

## Clinical validation of the Preterm Oral Feeding Readiness Assessment Scale<sup>1</sup>

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**Introduction:** Health professionals have great difficulties to establish the adequate and safe time to start breast feeding in preterm infants. There is a need to develop a standardized tool to help health professionals to comprehensively evaluate preterm infant readiness to transition preterm infants' feeding from gastric to oral, and encourage breast feeding practice in neonatal units. **Aims:** To clinical validate the accuracy of a Preterm Oral Feeding Readiness Assessment Scale with 60 clinically stable preterm infants. **Methods:** Global accuracy, sensitivity and specificity of Preterm Oral Feeding Readiness Assessment Scale cut-offs, compared to milk intake through transactation, were estimated through ROC curves (Receiver Operating Characteristic Curves). **Results:** The global accuracy of Preterm Oral Feeding Readiness Assessment Scale was 74.38%. The highest sensitivity and specificity were obtained for three cut-offs: 28, 29 and 30. Since higher specificity (75.68%) for the Preterm Oral Feeding Readiness Assessment Scale was found at a score cut-off=of 30 showed higher specificity (75.68%), it should be used as a cut-off score to select initiate breastfeeding the preterm newborns' oral feeding readiness. **Conclusion:** The Preterm Oral Feeding Readiness Assessment Scale is considered valid to assist health professionals to initiate preterm feeding in view of promoting safe and objective breastfeeding.

**Descriptors:** Infant, Premature; Feeding Behavior; Breast Feeding; ROC Curve.

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## Validação clínica do Instrumento de Avaliação da Prontidão do Prematuro para Início da Alimentação Oral

**Introdução:** profissionais de saúde têm grande dificuldade para estabelecer o momento adequado e seguro para iniciar a amamentação em prematuros. Há necessidade de desenvolver um instrumento padronizado para auxiliar esses profissionais, na transição da alimentação gástrica para via oral do prematuro, incentivando a prática da amamentação nas unidades neonatais. **Objetivo:** avaliar a acurácia do Instrumento de Avaliação da Prontidão do Prematuro para Início da Alimentação Oral. **Método:** participaram do estudo 60 prematuros clinicamente estáveis e que não haviam recebido alimentação oral. A acurácia global, sensibilidade e especificidade do instrumento, em comparação à ingestão de leite por meio da translactação, foram estimadas através de curvas ROC (Receiver Operating Characteristic Curves). **Resultados:** a acurácia global do instrumento foi de 74,38%. A maior sensibilidade e especificidade foram obtidas para três pontos de corte: 28, 29 e 30. Como o ponto de corte=30 do instrumento apresentou maior especificidade (75,68%), sugere-se, aqui, que deverá ser usado para selecionar os prematuros com prontidão para início da alimentação oral. **Conclusão:** o Instrumento de Avaliação da Prontidão do Prematuro para Início da Alimentação Oral está validado para assistir os profissionais de saúde a iniciar a alimentação do prematuro, com vistas ao aleitamento materno, de forma segura e objetiva.

**Descritores:** Prematuro; Comportamento Alimentar; Aleitamento Materno; Curva ROC.

## La validación clínica del Instrumento de Evaluación de la Prontitud de los Prematuros para Iniciación de la Alimentación por Vía Oral

**Introducción:** Profesionales de la salud tienen grandes dificultades para establecer el momento adecuado y seguro para iniciar la lactancia en prematuros. Hay una necesidad de se desarrollar un instrumento para ayudar a estos profesionales en la transición de la alimentación gástrica para oral en prematuros mediante el fomento de la lactancia en las unidades neonatales. **Objetivo:** Evaluar la precisión de el Instrumento de Evaluación de la Prontitud de los Prematuros para Iniciación de la Alimentación por Vía Oral. **Método:** Participaron 60 prematuros clinicamente estables y que no recibieron alimentación oral. La precisión global, la sensibilidad y la especificidad del instrumento, en comparación con la ingestión de leche por translactancia se estimaron mediante curvas ROC. **Resultados:** La precisión global del instrumento fue del 74,38%. La mayor sensibilidad y especificidad se obtuvieron para tres puntos de corte: 28, 29 y 30. Como el punto de corte=30 del instrumento mostró mayor especificidad (75,68%), sugerimos que debe utilizarse para seleccionar los prematuros con prontitud para la alimentación oral. **Conclusión:** El Instrumento se valida para ayudar a los profesionales de la salud en la iniciación de la alimentación en los prematuros, con vistas a la lactancia de manera segura y objetiva.

