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DISEASES OF THE ESOPHAGUS

Original article

Comparison of the effect of a cornstarch thickened formula and strengthened regular formula on regurgitation, gastric emptying and weight gain in infantile regurgitation

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SUMMARY. **The purpose of this study was to evaluate the efficacy of a specially selected cornstarch-supplemented formula on clinical symptoms, gastric emptying and weight gain in infants with regurgitation. We performed a prospective randomised trial evaluating the therapeutic efficacy of two different formula feedings (cornstarch-thickened formula, group A; 25% strengthened formula, group B) in 81 young infants with regurgitation/vomiting ≥ 3 times/day. A Tc-99 m milk scintigraphy was performed at inclusion and after 2 months to quantify gastric emptying time; all studied infants underwent a 2-month period of clinical follow-up evaluating regurgitation and body weight gain. At inclusion, group A and B had a similar age and weight. After the 2-month period of intervention, regurgitation and vomiting had both greater decrease (both $P < 0.001$ at 1 and 2 months) in group A (from a score of 4.19 ± 1.71 to 0.93 ± 0.42) than in group B (from a score of 4.15 ± 1.68 to 2.89 ± 1.16). Non-regurgitation symptoms (irritability, cough, choking, night-waking) decreased ($P = 0.045$ at 1 month and 0.017 at 2 months) in group A (from a score of 18 at baseline to 3 after 8 weeks) as compared to group B (from a score of 18 at baseline to 11 after 8 weeks). Weight increased more in group A (29.1 ± 3.9 g/day over 8 weeks) versus group B (23.6 ± 3.5 g/day over 8 weeks) ($P < 0.01$ at 1 and 2 months) Gastric emptying improved significantly in group A as compared with group B (all $P < 0.001$ for T1/2, and residual volume at 60 and 90 min). Ingested feeding volume was significantly larger in the group receiving cornstarch-thickened formula, both at 4 weeks (109.4 ± 24.5 *vs.* 98.5 ± 23.6 mL/meal) (P: 0.042) and at 8 weeks (137.6 ± 27.9 *vs.* 115.7 ± 26.5 mL/meal) ($P < 0.001$). Cornstarch-thickened formula feeding decreases the frequency of regurgitation/vomiting, provides better body weight gain and has an accelerated gastric emptying in comparison to a 25% strengthened regular formula in infants with regurgitation.**

KEY WORDS: **anti-regurgitation formula, cornstarch thickened formula, infant formula, regurgitation.**

INTRODUCTION

The involuntary passage of ingested material from the stomach into the esophagus, gastro-esophageal reflux (GER), is a common event in infants. GER disease (GERD) can arise when the refluxed material causes esophagitis,[1–5] resulting in pain, impaired esophageal function, or poor growth. Other symptoms associated with GERD include aspiration, wheezing, stridor, asthma and apnea.[6–11]

Dietary management has been recommended in infants with frequent regurgitation by the European Society of Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).[9] We performed a prospective randomised study to evaluate the effect of a cornstarch-thickened formula (Novalac AR) or 25% strengthened formula in the treatment of regurgitation and vomiting in infants, and evaluated weight gain and gastric emptying in both groups after an intervention period of 2 months.

MATERIALS AND METHODS

During a 2-year period (July 2002–July 2004), we prospectively compared the clinical effect on regurgitation, vomiting and weight gain between a cornstarch-thickened AR-formula (Novalac AR®,

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Table 1 Major composition of AR-formula and regular formula (per 100 mL)

Average composition	Novalac AR-formula	Regular formula
Energy (calories/100 mL)	64.5	65
Protein	1.7 g	1.6 g
Protein source	Whey: casein 20 : 80	Whey: casein 60 : 40
Fat	3.1 g	3.3 g
Carbohydrate	7.4 g	7.2 g
Carbohydrate source	Lactose 70% Amylopectin 30%	Lactose 90% Glucose polymers 10%
Osmolarity (mOsm/L)	240	245

