NCPD 2.0 Contact Hours

The Effect of Early Feeding of Full Liquids on Postoperative Infants

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Abstract: There is a lack of evidence-based guidance for postoperative feeding of infants after outpatient surgeries. This randomized controlled trial tested the hypothesis that infants, aged ≤12 months who are fed formula or milk at home, will have more oral intake, less pain, and less emergence delirium when fed formula/milk as compared with clear liquids in the postanesthesia care unit. Infants were randomized to receive formula/milk or clear liquids as first feeding after outpatient myringotomy and tube insertion. Pain (Faces, Legs, Activity, Cry, and Consolability) and emergence delirium (Pediatric Anesthesia Emergence Delirium) scores were recorded and compared immediately and again 15 and 30 minutes after arrival in the postanesthesia care unit. Infants randomized to the formula/milk first-feeding group had significantly more volume of oral feeding intake than infants randomized to the clear liquid first-feeding group (M = 80.5 ml, 95% CI [15, 146], p = .017). There was no significant difference in vomiting, pain scores, or emergence delirium scores between groups. These results support the practice of ad lib feeding of infants who preferred full liquids after outpatient surgical procedures.

KEY WORDS: feeding guidelines, infant, postoperative delirium, postoperative feeding, postoperative pain

INTRODUCTION

The purpose of preoperative infant fasting guidelines is to reduce the incidence and severity of complications from the perioperative aspiration of gastric contents (American Society of Anesthesiologists [ASA], 2017). Although clinical practice guidelines for preoperative fasting have been established by both the ASA and the European Society of Anesthesiology, there are no clinical practice guidelines for postoperative feeding of infants after outpatient surgery. First feedings of clear liquids have been favored based on the preoperative evidence of decreased risk of aspiration (ASA, 2017), but animal studies indicate that eating pleasurable foods decreases pain responses, suggesting an analgesic effect from eating (Foo & Mason, 2009; McVinnie, 2013). In

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addition, women exposed to experimental pressure pain reported higher pain thresholds after consuming soft drinks as compared with controls who consumed water (Mercer & Holder, 1997). A few studies also indicate that children reach feeding goals quicker, exhibit less pain, and are happier when allowed to liberally eat their preferred diet after surgery (Adibe et al., 2014; Paton et al., 2014; Radke et al., 2009).

To establish a benchmark of postoperative infant feeding practices, we surveyed 12 outpatient surgical centers. Most surgical centers required infants to take clear liquids as their first feeding after surgery (n = 8), but four surgery centers allowed infants formula/milk as their first feeding. We also analyzed 4 months of postoperative phone calls to parents of infants ≤ 12 months old who had a surgical procedure at our facility (n = 65). Postoperative complications were rare, with only one report of postoperative vomiting. Therefore, the purpose of this randomized controlled trial (RCT) was to determine if infants who are given formula/milk as a first postoperative feeding have greater oral feeding intake, less pain, and less emergence delirium than infants who are given clear liquids for their first postoperative feeding.

STUDY DESIGN

This prospective, single-blinded RCT was approved by the Nursing Research Council and institutional review board of Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's, IRB No. 2015-452). The study was conducted at the Westchester Outpatient Surgery Center (WOSC) of Lurie Children's. This freestanding suburban surgical center is solely affiliated with Lurie Children's, a 364-bed freestanding urban tertiary care children's hospital. Approximately 2,000 outpatient procedures are performed annually at WOSC, of which an average of 20% are myringotomy and tube placement under general anesthesia. Preoperative and postoperative patient care is provided by 20 perioperative nurses employed at WOSC, four of whom collected data for this study.

Sample

Eligible infants were 12 months old or younger who were scheduled for elective myringotomy and tube placement under general anesthesia. Breast-fed infants and infants with any preexisting comorbidities, other than frequent ear and upper respiratory infections, were excluded from study participation. A priori power analysis indicated 80% power to detect a clinically significant difference of 5% could be achieved with 32 infants.

Procedure

Parents were approached and informed about the study before surgery. After receiving informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization, infants received general anesthesia with sevoflurane in the operating room. Sevoflurane is a rapid-acting inhalation anesthetic used for short pediatric surgical procedures (Chandler et al., 2013). Pain was treated preemptively with intramuscular ketorolac during anesthesia, because no intravenous access or fluids were required for these brief surgical procedures. If patient safety dictated changes to this anesthetic plan, patients were then excluded from the study.

