Research Paper

A Pilot Study of Developing an Infant Sucking Tester Instrument

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Objectives: Most preterm infants experience oral feeding disorder. Sucking is the most appropriate way for oral feeding, but it may be immature in preterm infants. Regarding the increased risk of feeding problems in preterm infants, investigating and monitoring their sucking patterns to present appropriate and timely intervention is recommended.

The current research aimed to report the design of an instrument for measuring the suction pressure in preterm infants through a pilot study. We also checked the validity and reliability of the instrument.

Methods: A pilot study was conducted to measure the validity and reliability of this instrument. First, the instrument was developed, and in the next step, discriminant validity, test-retest reliability, and comparison in terms of sex were investigated by measuring the suction pressure of 20 full-term and 15 preterm infants. The Mann-Whitney U test and Wilcoxon test were used to establish the discriminant validity, comparison in terms of sex, and test-retest reliability in SPSS v. 23 software.

Results: Two groups showed a significant difference in the suction pressure (P<0.001) to support the discriminant validity of the instrument. We obtained satisfactory values for the test-retest reliability in two groups (r=0.97, P<0.001). Boys and girls did not significantly differ between full-term (P=0.9) and preterm infants groups (P=0.5).

Discussion: Performing the pilot study on 35 infants through an infant sucker tester proved the instrument’s discriminant validity and test-retest reliability. However, conducting the studies with a larger sample size is essential to make this instrument available commercially.
Highlights

First we invented a device to measure the sucking pressure.

Full term and preterm infants showed significant difference in sucking pressure.

Sex did not effect sucking pressure in both groups.

Plain Language Summary

We made a device to measuring the pressure during the sucking of infants. In preterm infants the sucking pressure was weaker than full term ones but girls and boys the pressure was similar.

1. Background

Preterm infants are a group of infants that are born earlier than 37 weeks of gestation [1]. Nearly 13% of newborn infants are preterm in Iran [2]. In recent decades, the survival rate of preterm infants has substantially increased due to improved neonatal care [3]. Despite this improvement, the preterm infants’ organs are still immature, and these conditions bring about some problems for them [4].

Preterm infants are at increased risk for oral feeding disorder, and extensive studies have shown a substantial association between feeding disorder and being preterm [5, 6]. The development of sucking behavior is expected to mature between 34 and 42 postmenstrual age and is usually continued for six months after birth in children [7]. The evidence shows that preterm infants with oral feeding disorder are identified as the high-risk ones for developmental delay, and the performance of infants in sucking may be regarded as the significant predictor of their developmental profile in the first year of old [4, 8]. In addition, the sucking performance is an indicator of the function of the brain in infants [8-10]. It has been demonstrated that prolonged feeding disorders in preterm infants might be the sign of brain injuries that has remained undiagnosed [10]. It appears that the development of sucking performance parallels neurologic development [8, 11].

Many preterm infants could not perform feeding independently. Several possible reasons have been suggested for the oral feeding disorder in preterm infants, including incomplete development of the orofacial organs, problems in the central nervous system, and immature development of the cardiorespiratory system. This disorder may lead to apnea and bradycardia in infants [3, 4, 12].

Previous studies have investigated and measured the oral feeding of preterm infants [13, 14]. The coordinated functions of breathing, swallowing, and sucking are required for successful feeding. Based on the existing studies, nutritive sucking is regarded as a changing behavior with three stages: intermittent, continuous, and pause. Each stage goes through during oral feeding depending on the breathing, swallowing, and sucking stages [4]. Infants can feed by a lower level of energy using nutritive sucking [4, 15]. However, the proper and simultaneous function of laryngeal, pharyngeal, and oral muscles in a few milliseconds seems challenging for preterm infants. The swallowing activity occurs before the next sucking and between inhalation and exhalation. The finding of some studies indicated that variables that are pertinent to the oral sensory stimulation positively impact oral feeding in preterm infants. So, the factors related to the coordination between breathing, sucking, and swallowing could be considered the main indicators for studying the oral feeding skills of preterm infants [4, 13]. For many years, patterns of nutritive sucking were indicators of the physiology and development of infants [16]. Suction pressure, as one of the main quantitative indices, is utilized to measure feeding behavior in infants [10]. The suction pressure is regarded as the negative intraoral pressure produced with the closure of nasal passages by the soft palate, lowering the lower jaw, and tightening the lips around the bottle or breast nipple that is created as a result of suction [17].

