Critical Review:

Effects of oral stimulation and non-nutritive sucking therapies on transitioning to oral feeding in preterm infants.

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This critical review examines the effectiveness of combining non-nutritive suck (NNS) and oral stimulation (OS) therapies to improve the transition time of preterm infants from gavage feeding systems to oral feeding. In online searches, three randomized block designs, a non-randomized control trial and a randomized control trial were found. Subsequently, the level of evidence of the articles was determined, based on the reliability and validity of their methodologies and statistical analysis. Additionally, implications for clinical practice were established. Overall, the evidence supporting the use of this combined methodology in clinical practice is compelling.

Introduction

Non-nutritive suck (NNS) appears in-utero at 15-18 weeks gestation and is fully established by 34 weeks gestation (Poore, Zimmerman, Barlow, Wang, & Gu, 2008). It is a precursory skill that fetuses develop prior to feeding orally outside the uterus.

Preterm infants born prior to 34 weeks are placed on enteral or gavage feedings because they have not yet developed the ability to express milk through sucking (Rocha, Moreira, Pimenta, Ramos & Lucena, 2006). Prolonged use of gavage or enteral feeds is often linked to longer hospital stays, medical complications, future feeding challenges, family stress, growth challenges, poor neural development and speech and language impairments (Song et al., 2019).

Often the use of gavage feedings is prolonged in the hospital neonatal intensive care units (NICU). The transition times off these feeds and the development of the sucking mechanism to allow oral feedings can take weeks or months to complete (Song et al., 2019).

Transitioning these preterm infants off these feeds earlier is linked to better outcomes and earlier discharge from the hospital (Fucile, Gisel & Lau, 2002). Intervention that accelerates the development of the functional sucking behaviour is essential to developing oral feeding.

Infant oral feeding is a complex process and the breathe, suck, and swallow pattern is coordinated by the central pattern generator in the brainstem (Song et al. 2019). This neural function uses sensori-motor input to entrain the sucking reflex in infants.

Both oral motor interventions (NNS) and peripheral somato-sensory input (OS), have independently proved to be beneficial to decreasing the transition time to oral feeding (Fucile, Gisel & Lau, 2002). Because both somato-sensory input and motor output are part of the regular sucking mechanism, it has been hypothesized that combining both NNS and OS treatments would better activate the central pattern generator and therefore improve outcomes.

An analysis of the literature is performed in this critical review to determine if combining NNS treatments and OS treatments reduces the transition time of preterm infants in the NICU to full oral feeding.

Objectives

The objective of this paper is to perform a critical appraisal of the literature on the efficacy of combining NNS therapy with OS in preterm infants to decrease transition times to oral feeding. Additionally, it will determine the clinical implications and recommendations based on the literature.

Methods

Search Strategy

Articles related to the topic of interest were found using the PubMed online database. Keywords used for the data base search were as follows:

[(premature) OR (preterm) and (non-nutritive suck) OR (pacifier stimulation) and (somatosensory stimulation) OR (sensory stimulation) OR (oral stimulation) OR (orocutanious stimulation) and (oral feeding)]

Selection Criteria

Articles were included in this review if they applied both NNS and OS therapies to the premature infants. Also, one of the outcomes measured in the articles needed focus on the time the premature infants took to transition to oral feeding. Articles that only analyzed the length of hospital stay, amount of milk consumed, or the efficiency of the suck were not included in this review.

Data Collection

Papers included in this review utilized randomized block designs (3), a nonrandomized clinical trial (1) and a randomized control trial (1).

Results

Randomized Block Design

Randomized block design is an appropriate research method for this population because it stratifies participants into groups prior to randomly assigning them to the treatment or the control group. This stratification controls for confounding variables. These studies control for the impact of birth age and weight on preterm infants' health and particularly on their lung development. Full randomization would not account for these extraneous factors, especially with lower participant numbers. A downside to the randomized block design, is the ability to generalize the results to other populations. It is level two evidence.

Fucile, Gisel and Lau (2002) conducted a randomized block design study on 32 preterm infants who were stratified based on their gestational age (GA) then randomized into experimental and control groups. The experimental group received a standardized, 15-minute OS and NNS protocol. Outcomes measured were number of days to transition to oral feeds, post menstrual age (PMA), number of days of life (DOL), weight, overall intake and rate of milk transfer at time of full oral feed. Only the length of time to full oral feed, PMA and DOL are analyzed in this paper. The outcome measure, 'full oral feeding' was clearly defined. The researchers noted variation in the practices of the attending physicians. There was no consistent protocol for transitioning infants off the gavage feeds. This inconsistency could be a nuisance variable in the study.

There were careful measures taken in this study to blind the family, nurses feeding the infants and the doctors in charge of increasing the feeds to the group allocation of the infants. Size of the sample was low for a randomized block design study.

The inclusion and the exclusion criteria of participants were clearly specified in this article. Infants with chronic medical complications were excluded from the study.

The methods used in the study were clearly defined and could be replicated in future studies. In the experimental group, prior to feeds the researcher provided OS to the infants' cheeks, lips, gums and tongue for 12 minutes and a pacifier was provided for NNS for three minutes.

