A Rice Starch Added Follow-On Formula for Infants with Sleeping Difficulty†

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Abstract

A total of 15 infants aged between 4-12 months with sleeping difficulty were enrolled in the study. All participants were given a test follow-on formula (cow's milk based), with added rice starch. The test formula was advised to be given at night-time for a 7-day period. Sleeping patterns were recorded 2 days prior to the study and during the 7-day study period. It was shown than 11 out of 15 cases (73.3%) had satisfactory results. Two cases (13.3%) were withdrawn from the study by their parents due to vomiting after taking the formula. We found that both cases developed concomitant respiratory tract infection one day after starting the study, and 2 cases (13.3%) were lost to follow-up. In conclusion, the majority of cases showed satisfactory results in terms of night sleeping pattern after switching to the rice starch added follow - on formula.

Key word : Rice Starch, Formula, Sleeping Difficulty

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Problems of crying, colic and spitting are commonly found in young infants aged between 2-6 weeks. It is claimed that colic may be due to cow milk protein allergy[1-3]. Lucas et al[4] related persistent crying or colic to the pattern of feeding. They found that infants who were breast fed cried more than those who were formula fed. It is rare that these symptoms continue into older infants. However, parents of certain older infants complain that their children have sleeping difficulty or frequent awakening. Until now no literature has mentioned this condition in either the context of cause

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or method of management. Generally, pediatricians advise parents to feed more supplementary foods to their infants before bedtime.

Today it is recommended to exclusively breast-feed or give infant formula until the infant is approximately 6 months. However, from around 4 months of age, and sometimes even earlier, infants fed only milk (breast-milk or infant formula) have a tendency to wake up shortly after the last night feed. It is our hypotheses that the infant may wake up because of hunger. We, therefore, propose that a rice-starch added follow-on milk formula, which is close to cereal diets of infants in terms of contents of major nutrients, consumed before bedtime, may have beneficial effects on the sleeping pattern of these infants.

MATERIAL AND METHOD

The subjects were infants aged between 4-12 months who were not breast fed and whose parents complained that their babies had either symptoms of difficulty in falling asleep, irritability or frequent awakening during the night. During daytime, these infants were perfectly normal.

Low birth-weight, premature babies, infants who had suffered from severe infectious or were suspected or proven to have inborn errors of metabolism were excluded from the study.

After informed consent was signed by the parents, the infants were recruited into the study. The study protocol was approved by the Committee on Human Rights Related to Research Involving Humans, Faculty of Medicine Siriraj Hospital, Mahidol University.

Participants were advised to administer the test formula as the last feed of the day for 7 days. While during daytime, infants still consumed their previous formula. Sleeping patterns of each infant were recorded from 2 days prior to the 7-day study period and during the 7-day study period. The test-formula was a follow-on formula in which 18.5 per cent of the lactose (of the ready-to-feed formula) had been substituted by rice-starch. Contents of the test formula are listed in Table 1.

RESULTS

From August 1998 to July 1999, a total of 15 infants fulfilling the inclusion criteria were

Table 1. Contents of the test formula.

Average Analysis		Per 1000 ml	Average Analysis		Per 1000 ml
			Folic Acid	mcg	114
Vegetable Fat	g	28.6	Pantothenic Acid	mg	4.3
Milk Protein	g	25.0	Biotin	mcg	36
Carbohydrates	g	80.5	Inositol	mg	64
Lactose	g	61.1	Vitamin B12	mcg	2.9
Rice-starch	g	19.3	Choline	mg	114
Minerals (Ash)	g	5.4	Vitamin C	mg	129
Moisture	g	3.6			
			Calcium	mg	930
Energy	kcal	679	Phosphorus	mg	629
	kJ	2841	Magnesium	mg	86
			Sodium	mg	286
Linoeic Acid	mg	4290	Potassium	mg	1108
Linolenic Acid	mg	429	Chloride	mg	669
Phospholipids	mg	501	Iron	mg	10
Taurine	mg	53	Zinc	mg	6.4
Cystine	mg	300	Copper	mcg	515
Beta-Carotene	mcg	429	Iodine	mcg	72
Vitamin E	I.U.	21	Manganese	mcg	222
Vitamin K1	mcg	100	Selenium	mcg	8.0
Vitamin B1	mcg	1001			
Vitamin B2	mcg	1716			
Niacin	mg	6.4			
Vitamin B6	mcg	858			

Table 2. Patients' characteristics.