Some studies have been conducted to develop instruments for measuring oral feeding abilities in preterm children. Chen et al. introduced the wireless system for assessing oral feeding in preterm infants. They demon-
strated that this system is a non-invasive and appropriate instrument for measuring the suck-swallow-breath pattern in premature infants [4]. Some studies focused on the pattern of tongue, jaw, and lips movements by ultrasound instruments [18-20]. Lang et al. reported quantitative measurements through a novel instrument with two parts: an orometer and a suck editor [7]. The function of this instrument was investigated on full-term infants. They reported that this instrument is a valid one for measuring intraoral pressure [7]. Medoff-Cooper et al. evaluated the sucking function of preterm infants in some studies [8]. They used a “nutritive sucking apparatus” for evaluating the sucking behavior in infants and reported a significant association between the developmental profile of 1-year-old infants and sucking performance at 40 weeks of postmenstrual age [8].

In our research, conducted for the first time in Iran, the first objective was to develop the Iranian version of the device “infant sucking tester” (IST) instrument that can measure negative pressure in newborn infants during nutritive sucking cycles. Clinical evaluation of functions of swallowing and sucking performance in infants brings an invaluable measure of their early neurological performance [21]. The second objective was to investigate the validity and reliability of the instrument. We hypothesized that the suction pressure as a performance of the oromotor ability might be different in boys and girls. So, the third objective was to compare the function of suction pressure in terms of sex between two genders.

2. Materials and Methods

Study design

We conducted a descriptive-analytical and cross-sectional study to establish the validity and reliability of this instrument.

Development of the instrument

IST consisted of three parts: an infant bottle, a mainboard, and a computer. The instrument was designed to record and calculate the air pressure difference between the inside and the outside of the infant’s mouth during nutritive sucking with the frequency of 10 times per second. So, a thin plastic, sterilized pipe was placed into the infant bottle and connected to a pressure sensor. We adapted the size of the nipple to the size of the infant’s mouth. The sensor in this instrument is a barometric pressure sensor (Model: MPXV7002DP) that measures the air pressure in analog form. The data received from the sensor would be transformed into a digital one by analog-digital converter protocol and sent to the microcontroller (Model: ATMEGA1284PU). The microcontroller calibrates the sensor and converts the pressure data into kilopascal. The main processor of this board is an 8-bit microcontroller that processes raw data from the sensor with an 8 MHz frequency and can save the information for 20 seconds. Liquid crystal display characters were used to show instant data of microcontrollers. Finally, the data were sent to the computer through a USB port and analyzed using a computer by MATLAB software.

Study participants

Infants were chosen through the convenience sampling method. Table 1 presents the descriptive statistics of the participants. They consisted of 20 full-term and 15 late-preterm infants who were selected from newborn infants on their first day of life at Rouhani Hospital of Babol City, Iran, in 2018. After completing the consent form, the parents were asked to complete the questionnaire related to the information about their infants. Infants who met the inclusion and exclusion criteria entered the study. The inclusion criteria for the full-term were as follows: the ability of the infants to suck, being one day old (after the 1st hour of delivery), having birth weight ≥2.5 kg, and having 38-40 weeks of gestational age. The exclusion criteria for them were problems like having complications in delivery, high bilirubin, asphyxia, different medical syndromes, and cleft lip and or palate. The inclusion criteria for late preterm infants were as follows: a birth weight of 1.5 kg and gestational age between 34-36 weeks. The other criteria in the preterm infant group were identical to those of full-term infants.

Study procedure

The sucking examination was performed while the infant was awake in the supine position using IST. At first, the bottle was installed and filled up with some milk. Before starting the sucking, the inside pressure must be zero, calibrated by an experienced speech and language pathologist with experience in working with infants in the Neonatal Intensive Care Unit. The sucking data of the participants were recorded for 20 seconds.

Analyses and measures

The study data were analyzed by SPSS software v. 23.0 (SPSS, Inc., Chicago, IL). The Kolmogorov-Smirnov test tested the normality of the data distri-
The Mann-Whitney U test was used to compare the mean value of suction pressure between full-term and preterm infants and between girls and boys in each group. The Wilcoxon test was used to compute the test-retest reliability by 15 minutes intervals. Statistical analysis was considered significant at the level of $P<0.05$.

**Ethical Issues**

Before starting the research, the parents were asked to fill out the consent form. The current work received ethical code (Code: IR.MUBABOL.HRI.REC.1397.172) from the Ethics Committee of Babol University of Medical Sciences.

### Results

#### Discriminant validity of IST

Table 2 presents the Mean±SD of the suction pressure of the two study groups. As shown in Table 2, the two groups had statistically significant differences ($P<0.001$), supporting the discriminant validity of the IST.

#### Measurement of test-retest reliability

Results of the test-retest of measurements of suction pressure through IST were calculated. The results showed a high and excellent value for suction pressure ($r=0.974$, $P<0.001$).