Table 2 Comparison of demographic data and clinical characteristics between group A and B infants

Variables	Group A ($n = 41$)	Group B ($n = 40$)	P-value
Age (days)	90.2 ± 26.9	90.5 ± 27.4	0.960
Sex (M/F) (No. of patients)	21/20	21/19	0.827
Frequency of regurgitation/vomiting	4.19 ± 1.71	4.15 ± 1.68	0.915
Non-regurgitation symptoms	18	18	1.000
Irritability	12	13	
Cough	5	4	
Choking	3	3	
Crying awake	4	5	
Body weight (grams)	5423.4 ± 845.7	5466.1 ± 857.3	0.822

P-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Continuous data are analyzed by Student's t-tests. Categorical data are analyzed by Chi-square tests.

Paris, France) and a 25% strengthened regular infant formula (Novalac 1®, Paris, France) in non-breastfed infants (age 2–4 months) presenting with frequent regurgitation/vomiting (≥ 3 times/day) during a 2-month intervention period. In order to obtain a 25% strengthened formula, five measurements of formula are added to 120 mL of water instead of the recommended four. Randomization was performed according to an envelope-drawing system. Mechanical obstruction such as infantile hypertrophic pyloric stenosis and malrotation were excluded with an upper gastrointestinal barium study before inclusion. Infants with atopic symptoms such as eczema, watery rhinorrhea or diarrhea suspecting cow's milk allergy were excluded. All patients were randomly assigned to one of two groups: group A received a cornstarch-thickened AR formula, group B received 25% strengthened regular formula. The cornstarch-thickened AR formula is a nutrionally balanced formula with increased viscosity (Table 1: composition of both formulas), thickened with a specially selected cornstarch. Infants were fed ad libitum, and parents recorded the ingested volume. It has been a tradition in Taiwan for many years to strengthen infant formula to treat infant regurgitation. Parameters that were followed are: mean frequency of episodes of regurgitation and/or vomiting, mean feeding volume tolerated during the 3 days prior to a visit, and weight gain. All the parameters were recorded by the family in a diary.

A 90-min milk scintigraphy with 500 μCI technecium was used to quantify gastric emptying. A second milk scintigraphy was performed in each infant at the end of the 2-month intervention period. At baseline, the infants were given a regular infant formula ad libitum. The second scintigraphy was preformed with the intervention formula ad libitum: cornstarch-thickened formula or 25% strengthened infant formula. Parents recorded clinical parameters including baseline ingested volume (per meal), baseline meal times (per day), baseline weight increment, frequency of regurgitation or vomiting, associated symptoms (irritability, cough, choking, crying) and weight gain. The ingested volume per meal feeding was calculated as an average data 1 week before entering into the study. The baseline weight increment per day was calculated as an average data 1 month before entering into the study.

The differences in regugitation, vomiting, GER-associated symptoms, tolerated feeding volume, gastric emptying and body weight increase between both groups were statistically analyzed using the two-paired Student t-test, Wilcoxon signed rank test, and Chi-square test. A P-value of 0.05 or less was accepted as statistically significant.

RESULTS

On a total of 100 included infants, 81 completed the 2-month clinical follow-up and were finally recruited into the study. Nineteen infants were excluded: eight developed marked diarrhea or enteritis, five experienced upper respiratory infection, and six did not have regular follow-up.

Demographic data and clinical characteristics at inclusion of the 81 infants are listed in Table 2.

Table 3 Comparison of R/V, associated non-regurgitation symptoms and body weight gain after 1 month intervention between group A and B infants

	Group A		Group B		
Variables	Before	After	Before	After	*P*-value
Frequency of R/V	4.19 ± 1.71	1.90 ± 0.72	4.15 ± 1.68	3.15 ± 0.93	< 0.001
Non-regurgitation symptoms	18	6	18	13	0.045
Irritability	12	4	13	10	
Cough	5	2	4	3	
Choking	3	1	3	3	
Crying awake	4	1	5	4	

R/V: regurgitation/vomiting. *P*-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Change of frequency of R/V were analyzed by Wilcoxon signed rank tests. Change of non-regurgitation symptoms were analyzed by Chi-square tests.