**Descriptores:** Prematuro; Conducta Alimentaria; Lactancia Materna; Curva ROC.

## Introduction

Preterm infants have not managed to coordinate sucking and swallowing with breathing. The transition from gavage to full oral feeding is important to obtain adequate nutritional intake for growth, maintain physiologic regulation and remain engaged in the feeding process<sup>(1)</sup>. Breast feeding is the recommended feeding method for preterm infants due to its countless nutritional, immunological, psychological and emotional benefits, favoring maternal bonding<sup>(2)</sup>.

In clinical practice, health professionals (e.g. physicians, nurses and speech-language pathologists) have difficult to establish the adequate time to start breast feeding in preterm infants. Gestational age and weight are the most common indicators used by these professionals to assess oral feeding readiness in preterm infants. Gestational age is a criterion that indicates the preterm infant's maturity. On the other hand, weight does not indicate the maturity of the infant or oral skills,

especially in cases of very low birth weight neonates. These preterm infants suffer prolonged multisensory deprivation, hence take time to gain weight but do not necessarily present delays in neurodevelopment and oral-motor maturity<sup>(1)</sup>. Thus, these are not objective criteria to indicate breast feeding for preterm infants. Maturity should also be considered associated with other variables, such as clinical stability, state of consciousness, oral-motor skills and coordination of sucking, swallowing and breathing functions<sup>(3)</sup>.

Current available oral feeding assessment scales for preterm infants were developed only for transition to bottle-feeding<sup>(1,3-7)</sup>. The World Health Organization (WHO) promotes breast feeding as the best practice worldwide; however it poses a challenge for those health professionals who have to decide when to initiate breast feeding for a preterm infant. Due to the lack of standardized evidenced-based methods to evaluate preterm readiness to breast feeding we developed the Preterm Oral Feeding Readiness Assessment Scale (POFRAS)<sup>(8-9)</sup> to help health professionals to systematically establish the adequate time to safely initiate breast feeding in preterm infants and encourage breast feeding practice in neonatal units. The current study aimed to evaluate the accuracy of POFRAS in preterm newborns.

## Methods

The study sample consisted of 60 preterm infants who had  $\leq 36$  weeks and 6 days of corrected gestational age; no facial deformities; absence of respiratory, cardiovascular, gastrointestinal and neurological disorders or syndromes; and no oral feeding intake.

The study was conducted at the neonatal intermediate care unit of a university hospital at Ribeirão Preto-SP, Brazil. At this unit breast feeding and kangaroo care are encouraged for all stable preterm infant and a human milk bank is available to assist the mothers in maintain lactation<sup>(10)</sup>. The present study was approved by the Research Ethics Committee (protocol n. 6225/2003) at the institution and informed consent was obtained from all mothers.

POFRAS is comprised of five main categories with a total of 18 items that consist of: 1) corrected gestational age ( $\leq 32$  weeks; 32-34 weeks and  $\geq 34$  weeks); 2) behavioral organization (behavioral state, global posture and global tonus); 3) oral posture (lips and tongue posture); 4) oral reflexes (rooting, sucking,

biting and gag reflexes) and 5) non-nutritive sucking (tongue movement, tongue cupping, jaw movement, sucking strain, sucking and pause, maintenance of sucking/pause, maintenance of alert state and stress signs). The preterm infant's performance in each item is assessed from 0 (zero) to 2 (two), with total score ranging from 0 to 36<sup>(8-9)</sup>. It was previously assessed by fifteen judges for content and face validation, with an inter-rater agreement level of 0.85 or higher<sup>(8)</sup>. In other study, inter-rater reliability reached excellent agreement scores for behavioral state, global posture and tonus, lips and tongue posture, gag reflex and maintenance of alert state categories ( $K \geq 0.75$ ); satisfactory for rooting reflex, sucking and biting and jaw movement, sucking strain and sucking and pause ( $K = 0.40 - 0.75$ ) and unsatisfactory for tongue cupping, maintenance of sucking/pause and stress signs ( $K \leq 0.40$ )<sup>(9)</sup>.