**Table 1. Descriptive Information of the Participants**

| Demographic characteristics | Full-term Infants | Preterm Infants |
|----------------------------|-------------------|-----------------|
| Number of participants     | 20                | 15              |
| Sex                        | 11 boys and 9 girls | 10 boys and 5 girls |
| Apgar                      |                   |                 |
| 1 minute                   | 9.20±0.76         | 6.86±1.06       |
| 5 minute                   | 9.40±0.75         | 7.66±0.51       |
| Mean of gestational age(min-max) | 38.90(38-40) | 35.93(34-37) |
| Birth Weight               | 3.34±0.36         | 2.22±0.14       |
| Type of delivery           |                   |                 |
| Vaginal                    | 8                 | 8               |
| Cesarean                   | 12                | 7               |
| Sex                        |                   |                 |
| Female                     | 9                 | 6               |
| Male                       | 11                | 9               |
| Age at assessment          |                   |                 |
| Age at assessment          | 9.30±1.08         | 9.33±1.11       |

Note: * the gestational age was considered in terms of weeks and the weight was computed in terms of kg. Age at assessment was reported in terms of hours.

**Table 2. Comparison of Suction Pressure in Two Groups using Man-Whitney U test**

| Groups of Infants | Mean±SD | P     |
|-------------------|---------|-------|
| Suction Pressure  |         |       |
| Full-term         | 0.413±0.447 | <0.001 |
| Late-preterm      | 0.004±0.003  |       |

Note: Suction pressure was calculated in terms of KPa.
Table 3. Comparison of Suction Pressure in Girls and Boys in Two Groups using the Man-Whitney U test

| Variable        | Full-term Infants | Pre-term Infants | P    |
|-----------------|-------------------|------------------|------|
|                 | Mean±SD           | Mean±SD          |      |
|                 | Girls             | Boys             | Girls| Boys       |      |
| Suction pressure| -0.580±0.54       | -0.337±0.239     | 0.90 | 000.2±0.004| 0.003±0.003| 0.50|

Comparison of the Suction Pressure in Girls and Boys

As seen in Table 3, boys and girls did not show a statistically significant difference in suction pressure in the two groups of full-term (P=0.9) and preterm infants (P=0.5).

4. Discussion

In the present study, the development and validation of the instrument for measuring the suction pressure in preterm infants were addressed. Additionally, the function of boys and girls was compared by using this instrument.

Validity is a way to ensure that the error measurement of the scale is at the minimum level. This property refers to whether the tool measures what it has been designed to measure [22]. To test IST’s validity, the suction pressure was compared between full-term and preterm infants. This analysis showed that IST could differentiate between full-term and preterm infants for suction pressure. Therefore, it seems that IST is a valid instrument for measuring the suction pressure in infants. The difference in sucking measures of preterm and full-term children was reported in similar studies [23]. According to IST results, preterm infants not only have weaker suction pressure but also produce positive suction pressure. However, the findings in full-term infants are negative, and their sucking pattern is stronger than in preterm ones. This finding may be attributed to the pattern of sucking. Preterm infants suck through the

Appendix 1. The Photo of Infant Sucking Tester
tip of their tongue; in contrast, full-term infants suck by the stem of the tongue and buccinators muscles.

Although examining the validity of the scale or the instrument is essential, it is not enough, and its reliability should be evaluated too [22]. Test-retest reliability is defined as the ability of the scale or test to measure the construct or variable in the same conditions constantly. The obtained values of the test-retest reliability proved that IST is a reliable instrument for measuring the suction pressure in infants. This finding is somewhat in line with de Costa et al., who reported fair to almost perfect values for reliability measurement [24].

Boys and girls had similar performance for suction pressure in the present work. In similar studies, the participants’ performance was not studied regarding sex. Therefore, we could not compare our results with other studies. However, in de Costa et al. research, sex was not associated with abnormal sucking patterns in preterm infants [24], which could be in line with the findings of this study.

Some limitations were observed in our study that should be mentioned. This study was a pilot one. A pilot study could be defined as a study with a small sample size to test the scales of data sampling. Conducting this stage prepares researchers to perform their full and final study. This study is a crucial phase for detecting major challenges that researchers may face in their study [25]. In this work, the function of IST was investigated by measuring the suction pressure of 35 infants. Indeed, further studies should be conducted to use this instrument in clinical settings. Inter-rater reliability was not computed for the IST, and this issue is needed to target in the future. Another suggestion might be using this instrument in clinical studies to assess the effects of intervention procedures appropriate for the sucking performance of preterm infants.

5. Conclusion

The findings of the current project as the pilot study demonstrate the validity and reliability of IST. Though, conducting further studies is suggested to introduce this instrument as a commercial product for use in hospitals and clinical settings.

Ethical Considerations

Compliance with ethical guidelines

Before starting the research, the parents were asked to fill out the consent form. The current work received ethical code (Code: IR.MUBABOL.HRI.REC.1397.172) from the Ethics Committee of Babol University of Medical Sciences.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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