Upon arrival in the postanesthesia care unit (PACU), infants whose parents consented to study participation were randomly assigned (using a web-generated randomization table) to receive clear liquids, either 5% glucose water or apple juice (clear liquid group), or their home diet of formula or milk (formula/milk group). At WOSC, infants are fed as soon as they are awake and physiologically stable. Infants are allowed to self-limit their feeding intake; in other words, no infant is forced to feed if they show lack of interest in eating by turning away from or refusing to latch onto a bottle.

Infants were assessed before their first feeding and 15 and 30 minutes after their first feeding with the Faces, Legs, Activity, Cry, and Consolability (FLACC) pain scale and the Pediatric Anesthesia Emergence Delirium (PAED) scale. To prevent bias, nurses who assessed infants were blinded to the infants' feeding assignments and did not provide direct care to the infants they assessed. The nurses assessing infants with the FLACC and PAED scales had shown clinical competency using these scales before this study, and to ensure interrater reliability, these nurses completed prestudy interrater reliability testing. Nurses providing direct care to infants enrolled in the study recorded the type and total volume of feedings as well as any episodes of emesis before the infants' discharge from the surgical center.

Before discharge, parents were asked to rate their satisfaction regarding their infant's feeding using a one-question Likert scale developed for this study. In addition, a nurse contacted the family 1–7 days after surgery to ask if the infant vomited in the 24 hours after discharge from WOSC.

Measures

FLACC

The FLACC scale is a valid and reliable observational pain scale used to assess pain in preverbal or nonverbal children (Herr et al., 2019; Merkel et al., 1997). The

scale helps nurses systematically quantify pain-related reactivity and behaviors of children 0–7 years of old in the PACU (Herr et al., 2019). Specific criteria are provided for nurses to determine a score of 0, 1, or 2 for each of five behavioral categories (face, legs, activity, cry, and consolability), resulting in a summative score of 0–10. Content validity was established by responsiveness to analgesics, internal consistency is good (alpha correlation coefficient = .88), and interrater reliability is excellent (r = .97, intraclass correlation coefficient = .9; Crellin et al., 2018).

PAED

The PAED scale is a valid and reliable five-item scale used to measure the presence of anesthesia emergence delirium in pediatric patients (Reduque & Verghese, 2013; Stamper et al., 2014; Stewart et al., 2019). Whether the child makes eye contact with the caregiver, the child's actions are purposeful, and the child is aware of surroundings is scored from 0 to 4, where 0 = *extremely* and 4 = *not at all*. The child is restless and the child is inconsolable are scored from 1 to 4, where 1 represents *just a little* and 4 represents *extremely*. Scores range from 0 to 20, with scores greater than 10 indicating the presence of emergence delirium.

Parent Satisfaction

To assess parent satisfaction with feeding in the PACU, parents were asked to indicate their level of satisfaction with their infant's feeding after surgery using a 0–4 Likert scale. A score of 0 indicated *no satisfaction*, and a score of 4 indicated an *extreme level of satisfaction*. This satisfaction measure was developed by the first author; and the data were obtained by the nurse caring for the infant at the time of surgical center discharge.

DATA ANALYSIS

The primary outcomes evaluated were volume of oral feeding intake, pain (FLACC) scores, and emergence delirium (PAED) scores. Any missing data points for oral feeding intake were imputed with the mean value. Any missing data points for initial PAED and FLACC scores were imputed with the mode. FLACC and PAED scores for the two groups of infants were compared using the Mann–Whitney U test. In addition, a mixed between- and within-subject analysis of variance was conducted to assess the impact of type of feeding on pain and delirium scores across the three time points (prefeeding, after 15 and 30 minutes in the PACU).

The secondary outcomes were parental satisfaction with feeding and the occurrence of postoperative vomiting. Any missing parent satisfaction data points were imputed using the mode. Parental satisfaction with feeding and the occurrence of postoperative vomiting for the two groups of infants were compared using the Mann–Whitney U test.

Descriptive statistics, including measures of central tendency were calculated for patients' age, weight, time to first feed, and all outcomes. An independent t test was used to compare the demographic data between the two study groups to examine for group differences. Statistical analysis was conducted using SPSS Version 26 software (SPSS Inc., Chicago, IL). Level of statistical significance for all statistical tests was set at $p < .05$.