Table 4 Comparison of regurgitation/vomiting, associated non-GI symptoms and body weight gain after 8-week trial between group A and B infants

	Group A		Group B		
Variables	Before trial	After trial	Before trial	After trial	*P*-value
Frequency of R/V	4.19 ± 1.71	0.93 ± 0.42	4.15 ± 1.68	2.89 ± 1.16	< 0.001
Non-regurgitation symptoms	18	3	18	11	0.017
Irritability	12	1	13	8	
Cough	5	0	4	2	
Choking	3	0	3	1	
Night awake	4	1	5	2	

R/V: regurgitation/vomiting. *P*-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Change of frequency of R/V were analyzed by Wilcoxon signed rank tests. Change of non-regurgitation symptoms were analyzed by Chi-square tests.

Both groups were comparable at inclusion. Table 3 shows a reduced frequency of regurgitation and vomiting after 1-month intervention in group A as compared to group B; clinical symptoms, tolerated volume of feeding and weight were significantly better. After the first month of intervention, the regurgitation/vomiting episodes decreased significantly in group A (AR formula) but in group B (strengthened formula) there was no significant decrease (Table 3). Concomitant non-regurgitation symptoms (irritability, cough, choking, crying at night) decreased in group A whereas in group B only a non-significant trend was observed (Table 3).

Table 4 compares clinical data and body weight gain obtained after 2 months of intervention. Group A showed statistically significant improvements of clinical symptoms, tolerated amount of feeding and weight gain grouping in comparison to group B.

Table 5 compared gastric emptying time between group A and group B infants. T1/2 gastric emptying time, residual radioactivity at 60 min, residual radioactivity at 90 min evaluated with milk scintigraphy, was similar at baseline ($P = 0.873$, 0.966, and 0.922, respectively). After 2 months of intervention, T1/2 gastric emptying time in group A had decreased to 82.1 ± 13.2 min ($P < 0.001$) and to 98.8 ± 15.6 min in group B ($P = 0.397$). Significant differences of residual radioactivity at 60 and 90 min after feeding intervention were found in group A infants (both $P < 0.001$), but no statistical significance was found in group B ($P = 0.070$, 0.116). As shown in Table 5, after 2 months of intervention, the difference in T1/2 gastric emptying time, residual radioactivity at 60 and 90 min between groups A and B had become significant ($P < 0.001$, $P < 0.017$, $P < 0.001$, respectively, Student's *t*-test).

Table 5 Comparison of gastric emptying between group A and B infants (before and after trial)

Parameters	Group A	Group B	*P*-value
Tc-99 m gastric scintigrophy			
T1/2 gastric emptying (min)			
Baseline	102.5 ± 17.1	101.9 ± 16.9	0.873
After	82.1 ± 13.2	98.8 ± 15.6	< 0.001
Residual radioactivity (%)			
60 min			
Baseline	60.8 ± 10.9	60.7 ± 10.5	0.966
After trial	52.4 ± 8.1	56.8 ± 8.4	0.017
90 min			
Baseline	52.3 ± 9.3	52.5 ± 9.2	0.922
After trial	42.9 ± 7.3	49.3 ± 8.8	< 0.001

P-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Continuous data are analyzed by Student's *t*-tests.