No.	Sex	Age (month)	Frequency of Supplementary food/d	Problem
1.	M	10	1	short sleep duration
2.	M	7	2	short sleep duration
3.	F	7	3	short sleep duration
4.	M	7	-	short sleep duration
5.	M	12	3	short sleep duration
6.	M	10	3	short sleep duration
7.	M	7	3	short sleep duration
8.	F	8	2	short sleep duration
9.	F	5	4	short sleep duration
10.	M	8	2	irritability during sleeptime
11.	M	4	1	irritability before sleeping
12.	M	8	2	irritability before sleeping
13.	F	4	1	short sleep duration
14.	F	7	1	short sleep duration
15.	M	8	2	irritability during sleeptime

Table 3. Changes in sleep problem after taking the test formula.

No.	Problem	Change
1.	Short sleep duration	longer sleep duration
2.	Short sleep duration	longer sleep duration
3.	Short sleep duration	longer sleep duration
4.	Short sleep duration	longer sleep duration
5.	Short sleep duration	lost to follow-up
6.	Short sleep duration	withdrawn by parents due to vomiting
7.	Short sleep duration	withdrawn by parents due to vomiting
8.	Short sleep duration	longer sleep duration
9.	Short sleep duration	longer sleep duration
10.	Irritability during sleeptime	no irritability
11.	Irritability before sleeping	no irritability
12.	Irritability before sleeping	no irritability
13.	Short sleep duration	lost to follow-up
14.	Short sleep duration	longer sleep duration
15.	Irritability during sleeptime	no irritability

enrolled into the study. Two infants were lost to follow-up because the parents did not return (number 5 and 13) and 2 infants were withdrawn from the study by their parents due to vomiting after taking the test formula (number 6 and 7). We found that both cases had concomitant respiratory tract infection which developed one day after starting the study. The infection was judged not to be related to the formula. The rest of the infants (11 out of 15 cases) continued throughout the 7-day study period. Table 2 shows the infants' characteristics including sex, age and chief symptoms. Table 3 shows the sleep problem before the study and change of the problem at day 7 after taking the test formula. Eleven infants' sleep problem had improved. Fig. 1 depicts the percentage of satisfaction with the test formula reported by the parents.

DISCUSSION

Sleeping disorders defined as either difficulty in falling asleep or frequent awakening during the night are infrequently found in older infants aged between 4-12 months. All of the study infants had no history of infantile colic during their

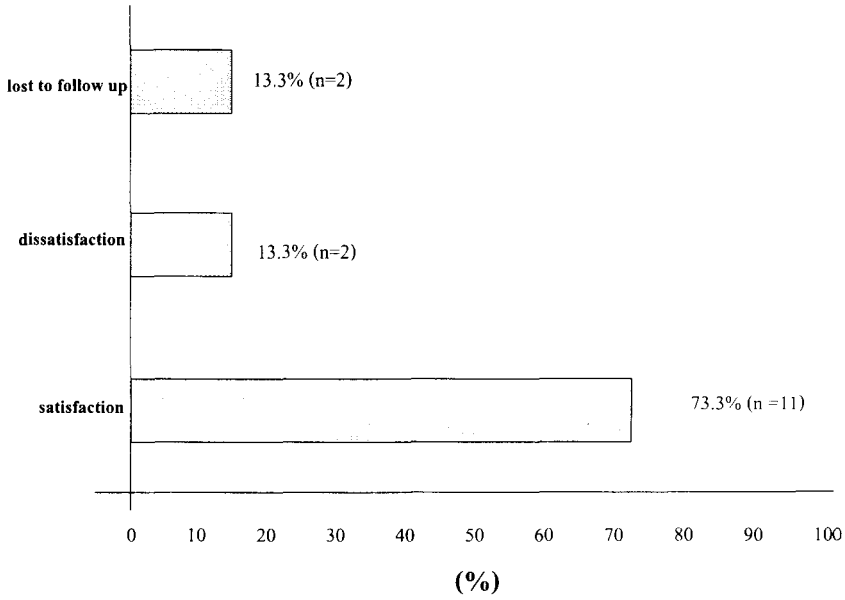

Fig. 1. Percentage of satisfaction with the formula.

early infancy periods. Many studies of nutritional modification for younger infants with colic have been published[5-7]. Fiber-enriched formula was not found to reduce crying and fussing in these infants[8]. There have been conflicting results of changing protein from cow milk protein to soy protein or casein hydrolysate[9,10]. However, most studies demonstrated favourable results[11].