In order to assess infant's oral feeding readiness all participants were assessed with POFRAS by the main researcher (C.I.F.) 15 minutes before preterm infants have initiated gavage feeding.

The researcher first positioned the infant in lateral decubitus inside the incubator and stimulated the infant to wake up by audio (e.g. call baby's name), visual (e.g. eye-to-eye contact) and tactile stimuli (e.g. extension of limbs movements). Then, the researcher assessed infant's behavioral organization and oral posture. Next, the researcher observed infant's oral reflexes and nonnutritive sucking using a gloved little finger.

After POFRAS application, the researcher placed the infant at the mother's breast for breast feeding. To objectively quantify the milk volume intake by the infant we used the translactation technique. Translactation is an adaptation of the relactation technique<sup>(11)</sup> and represents an alternative feeding method for prematures<sup>(12-13)</sup>. The researcher offered 5ml of breast milk pumped from the mother through a tube connected to a syringe, fixed between the mother's breasts, with the other end of the tube fixed next to the mother's nipple. The syringe milk flow was controlled by the preterm's suction with pauses for breathing while breast feeding<sup>(12)</sup>. Thus, the milk only flows into the preterm's oral cavity when sucking is present.

The following criteria were adopted to interrupt the breastfeeding session: absence of suction for more than 5 minutes and/or presence of clinical signs interfering with the preterm infant's stability (e.g. apnea or cough).

Few studies address preterm infants' breast feeding performance<sup>(14-15)</sup>. In the present study, we considered as the "gold standard" when the infant was able to feed 5ml of breast milk. This decision was based on previous studies that considered efficient sucking at the maternal breast as either milk intake of 5ml with the presence of sucking movements upon the preterm's initial contact with the mother<sup>(16)</sup>, or the presence of oral milk intake, independently of the device used (bottle, cup or bottle with fine nipple)<sup>(7)</sup>.

Global accuracy, sensitivity and specificity of POFRA cut-offs, compared to the gold standard (ingestion of 5ml of breast milk by the infant), were estimated through ROC curves (Receiver Operating Characteristic Curves) using Stata vs. 8.2.

## Results

Infant's mean birth weight was 1418g ( $\pm 326$ g), mean gestational age of 32 weeks and 3 days determined by Ballard, mean Apgar score at 1<sup>st</sup> minute was 6 and at 5<sup>th</sup> minute was 9. On the day of data collection, infant's mean postnatal age was 13 days, mean corrected gestational age of 34 weeks and 3 days and a mean weight of 1484g.

The distribution of POFRAS total scores for the assessed infants was normal. Minimum score was 14 and maximum 36, with an average score of 27 ( $\pm 4.58$ ).

The area under the ROC curve (global accuracy) was 74.38% (Figure 1).

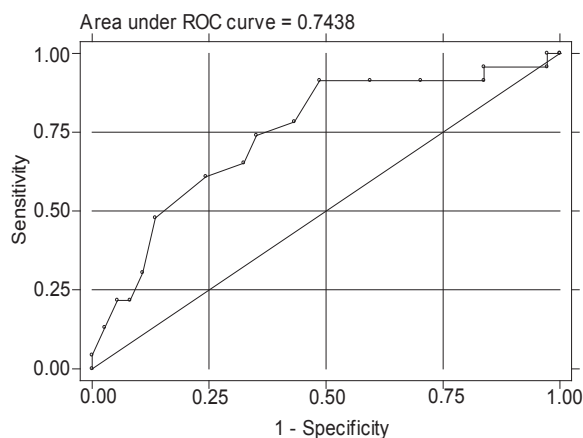


Figure 1 - ROC curve obtained from the sum of the scores of each premature for the instrument items, versus the gold standard, Ribeirao Preto, SP, Brazil, 2005

Three cut-offs: 28, 29 and 30 showed the highest values for sensitivity and specificity (Table 1).