Table 6 compares the body weight gain. The mean weight increment per day before entering into the study was similar in both groups (group A:

Table 6 Weight gain after 2 weeks, 1 and 2 months

Variables	Group A Total (daily)	Group B Total (daily)	*P*-value
Baseline weight (g)	5423.4 ± 845.7	5466.1 ± 857.3	0.822
Weight gain (g)			
2 weeks	353.2 ± 53.3 (25.3 ± 3.8)	334.1 ± 51.5 (23.9 ± 3.7)	0.101
1 month	782.9 ± 109.2 (28.0 ± 3.9)	641.9 ± 89.6 (22.9 ± 3.2)	< 0.001*
2 month	1629.5 ± 215.8 (29.1 ± 3.9)	1321.7 ± 193.7 (23.6 ± 3.5)	< 0.001*

P-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Continuous data are analyzed by Student's *t*-tests.

Table 7 Ingested volume (mean per feeding) at baseline, after 4 and 8 weeks of intervention

Ingested volume (mL per meal)	Ingested volume		*P*-value
	Group A	Group B	
Baseline	83.6 ± 22.3	84.1 ± 22.6	0.919
4 weeks	109.4 ± 24.5	98.5 ± 23.6	0.042
8 weeks	137.6 ± 27.9	115.7 ± 26.5	< 0.001

**P*-value < 0.05 as considered statistically significant. Data of continuous variables and expressed as mean ± SD. Continuous data are analyzed by Student's *t*-tests.

18.5 ± 6.8 g/day; group B: 18.7 ± 6.9 g/day, $P = 0.895$) (the weight increment per day was calculated as an average data 1 month before entering into the study). The body weight increased 782.9 ± 109.2 g (28.0 ± 3.9 g/day) in group A, and 641.9 ± 89.6 g (22.9 ± 3.2 g/day) in group B after 1 month's intervention ($P < 0.001$, Student's *t*-test) and 1629.5 ± 215.8 g (29.1 ± 3.9 g/day) versus 1321.7 ± 193.7 g (23.6 ± 3.5 g/day) after 2 month's intervention ($P < 0.001$, Student's *t*-test).

Table 7 compares volume of each feeding after 8 week's intervention. The ingested formula by the volume per feed before entering into the study was 50–120 mL (mean: 83.7 ± 22.3) for 6–8 feedings (6.5 ± 1.1). Mean ingested volume in group A and group B was similar (group A: 83.6 ± 22.3 mL, group B: 84.1 ± 22.4 mL, $P = 0.919$) (the ingested volume per meal was calculated as an average data 1 week before entering into the study). The volume of each feeding increased dramatically after 4 weeks and 8 weeks in the infants receiving cornstarch formula. Although there was no difference in ingested volume at baseline between both groups, after 4-week and 8-week intervention the volume ingested in the thickened-formula group was much larger ($P = 0.042$ [4-week], $P = 0.001$ [8-week], Student's *t*-test).

DISCUSSION

Parental reassurance and dietary management avoiding overfeeding and feeding thickened formula are expected to be the important components of managing infants with excessive regurgitation. Anti-regurgitation formulae are available in many European countries.

Thickening agents, such as rice cereal, gelatin and various polysaccharides, carob bean gum or galactomannan, have been successfully administered for the treatment of regurgitation in infants.[12] Adding rice starch to formula may provide additional buffering of acid, which may alleviate irritability. Moreover, rice cereals have an excellent digestibility in infants as young as 1–3 months.[13,14] Theoretically, increase of the energy density in this manner may be an appropriate strategy for infants who fail to thrive because of inadequate intake of excessive loss because of regurgitation. However, Fornon *et al*. reported that young infants tend to self-regulate their intake.[15]