The condition of this study's infants was totally different from infantile colic. The condition of frequent awakening during the night caused moderate distress to parents, but not as grave as that from infantile colic. In this study it was more common in male infants. Some infants had difficulty in falling asleep before bedtime, while some had difficulty in falling asleep again after awakening during the night. Most of the infants in the study group had frequent awakening ranging from 3 to 5 times each night.

Since this condition is commonly found in infants who are fed cow milk formula, the compositions of the formula per se may be the cause of this condition. Supplementary foods in addition to the milk formula recommended for infants after 4-6 months of age might make infants feel full and they fall deeply asleep. The formula in our study with rice starch added is close to the contents in weaning cereals. The study formula caused the fussy condition to subside in over 70 per cent of the study infants. Infants at these ages already have amylase released from the pancreas[12]. Then rice starch in the formula might be slowly digested and have a continuous supply of glucose to the infants while they are sleeping. This is probably the main reason why almost 75 per cent of our subjects responded to this formula.

Adding rice starch might raise concerns about interference of mineral absorption from the formula. Lifschitz, et al[13] recently showed that rice cereal added to the formula did not impair bioavailability of calcium and iron from infant formula. Regarding fiber in the cereal, Davidsson et al[14] clearly demonstrated that even fiber has no negative effect on the absorption of energy and nutrients in primarily formula-fed infants. From our study, there were 2 cases (13.3%) who were lost to follow-up and 2 cases (13.3%) who showed dissatisfaction with the formula. However, both of the latter had concomitant upper respiratory tract infection which developed one day after taking the formula. The frustration level of the whole family was reduced in the majority of cases who took the test formula. Moreover, infants who sleep longer when fed with this formula will experience improvement in motor and mental development.

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การศึกษาการใช้นมผงสูตรดัดแปลงที่เติมแป้งข้าวเจ้าสำหรับทารกที่มีปัญหาการหลับ

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การศึกษาทารกที่มีปัญหาการหลับจำนวน 15 ราย อายุระหว่าง 4–12 เดือน ด้วยการเปลี่ยนสูตรนมที่เคยรับประทานอยู่ในช่วงกลางคืนมาเป็นสูตรนมที่เติมแป้งข้าวเจ้า ทารกทั้งหมดที่เข้าร่วมการศึกษาครั้งนี้ จะมีปัญหาการหลับที่มักจะตื่นบ่อย นอนหลับแต่ละครั้งจะเป็นช่วงสั้น ๆ หรือ บางรายมีปัญหาในการเริ่มหลับนอนและบางรายมีปัญหาคือ เมื่อตื่นขึ้นมากลางดึกแล้วจะหลับนอนอีกยาก ผลการศึกษาพบว่าทารกจำนวน 11 ราย มีการหลับนอนที่ดีขึ้น โดยผู้ปกครองของทารกทั้ง 11 ราย (73.3%) พึงพอใจกับสูตรนมชนิดนี้ มีทารก 2 ราย (13.3%) ที่ผู้ปกครองขอถอนตัวทารกจากการศึกษาเนื่องจากทารกมีอาการอาเจียนหลังดื่มสูตรนมชนิดนี้แต่ผู้วิจัยพบว่าทารกทั้ง 2 รายนี้มีอาการไข้หวัด หลังเข้าร่วมศึกษา และมีทารก 2 ราย (13.3%) ที่ขาดการติดต่อ โดยสรุปแล้วการรักษาทารกที่มีปัญหาการหลับนอนด้วยการเปลี่ยนสูตรนมที่เติมแป้งข้าวเจ้าให้ผลการรักษาค่อนข้างดี ผู้ปกครองส่วนใหญ่พอใจกับสูตรนมชนิดนี้

คำสำคัญ : แป้งข้าวเจ้า, นมผงสำหรับทารก, นอนหลับยาก

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