

Critical Review:
Does Fucile's pre-feeding oral stimulation program enhance oral feeding readiness in tube-fed, pre-term infants compared to routine care?

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Fucile, Gisele and Lau (2002) published a pre-feeding oral stimulation protocol that they showed to have accelerated the transition time from tube-feeding to full oral feeding in pre-term infants. This review examined the published evidence for the pre-feeding oral stimulation program proposed by Fucile et al. (2002) and its effects on feeding and swallowing in preterm, tube-fed neonates. The results were suggestive of an accelerated transition time to autonomous feeding, but other outcome measures (including weight-gain and time of hospital discharge) were mixed.

Introduction

Preterm infants frequently experience difficulty with oral feeding due to underdevelopment of oral-facial musculature, the respiratory system, or central nervous system (Fucile, Gisele, & Lau, 2002). The coordinated suck-swallow-breathe suckling pattern required for neonate oral intake does not develop before 32-34 weeks gestational age (GA) (Khalessi, Nazi, Shariat, Saboteh, & Farahani, 2015). Thus, pre-term infants are especially vulnerable to pediatric dysphagia and feeding challenges and must frequently be tube-fed prior to the introduction of oral intake. Commonly, these infants will have difficulty achieving independent feeding, will experience limited weight-gain, and are at risk for nutritional deficiency, delayed hospital discharge, and long-term health problems (Bache, Pizon, Jacobs, Vaillant, & Lecomte, 2014). Despite the critical need for proactive feeding and swallowing intervention for this high-risk population, caregivers and speech-language pathologists report uncertainty regarding which kind of intervention is most effective (Asadollahpour, Yadegari, Soleimani, & Khalesi, 2015).

Oral stimulation is a treatment strategy for feeding delays which involves activating the muscles of the face and mouth through tactile stimulation. Oral stimulation has been reported to accelerate transition time between tube-feeding and independent oral feeding (Gaebler & Hanzlik, 1996). Historically, oral stimulation strategies or other therapy techniques were only implemented once oral feeding difficulties became evident. There is a great need for the development of proactive and evidence-informed intervention options for these high-risk infants.

Fucile et al. (2002) published a pre-feeding (i.e., prior to intake by mouth) protocol with heavy focus on oral stimulation of the facial structures. The program consists of 15-minute intervention sessions each day for the 10 consecutive days leading up to the introduction

of oral feeding. A health-care professional or caregiver is instructed to stroke the infant's cheek, lips, gums, buccal cavity, and tongue for the first 12 minutes, and finish with 3 minutes of pacifier sucking. The intervention must take place 15-30 minutes prior to tube-feeding (meal time). They hypothesized that this protocol would enhance oral feeding in tube-fed, preterm infants.

Fucile et al. (2002) tested the efficacy of their own protocol in a randomized block design looking at the program's effect on time to attainment of independent oral feeding (IOF), overall intake, rate of milk transfer, and length of hospital stay in 32 preterm infants.

Results showed that this oral stimulation program significantly accelerated time to full IOF (defined as 8 oral feedings/day) when compared to control infants who received only routine care. Overall, Fucile et al. (2002) presented suggestive evidence in their study that their prefeeding oral stimulation program may significantly benefit a preterm infant's time to IOF and rate of transfer. However, more research is needed to determine whether Fucile's protocol is superior to other oral stimulation programs in terms of oral feeding readiness.

Understanding best practices for enhancing oral feeding readiness in tube-fed preterm infants is essential for preventing long-term feeding difficulties, prolonged hospital stays, and promoting independent feeding and growth.

Objectives

The primary objective of this paper is to critically evaluate existing literature regarding the effectiveness of Fucile's prefeeding oral stimulation protocol in preterm, tube-fed infants.

Methods

Search Strategy

A variety of computerized databases, including Google Scholars and PubMed, were searched using the following terms:

(preterm) OR (premature) AND (oral stimulation) AND (non-nutritive suck*) AND (independent oral feed*)

All literature searched within the citing articles of (Fucile et al., 2002).

Selection Criteria

Studies selected for inclusion in this review paper were required to follow the protocol outlined by Fucile et al. (2002), (Table I).

Data Collection

The results of the literature search yielded six randomized control/clinical trials (RCT).