Although thickening of formula is widely recommended, there is no consistency in the data about its efficacy in alleviating GER. The effect of thickened feeding on GER documented by milk scintigraphy, 24-h esophageal pH monitoring or impedancemetry is still controversial. Orenstein *et al*. indicated thickened formulas were associated with significantly more coughing, which led to the hypothesis that thickened formulas may worsen non-regurgitant reflux.[16] A controlled trial that evaluated the use of formula thickened with 4% rice starch in infants with GER showed decreased regurgitation and crying and increased sleeping time, even though the number of reflux episodes documented by scintigraphy did not decrease.[17] Vandenplas *et al*. previously reported that milk thickened with carob bean gum decreased the number of acid reflux episodes, but the total duration of acid exposure remained unchanged, presumably because of slower clearance of the thickened acid refluxate from the esophagus.[19] However, a recent multicentre trial found a casein-dominant formula thickened with a specifically treated cornstarch to reduce esophageal acid exposure, and to reduce clinical symptoms.[20] Our data confirm a reduction in the frequency of regurgitation and vomiting with the same formula (Novalac AR). Moreover, 25% strengthening of the formula, a traditional approach in Taiwan, did not seem to decrease regurgitation. The effet of cornstarch seems to be at two levels. At the one side, there is the thickening effect resulting in reduction of clinically

visible regurgitation and vomiting. On the other side, there seems to be an effect on GER itself, possibly related to an enhanced gastric emptying. This hypothesis needs further evaluation. The effect on non-regurgitation GER may explain why extra-esophageal symptoms such as cough and crying decreased significantly with the cornstarch feeding.

The pathogenesis of regurgitation and GER is not fully understood. The role of gastric emptying in patients with symptomatic reflux remains controversial. There have been reports suggesting that delayed gastric emptying may contribute towards perpetuating GER for longer periods of time after feeding.[11,21] Gastric distension has been shown to increase the frequency of transient inappropriate lower esophageal sphincter relaxations, presumably through neural pathways involving mechanical receptors in the stomach wall.[22] With prolonged gastric emptying, material available for reflux lingers in the stomach.[12] Therefore, it is useful to evaluate gastric emptying in regurgitating infants. Milk scintigraphy is considered to be a simple and reliable tool in evaluating gastric emptying in children.[12] Advantages of this test are that it is non-invasive and exposes the patient to minimal amounts of radiation. Shay and associates demonstrated that scintigraphy identified 61% of postprandial reflux events as opposed to 16% for pH monitoring.[23] There was a non-significant small trend towards more rapid gastric emptying in the group receiving the 25% strengthened formula. This trend could be age-related since there is a difference of 8 weeks between baseline and control. However, improvement of gastric emptying was significant in the group receving the cornstarch-thickened formula. Our data show gastric emptying of a 25% strengthened formula is significantly slower that a cornstarch-thickened casein-predominant formula, suggesting the role of osmolarity in gastric emptying.

There are only very limited nutritional data on antiregurgitation formula. A benefit of thickened formula in infants who spit up frequently is that as a consequence of the decreased regurgitation the losses of nutrients decrease, which can be advantageous for infants who fail to thrive in this situation.[18–20] Studies of various thickening agents, including guar gum, carob bean gum, and soybean polysaccharides, indicate the potential for: decreased intestinal absorption of carbohydrates, fats, calcium, iron, zinc, and copper; alterations in metabolic utilization of dietary substrates; and alterations of mucosal and endocrine responses.[24] However, no conclusive information is available on the potential effects of thickening agents on the bioavailability of dietary nutrients and growth in infants.[25] Our data showed a satisfactory weight gain, increasing significantly better in the thickened formula than in the strengthened formula group. This improved weight gain correlates with an increased mean ingested volume, which is in line with the accelerated gastric emptying.

Previous experiences indicated thickened formula might have a delayed gastric emptying and gastrointestinal transit. Galactomannan (a water-soluble fiber) increases the formula's viscosity to trap the milk in the stomach and prevent it from rising into the esophagus, possibly also delaying gastric emptying.[26–28] Our data showed that delay of gastric emptying was not found in infants consuming 25% strengthened regular formula, but it appeared significantly shortened in infants consuming cornstarch-thickened formula.

In conclusion, this study indicates that the addition of cornstarch to a standard formula significantly reduces regurgitation and promotes gastric emptying in infants with regurgitation. Besides, the cornstarch-supplemented formula tested induces a better body weight gain than 25% strengthened regular formula. Further studies are required to evaluate the nutritional effects of the prolonged administration of thickened formula.

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