Table 1 – Cut-off scores of the instrument and results of sensitivity and specificity, Ribeirao Preto, SP, Brasil, 2005

Cut-off scores $\geq$	Sensitivity (%)	Specificity (%)
14	100,00	0,00
20	100,00	2,70
21	95,65	2,70
22	95,65	16,22
23	91,30	16,22
24	91,30	29,73
25	91,30	40,54
26	91,30	51,35
27	78,26	56,76
28	73,91	64,86
29	65,22	67,57
30	60,87	75,68
31	47,83	86,49
32	30,43	89,19
33	21,74	91,89
34	21,74	94,59
35	13,04	97,30
36	4,35	100,00
> 36	0,00	100,00

## Discussion

POFRAS is the first scale that includes objective criteria to assess preterm infants' readiness to start breast feeding. Few studies describe preterm infants' behavior at the mother's breast. A protocol to assess the development of the preterm's behavior at the mother's breast is being validated<sup>(17)</sup>.

Although other assessment scales are current available, they were developed mainly for bottle feeding<sup>(4,18)</sup> and only one has been validated. Two studies tested the validity and reliability of The Neonatal Oral-Motor Assessment Scale (NOMAS) in term and preterm infants<sup>(18-19)</sup>. Two of the three categories of NOMAS, normal and disorganized, have soundly psychometric properties and have demonstrated to be useful in the clinical setting. However, the dysfunction category needs further validation<sup>(19)</sup>. NOMAS should be re-adjusted in order to improve inter-rater agreement and, at the same time, current insights into the development of sucking and swallowing should be incorporated in the method<sup>(18)</sup>.

In the present study, three cut-offs presented sensitivity and specificity values  $> 60\%$ . Although, we recommend 30 the best cut-off point to select preterm oral feeding readiness assessment, since the correspondent specificity (75.68%) indicated a lesser proportion of false-positives.

The translactation technique was the method of choice to objectively measure the quantity of milk the infant consumed. In this technique, the preterm's movements are similar to what occurs during breast feeding<sup>(12-13)</sup>. Studies have used the weight difference before and after breast feeding to verify the milk volume ingested by the preterm<sup>(3,16-17)</sup>. However, this difference is questionable<sup>(20-21)</sup>, mainly when considering the small quantity ingested and the low-weight of these infants<sup>(22)</sup>. Specialists consider video fluoroscopy a gold standard to assess suction and swallowing. But this exam requires the intake of food with barium, involving risk for the preterm infant's health. Moreover, it is expensive and available at few hospitals only. Another disadvantage is that it does not permit verifying suction at the maternal breast.

We consider the POFRAS an easily applicable instrument in clinical practice to assist health professionals to decide when to initiate breast feeding and encourage breast feeding practice in neonatal units. Early initiation of breast feeding has several beneficial effects to the preterm such as physiological, affective, social and developmental advantages and improves quality of life<sup>(2-3,23)</sup>. Additionally, it increases milk production, reducing hypogalactia and early weaning among preterms<sup>(24)</sup>.

For a long time, breast feeding was considered more demanding for preterm infants, due to the belief that breastfeeding would lead to greater energy consumption and, hence, greater weight loss. Studies demonstrate, however, that breast feeding, in comparison to bottle feeding, result in less variation in oxygen saturation and put the infant in a lower risk of adverse effects<sup>(25)</sup>. Cup feeding is another method used in the transition from gastric to oral feeding but, in this technique infants practice a different oral-motor pattern than what is used for breast or bottle feeding<sup>(2)</sup>. Other alternative techniques to support the preterm infants to make a transition from oral feeding to breast feeding are relactation, translactation and the breast-rogastic tube. These techniques contribute to a more physiological feeding transition and an earlier hospital discharge in full breast feeding, besides having mother in an active role<sup>(13)</sup>.

## Conclusions

POFRAS has demonstrated to be a precise and comprehensive instrument to help health professionals (e.g. physicians, nurses and speech-

language pathologists) to assess preterm oral feeding readiness to start breast feeding, without risks for the infant. An advantage of POFRAS is that it consist of a comprehensive instrument that assess different factors, including maturity, oral-motor skills, oral-motor, neural and sucking development in the preterm infant.

One limitation of this study is the small sample size. The researchers are currently validating a brief version of POFRAS with a larger number of infants.

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