Results

RCTs are studies in which participants are allocated at random to various experimental or control groups. Results of RCTs are quantitative and comparative. In the following studies, infants in the control group received “routine care”, or the standard of care for preterm infants in each of the hospitals or institutions where the research took place. Routine care for preterm infants may differ between institutions but will typically include nurse-assisted tube-feeding, weight and oxygen-level monitoring, and management of other health related concerns.

Younesian et al. (2014) investigated the impact of Fucile’s prefeeding oral stimulation program on 20 preterm infants (30-32 weeks gestational age). The experimental group underwent Fucile’s complete protocol for the 10 consecutive days leading up to the introduction of oral feeding, while the control group received routine care.

The participants included ten boys and ten girls recruited via convenience sampling from the NICU. Each participant was randomly assigned their sample group. Both nurses and physicians were blinded to group assignment.

Outcome measures selected for investigation included: time until IOF, age at hospital discharge, and weight gain. To measure weight gain, infants were weighed by the same nurse, on the same scale, at the same time each day. The length of hospital stay was calculated from the infant’s date of birth. Appropriate statistical analyses were conducted.

The results of the study showed that the experimental group achieved IOF an average of two weeks sooner

than control. Time to discharge was also shorter (by one week) in the experimental group. No difference was detected between groups in terms of weight gain rate.

Strengths of this article include its diligence in blinding healthcare professional to group assignments, and outcome measures that directly aligned with Fucile’s program. Limitations of this study included small sample size. Additionally, this article failed to mention who carried out the intervention and what training they obtained regarding its administration, and thus the quality of the intervention may be unreliable.

Overall, this study presents suggestive evidence that Fucile’s prefeeding oral stimulation accelerates time to IOF and the hospital discharge time of preterm infants.

Zhang et al. (2014) compared the effectiveness of nonnutritive sucking (NNS) and oral stimulation (OS), either applied independently, or in combination via Fucile’s oral stimulation protocol (OS + NNS), on 112 preterm infants (29-34 weeks GA). In the NNS group, infants sucked on pacifiers for five minutes, seven to eight times per day. OS consisted of Fucile’s program *excluding* the three minutes of NNS at the end. The combined group’s methods followed Fucile’s prefeeding program. Finally, the control group received only routine care.

The primary outcome measure was time to IOF. Other outcome measures included: rate of milk transfer, proficiency of transfer (defined as intake in the first five minutes of feeding / volume ordered), volume of transfer (volume transferred during the entire feeding / volume prescribed), weight, and hospital discharge time. These outcome measures were appropriate and aligned with the study’s objectives. Two experienced researchers administered the intervention, but their qualifications were not further elaborated. Appropriate statistical analyses were conducted.

Results showed that overall, all intervention groups achieved IOF significantly faster than the control group. However, the combined group achieved IOF at a significantly lower birthweight, and days of life than the controls. Similarly, rate of milk transfer was significantly greater in the intervention groups than in the control group. Proficiency in the NNS and OS groups did not exceed the controls, but the combined group was significantly greater. No difference was detected among all groups in terms of volume of transfer, weight gain, and hospital stay.

Strengths of this study include the large sample size, and clear, replicable methods. The depth and variety of outcome measures both allowed for comparisons to

Fucile's original study and for expansions to be made. A limitation of this study was the inclusion of "older" preterm infants.

Overall, this article presents compelling evidence that Fucile's prefeeding oral stimulation program reduces transition time to full oral feeding and enhances feeding proficiency.

Bache et al., (2014) investigated the effects of Fucile's oral stimulation program on 86 preterm infants (26-33 weeks GA). Infants were randomly assigned to an intervention group, who received Fucile's protocol, or a control group, who received routine care. Administrators of the intervention were trained by paediatric physical therapists. Administrators were regularly observed to ensure reliability of the intervention. Statistical analyses were appropriate.

Outcome measures investigated time until IOF, length of hospital stay, and breastfeeding rates. Unlike previous studies, Bache et al. (2014), outlined a strict protocol for oral feeding in its methods. On the first day, one oral feeding dose of 5 ml or one breastfeeding opportunity was presented to the infant. If the infant ingested 5 ml in less than ten minutes, the dose was double the next day to 5 ml twice a day. Otherwise, the same number of feedings was maintained until the entire quantity could be ingested orally. The member of the medical staff deciding on discharge was not blinded.

