexes | (2) Present | (1) Weak | (0) Absent |
| Sucking reflexes | (2) Present | (1) Weak | (0) Absent |
| Biting reflexes | (2) Present | (1) Exacerbated presence | (0) Absent |
| Gag reflexes | (2) Present | (1) Present in anterior region | (0) Absent |
| Non-nutritive sucking (The test should take 1 minute) | | | |
| Tongue movement | (2) Adequate | (1) Altered | (0) Absent |
| Tongue cupping | (2) Present | | (0) Absent |
| Jaw movement | (2) Adequate | (1) Altered | (0) Absent |
| Sucking strain | (2) Strain | (1) Weak | (0) Absent |
| Sucking and pause | (2) 5 to 8 | (1) >8 | (0) <5 |
| Maintenance of rhythm | (2) Rhythmic | (1) Arrhythmic | (0) Absent |
| Maintenance of alert state | (2) Yes | (1) Partial | (0) No |
| Stress signs | (2) Absent | (1) Up to 3 | (0) More than 3 |
| Saliva accumulation | () Absent | () Present | |
| Nose wings trembling | () Absent | () Present | |
| Skin color change | () Absent | () Present | |
| Apnea | () Absent | () Present | |
| Tonus variation | () Absent | () Present | |
| Posture variation | () Absent | () Present | |
| Tongue or jaw tremors | () Absent | () Present | |
| Hiccupping | () Absent | () Present | |
| Crying | () Absent | () Present | |
| Maximum score: 36 | | | |