Appropriate statistical analysis was conducted based on the outcome of interest. All data was pooled as there was no difference between the age groups. Number of days to transition to oral feeds was an average of seven days faster for the experimental group. The PMA and the DOL at eight oral feeds a day were not statistically significant.

Overall, this study provides a minimally compelling level of evidence that the therapy protocol is effective and practical to implement into practice as it requires no additional technology.

Rocha Moreira, Pimenta, Ramos and Lucena (2006) conducted a randomized block design study on 98 very low birthweight preterm infants who were stratified based on GA into an experimental group and a control group. The experimental group received a previously standardized 15-minute OS and NNS protocol. Outcomes measured in the study included weight gain, length of stay, number of days until initiating oral feeds and number of days until complete oral feeding. Only number of days until complete oral feedings is examined in this review. A clear definition of this measurement was provided in the article.

Double blinding was noted in the study. It was not explicitly explained how blinding occurred and who was blinded to the groupings.

The inclusion and exclusion criteria of participants in the study was clearly identified. Infants were required to be preterm, below a specific birth weight to reach the very low distinction, and free of additional medical complications that would impact feeding.

The methods used in the intervention were not clearly explained. The researchers used a previously validated standardized OS and NNS protocol that included 12 minutes of OS combined with 3 minutes of NNS. To replicate this study, someone would need to refer to the original study's methodology.

Appropriate statistical analysis was performed in the study. There was a statistically significant difference in the number of DOL at the time of full oral feeding in the treatment group compared to the control group. Full oral feeding occurred an average of 8.2 days earlier. There was no statistical difference in the GA of the infants at the time of full oral feeds.

Overall, this study provides compelling evidence that OS combined with NNS can allow low weight preterm infants to transition to oral feeds sooner. It would be reasonable to implement this protocol into clinical practice.

Song, et al. (2019) conducted a randomized block design on 210 preterm infants who were stratified based on GA. Additionally, infants from multiple births were placed in the same grouping. The experimental group received three, three-minute NNS patterned burst of pulses through a specially designed pacifier nipple over a 20-minute period. Outcomes measured in the study were the number of days from the initiation of oral feeding to full oral feeding, length of stay, PMA at the time of full oral feeding and weight gained. Number of days until full oral feeding and PMA at full oral feeding are the only outcomes examined in this review.

NICU staff who were not involved in providing treatment were blinded to the group allocation of the infants. Staff included in providing treatment were not blinded to the groupings.

The inclusion and exclusion criteria of the infants was clearly explained in the study. These criteria were altered post hoc to exclude infants born between 24 and 26 weeks because they were not medically stable enough to participate. Reasons for participant drop out were clearly explained.

The methods used in the study were clearly articulated. The experimental group received 20-minute sessions of OS through a pulsating nipple to mimic NNS burst up to four times a day. The study indicated when the intervention would be initiated, when feeds would progress and when feeds would be attempted and situations when the intervention would not be performed.

Appropriate statistical analysis was completed in the study. Time to transition to full oral feeds was significantly shorter by an average of 4.1 days than the control group. PMA at full oral feeding was not significantly lower for the intervention group.

Overall, this study provided compelling evidence that the pulsing pacifier nipple decreased the time it takes infants to transition to full oral feeds. Implementation into clinical practice is reasonable based on this evidence.

Nonrandomized Clinical Trials

Nonrandomized clinical trials allocate participants to treatment groups in a non-randomized method such as matching participants to characteristics of the treatment group. This method of research allows more participants to be placed in the treatment group than the control group. Therefore, more of the subjects receive the benefits of treatment. Matching of characteristics also accounts for extraneous variables. It is level 2 evidence.

Poore, Zimmerman, Barlow, Wang and Gu (2008) conducted a non-randomized clinical trial on 31 preterm infants who were age matched based on PMA. 21 infants were placed in the treatment group, receiving pulsatile pacifier nipple treatment. Outcome measures were time and amplitude of sucking pressure, and percent of oral feeds. The increase in percent of oral feeds is the only outcome examined. The calculation for determining the percentage of oral feeds pre and post treatment was clearly outlined in the study.

Blinding was not mentioned in the study of the medical staff, or the researchers.

Inclusion and exclusion criteria of the participants was clearly defined in the study. Infants were medically stable and feeding less the 25% orally at the time of pre-intervention.

The methods in the study were clearly defined and could be replicated with the specialized equipment required. The experimental group receive three minutes of patterned orocutanious stimulation during gavage feeds that mimicked the pattern of a non-nutritive suck burst. The control group received the same pacifier nipple for NNS but the pulsatile function was not turned on to provide the OS.

Appropriate statistical analysis was conducted in the study using a mixed method of comparing outcomes. There were no significant interactions of birthweight and PMA on outcomes. The study found a statistically significant improvement in percent of oral feeds in the treatment group. The treatment group had a 16.8-fold increase in percentage of oral feeds from pre-treatment to post-treatment, compared to the 3-fold increase in percent of oral feeds in the control group.