Results showed no difference between both groups in areas of time to IOF or length of hospital stay. However, breastfeeding rate in the intervention group was significantly higher than controls.

Strengths of this study include its adequate sample, the unique focus on breastfeeding which had gone unaddressed by the literature, and the inclusion of "transition time" as an outcome measure. The specific feeding regimen also increased this study's replicability. A comprehensive analysis was conducted to assure that both groups did not differ statistically in terms of demographics or medical characteristics.

Overall, this article presents suggestive evidence that Fucile's program enhances breastfeeding rate.

Khalessi et al., (2015) compared Fucile's prefeeding OS program with a higher-intensity modification of the same protocol. Forty-five preterm, tube-fed infants (26-32 weeks gestational age) were randomly assigned to one of three groups. Intervention Group A underwent Fucile's program (15 minutes of oral stimulation per day for 10 consecutive days). Group B underwent an

accelerated and modified version of Fucile's program (15 minutes twice daily for 5 consecutive days). Group C was the control group, which received only routine care. All subjects had similar baseline characteristics with respect to gestational age, birth weight, and gender. Trained nurses implemented the protocols. The attending physician was blinded to group assignment. Appropriate statistical analyses were conducted.

Outcome measures examined the initiation and progress to IOF, daily weight gain, and the date of hospital discharge. Results showed that infants' weight in Group A was significantly higher than the controls at 4 and 8 oral feedings per day, but no statistical significance was detected between Group A and B. Additionally, no significant difference was observed among the groups regarding time to IOF or length of hospital.

The methods and analyses were clear and aligned with the objectives of the study. Outcome measures may have benefited from further exploration of secondary effects, such as sucking rate or volume of intake. The smaller sample size was a further limitation to this study.

Overall, this article presents suggestive evidence that Fucile's may increase weight gain rate when compared to a higher intensity modification and routine care.

Asadollahpour et al., (2015) investigated the therapeutic effects of Fucile's prefeeding oral stimulation program compared to a nonnutritive sucking (NNS) prefeeding program. Thirty-two preterm infants (26-32 weeks GA) were randomly assigned to either (A) Non-nutritive sucking intervention (B) Fucile's prefeeding oral stimulation program or (C) routine care (control). For the infants in the control group, a speech pathologist placed her hands inside the infant's incubator daily for the length of time treatment would have occurred (15 minutes), but did not touch the infant.

Outcome measures looked at time until IOF, weight gain, and time until hospital discharge. All statistical analyses conducted were appropriate for the study. Results showed that there was no significant difference among the groups in terms of time to IOF, although the Group A and Group B achieved full feeding 7.55 and 6.07 days sooner than control, respectively. Weight gaining at time of discharge was significantly higher in Group A than in the other two groups.

A weakness of this study was that the method of randomization of the infants to their group is vaguely described and unclear. Methods regarding group assignment and discharge criteria are ambiguous and

therefore these methods would be difficult to replicate. A strength of this study is that a speech-language pathologist who was blinding to research conducted all therapy in both intervention groups. Therefore, the same person conducted all interventions.

This study provides suggestive evidence that an exclusively NNS program may have benefits over pre-feeding oral stimulation in terms of weight gain rate.

Fucile, Gisel and Lau (2005) aimed to further their seminal paper by investigating the sucking skill maturation of 32 preterm infants (26-29 weeks GA) following their prefeeding oral stimulation program. The control group received routine care. Infants were randomly assigned to their group via a random number generator. The principle investigators administered the program. All caregivers were blinded as to the assignment of their child via a screen placed over the isolette, preventing them from watching. All statistical analyses were conducted appropriately.

Outcome measures evaluated overall intake, rate of milk transfer, days until IOF, and amplitude of the expression component of sucking. Following treatment, no statistical difference was detected between the treatment and control group in terms of sucking stage maturation, sucking frequency, endurance, and amplitude of suction. However, results showed that the intervention group had an enhanced expression component of sucking when compared to the controls. Additionally, the intervention group achieved IOF significantly sooner than controls.