RESULTS

In total, 33 infants participated in this study: 20 were randomized to receive clear liquids as their first feeding, and 13 were randomized to receive formula/milk (see Table 1). No ineligible patients were included in the study. Mean oral intake was imputed for one infant in the formula/milk group. There was no significant difference in age, weight, or time to first feed for clear-liquid- and formula-fed infants (Table 1).

There was a statistically significant difference in volume of feeding intake for infants in the clear liquid group (M = 141 ml, SD = 96) and infants in the formula/milk group (M = 221 ml, SD = 78; $t(31) = 2.515$, $p = .017$; see Table 2). The magnitude of the difference in the means (mean difference = 80.5 ml, 95% CI [15, 146]) was small (eta squared = .032). A post hoc power analysis indicates that there was 44% power to detect a difference in volume of feeding intake at a 5% level with this sample size.

At the time of the initial (prefeeding) assessment, there was no significant difference in the initial FLACC scores ($U = 130$, $z = 0.00$, $p = 1$, $r = 0$), and there was no significant interaction between the type of initial feeding and the time of first FLACC score (Wilks' lambda = .998, $F(2, 30) = 0.25$, $p = .976$, partial eta squared = .002). There was, however, a substantial main effect for time (Wilks' lambda = .684, $F(2, 30) = 6.925$, $p < .001$, partial eta squared = .316), with both groups showing a reduction in FLACC scores across all three time points (prefeeding, 15 and 30 minutes after the first feed). The main effect comparing the two types of initial feedings was not significant ($F(1, 31) = 0.053$, $p = .820$, partial eta squared = .002), suggesting no difference in pain by type of initial feeding. No FLACC data were missing for prefeeding and 15-minute time points, but FLACC scores of the mode of 0 were

Table 1: Summary of Patient Age, Weight, and Time to First Feed

	Formula (n = 13) Mean (SD)	Clear Liquid (n = 20) Mean (SD)	Mean Difference (95% CI)	p Value
Age in months	9.75 (1.0215)	10.4 (1.095)	0.65 (−0.2, 1.5)	.13
Weight in kilograms	9.18 (1.078)	9.46 (1.045)	0.258 (−0.53, 1.05)	.51
Time to first feed in minutes	9.17 (5.86)	9.5 (6.6)	0.333 (−4.39, 5.06)	.89

imputed for three infants in the clear liquid group and one infant in the formula/milk group at the 30-minute time point. Post hoc power analysis indicates that, with this sample size, there was 7% power to detect a difference in FLACC pain scores at a 5% level.

At the time of the initial assessment before feeding, there was no significant difference in the initial PAED scores (U = 110, z = −0.742, p = .458, r = −.12). A mixed between- and within-subject analysis of variance was conducted to assess the variability of the initial feeding assignment on PAED scores across the three time points. There was no significant interaction between the type of initial feeding group and time (Wilks' lambda = .88, F(2, 30) = 2.02, p = .15, partial eta squared = .12); however, there was again a substantial main effect for time (Wilks' lambda = .46, F(2, 30) = 17.6, p < .001, partial eta squared = .54), with both groups showing a reduction in PAED scores across all three time points. The main effect comparing the two types of initial feeding groups was not significant (F(1, 31) = 0.006, p = .940, partial eta squared < .001), suggesting no difference in the impact of initial feeding on delirium. No PAED data were missing for prefeeding and 15-minute time points, but PAED scores of the mode of 0 were imputed for the same three infants in the clear liquid group and one infant in the formula/milk group at the 30-minute time point who were missing FLACC scores at this time point. A post hoc power analysis indicates there was only 2% power to detect a difference in PAED scores at a 5% level with this sample size.

There was no significant difference in secondary outcomes by groups. No episodes of postoperative emesis occurred in the PACU or were reported by parents during follow-up phone calls. Parents were very satisfied regardless of group, and a mode of 4 was imputed for parent satisfaction for two infants in the clear liquid group and one infant in the formula/milk group. Parent satisfaction rankings between the two groups were not significantly different (p = .068, U = 80.5).

DISCUSSION AND CONCLUSIONS

Infants randomized to the formula/milk group took in a larger volume of feedings in the PACU than infants in the clear liquid group (Table 2). This finding is consistent with previous research that showed that children who are allowed to eat liberally reach feeding goals quicker (Adibe et al., 2014; Radke et al., 2009). Incidentally, an infant in this study who refused to take formula within the 30-minute evaluation period tolerated a feeding of applesauce before leaving WOSC without vomiting. In fact, no infants in this RCT vomited. Thus, allowing infants to self-limit feeding after surgery may help them achieve satiation without increasing their risk of postoperative vomiting or aspiration (Adibe et al., 2014).