Overall, this study provides a minimally compelling level of evidence that the pulsing pacifier nipple increases preterm infants' percent of oral feeds more effectively than NNS alone. Therefore, it would be reasonable to include this treatment in clinical practice.

Randomized Control Trials

Randomized control trials are the highest level of evidence because participants are fully randomized into their treatment groups. A risk with a randomized control trial, with a small number of participants in each group, is nuisance variables will impact the results. An important aspect of randomized control trials is there

should be double blinding procedures. It is not always ethical to withhold treatment from patients in this type of trial.

Zhang, Lyu, Hu, Shi, Cao and Latour (2014) conducted a randomized control study on 112 preterm infants to compare the effects of combining NNS and OS and the outcomes of the individual treatments. Infants were randomized into four treatment groups: a combined treatment group, an NNS group, an OS group and a control group. Impacts on transition time to oral feeding, PMA and DOL at full oral feeding and the efficiency of the suck were the outcomes measured. Only transition time to oral feeding and PMA and DOL at full oral feeding are examined in this critical review.

The inclusion and exclusion criteria for participating in the experiment was clearly explained. The study only included healthy preterm infants who did not have other health complications besides dysphagia. A low dropout rate was reported and reasons for dropping out were clearly explained.

The methods of the 12-minute standardized OS protocol used in the OS and combined groups, were based on a proposed method with prior clinical evidence. To replicate this procedure, someone would have to refer to the original study that used this protocol. The dosage of the NNS treatment was inconsistent between the combined group and the NNS group. The definition of transition time was well defined in the article

The statistical information was limited, and the statistical analysis used by the researchers was unclear. The study indicated that the combined group achieved independent oral feeds at a significantly younger PMA, fewer DOL and had a faster transition time than the control group. The individual treatments did not show statistically significant PMA and DOL compared to the control group. There was no statistical difference between the transition times, PMA and DOL between the 3 treatment groups.

Overall, this study provides highly suggestive evidence. I would include this treatment in clinical practice with some hesitation based on this article alone.

Discussion

There were two main treatment protocols that combined oral stimulation and non-nutritive sucking therapies in the five studies.

The first was Fucile, Gisel and Lau's (2002) protocol that was clearly explained in their article. Both Rocha, et al. (2007) and Zhang, et al. (2014) used this protocol, however, to replicate the studies, a researcher would have to refer to the original article. Poore, et al. (2008) and Song et al. (2019) used a specialized pacifier designed to pulse in a pattern that mimics the newborn non-nutritive sucking burst rhythm.

Measurements of transitioning to oral feeds was different in the studies. Some studies used a time from start of intervention until full oral feeding, another used increase in percentage of oral feeds, many used the number of DOL at full oral feeds and others measured PMA at time of full oral feeding.

Many of the studies measured more than one of these outcomes and did not always have enough power to find statistical significance for all the measures. For example, Fucile, Gisel and Lau (2002) showed statistically significant results in the length of time from the beginning of intervention to oral feeding but not for the number of days of life or the postmenstrual age at the time of full oral feeds.

All studies from both intervention types found a significant difference in one of the outcomes measured. The studies that measured a difference in time or difference in the amount of oral feeds from start of treatment to end of treatment found statistically significant results. PMA at time of full oral feeding was often the measurement that was not statistically significant. This challenge may be because PMA is measured in weeks. A larger number of participants would be required to find a difference of 1 week than number of DOL.

The way each of the studies defined post treatment measurement was also different between the studies. Fucile, Gisel and Lau (2002) defined full oral feeding as 8 feeds a day whereas, Poore et al. (2008) defined it as when an infant received 90% of their feeds orally for two days. Alternatively, Rocha et al. (2006) defined full oral feeding as when all feeds were taken orally.

The generalizability of the results of the studies is limited. All the studies had extensive exclusion characteristics. Many premature infants with dysphagia have other health concerns placing them at risk, further studies on this combined therapy methodology need to include these populations. Rocha et al. (2007) was the only study in which an at-risk factor was included. This study specifically examined the effects of the treatment on very low birth weight preterm infants.

More research needs to be conducted to compare the combination of treatment protocols to the individual treatment methods. Only Zhang et al.'s (2014) article compared combining the treatments to the effect of both

NNS and OS individually. This study did not have enough statistical power to demonstrate a significant difference between the three treatments. The combined treatment did have statistically significant lower PMA and DOL than the control group, whereas the individual treatments did not. In Poore et al. (2008) and Song et al.'s (2014) studies, the control group received NNS therapy on a regular pacifier and both studies found statistically significant improvements between the groups. This result demonstrates that the combined treatment is more effective than NNS alone.

Clinical Implications

The clinical bottom line is that both treatment protocols using OS and NNS demonstrated overall compelling results therefore, it would be reasonable to implement these practices in a clinical setting.

Although both treatment protocols in the study showed decreased transition times for the infants, the costs of treatment would be a factor when a clinician is deciding between the two effective methods. Fucile, Gisel, and Lau's (2002) protocol would take a significant amount of clinician or nursing time to implement (15 minutes prior to each infant's feed). Alternatively, there would be a significant upfront cost to using the specialized pacifier device.

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