Strengths of this study include the detailed selection criteria for its participants and a comprehensive breakdown of outcome measures pertaining to sucking maturation. The outcome measures assessed were extremely thorough and relevant to the study's aim of measuring the oral stimulation program's effect on sucking maturation. Since these investigators are also the creators of the original program, the quality of treatment administration was likely very high, although results may be therefore subject to some bias. A significant limitation of this study is that no specification was made regarding feeding method following treatment (breast or bottle feeding).

Overall, this paper presents suggestive evidence that Fucile's prefeeding oral stimulation helps preterm infants achieve independent feeding sooner, but sucking maturation remains relatively unenhanced.

Discussion

Oral feeding is a crucial factor when determining infants' hospital discharge time and promoting typical developmental milestones in preterm infants. Fucile et al. (2002) developed a pre-feeding intervention to proactively address the needs of this high-risk population. Six randomized control trials have looked at the evidence surrounding Fucile's program in tube-fed preterm infants as it compared to infants receiving routine care. There is promising evidence to show that Fucile's program accelerates time to a fully independent oral diet when compared to routine care.

Zhang et al. (2014) had a compelling study which compared the oral stimulation alone, against nonnutritive sucking program alone, against fucile's combined program and controls in 112 preterm infants. This article has high clinical impact as it sought to address the effects of each distinct component of the Fucile method. Results of this study aligned with those found by Fucile et al. (2002) in that all infants who received the intervention achieved IOF sooner and experience increased milk-transfer rates.

Bache et al. (2014) presented an interesting question in their study. They were the only study that specified that infants were to be breastfed following intervention. They found that breastfeeding rate was higher in the intervention group, but no differences were found between groups in terms of time to IOF. This unexpected finding contradicts those found by Fucile et al. (2002). However, breastfeeding requires a more complex and mature physiological suck-swallow pattern than bottle-fed infants and may have slowed the progression of IOF.

A general trend found throughout the present evidence was the lack of specificity regarding which feeding method was implemented following therapy. Bache et al. (2014) was the only study which specified the feeding method the infants received. There are physiological differences between breast and bottle feeding that may influence feeding outcomes, and thus a distinction should be made between them when assessing oral feeding outcomes. Younesian et al. (2014) left the feeding method up to the mothers, while Khalessi et al. (2015) allowed mothers to switch between the feeding methods throughout the program.

Another trend was the lack of comparison between older and younger preterm infants. The older a preterm infant is at birth, the more developmental milestones that infant is likely to have achieved in-utero. At 32-34 weeks GA, preterm infants begin to develop the correct orofacial coordination needed for safe and efficient feeding. Fucile's original study investigated only very young preterm infants (<30 weeks GA), a population

which likely had very little orofacial coordination. However, the evidence surrounding Fucile's program commonly grouped very young and older preterm infants. Therefore, results of these studies may have overestimated the effects of the pre-feeding program.

Taken together, the results of the six reviewed articles provide promising evidence that Fucile's prefeeding oral stimulation program may accelerate the transition period between fully tube-fed diet to fully independent oral feeding in preterm infants. However, there is controversial evidence in the literature regarding effects of secondary outcomes such as weight gain rate and hospital discharge times. Clinicians should consider the evidence with caution and consideration to the amount of mixed evidence present.

Future Investigations

Future studies should consider comparing infants who receive a bottle-fed diet following the program against infants who received breastfeeding to determine if the program may be more suited for one type of feeding method over the other. Future studies should also investigate any long-term effects of the program with follow-up data 6-months or 1-year post-treatment. This data would be valuable as it would allow for the development of maintenance programs if outcomes diminish over time.

Lastly, no study ever compared Fucile's program to another available preterm oral stimulation program. Side-by-side comparisons between treatment programs would be greatly clinically impactful as it would allow for clinicians to select the most suitable program to meet each preterm infant's needs.

Clinical Implications

Due to the promising nature of the research results, implementing Fucile's prefeeding oral stimulation protocol may enhance time to independent oral feeding in preterm infants. However, there is no evidence to suggest this may lead to earlier hospital discharge, and there is mixed evidence supporting the program's ability to assist in weight gain and sucking maturity. As such, implementing this prefeeding oral stimulation regime within NICU's may be impractical at this time.

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