FLACC and PAED scores decreased for both groups at each of the three time points (prefeeding, 15 and 30

Table 2: Summary of Findings: Intake, Pain, Emergence Delirium, and Parent Satisfaction

Type of Intake	Formula	Clear Liquid	Total	p
n	13	20	33	
Intake, mean (SD; ml)	221 (78)	141 (96)	166 (101)	**.017***
Initial PAED scores, median (range)	11 (0–20)	8 (0–18)	10 (0–20)	.458
PAED scores (15 minutes), median (range)	0 (0–14)	2 (0–16)	1 (0–16)	.94
PAED scores (30 minutes), median (range)	0 (0–8)	0 (0–10)	0 (0–10)	
Initial FLACC scores, median (range)	4 (0–10)	4 (0–10)	4 (0–10)	1
FLACC scores (15 minutes), median (range)	0 (0–10)	0 (0–8)	0 (0–10)	.82
FLACC scores (30 minutes), median (range)	0 (0–6)	0 (0–6)	0 (0–6)	
Parent satisfaction, median (range)	4 (0–4)	3 (0–4)	4 (0–4)	.068

Note. PAED = Pediatric Anesthesia Emergence Delirium; FLACC = Faces, Legs, Activity, Cry, and Consolability.

*Statistically significant difference at <.05.

minutes after feeding). This is consistent with findings from previous studies that showed significant decreases in FLACC and PAED scores within 30 minutes of feeding (Adibe et al., 2014; Radke et al., 2009). Chauvin et al. (2017) extended these findings to show that infants given apple juice, a clear liquid (full liquids were not offered), postoperatively required less opioids. These studies may provide additional evidence of feeding analgesia (Foo & Mason, 2009; McVinnie, 2013).

As opposed to pain or emergence delirium, the behaviors shown by infants in this and previous studies could also indicate postoperative hunger (Adibe et al., 2014; Chauvin et al., 2017; Radke et al., 2009). With emerging evidence that preoperative feeding can be provided safely at times closer to surgery than previously allowed (Sisman et al., 2020), future studies that assess the impact of hunger on behaviors now associated with postoperative pain and emergence delirium are needed. With the move to Enhanced Recovery After Surgery becoming more prevalent in pediatrics, allowing an infant to self-limit their intake volume, as well as return to a full-liquid diet, is supported by evidence. Even with infants having much more invasive procedures, allowing early ad libitum feeding has been associated with decreased lengths of stay (Roberts et al., 2020).

On the other hand, pain associated with placement of tympanostomy tubes may be short-lived. Moreover, all the infants in this study received a dose of ketorolac as a preemptive pain treatment. The decrease in pain scores may be directly related to a rapid decrease in postoperative pain, which would occur whether the infants had been fed or not. Use of sevoflurane, which is associated with a high rate of emergence delirium (Chandler et al., 2013), may have confounded the results. The reduction in PAED scores may be related to the rapid drop in sevoflurane levels once the anesthetic was discontinued.

Although FLACC and PAED scores decreased over the 30 minutes after the initial feeding for both groups, there was no statistically significant difference between the groups in pain or delirium. A FLACC score difference of 1 is considered clinically significant (Herr et al., 2019) and was used to calculate our sample size of 32 infants. However, a post hoc analysis conducted with actual infant FLACC scores indicated 150 infants per group were needed, and 178 infants per group were needed based on PAED scores. Given recommendations for breastmilk up to the first year of life, the enrollment of 300 formula- or milk-fed infants would require a multisite study.

Most parents scored a 4 for their satisfaction with postoperative feeding in both groups. However, using a one-question Likert scale asked on-site by a nurse caring for a patient is not a rigorous method for evaluating parent satisfaction. Future studies allowing parental choice and input into initial postoperative infant feeding may be a better gauge for determining parent satisfaction and for engaging parents in evidence-based care planning.

Study results support allowing full liquids for initial feedings of infants 12 months old or younger. However, sample size and study procedures limit the generalizability of study conclusions and practice recommendations. Additional RCTs are needed to provide evidence-based guidance for postoperative feeding of infants after outpatient surgeries.

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