Comparing Growth Rates after Hospital Discharge of Preterm Infants Fed with Either Post-Discharge Formula or High-Protein, Medium-Chain Triglyceride Containing Formula

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Objective: *To evaluate whether a high energy, high-protein, MCT-containing formula (HPMCT) is as appropriate as a post-discharge formula (PDF) for feeding preterm infants after hospital discharge by comparing growth, adverse effects, and cost per gram of bodyweight gain.*

Material and Method: *The present study was a randomized controlled trial. The calculated sample size was 20 infants for each intervention group. After the consent procedure, preterm infants who had postconceptional age (PCA) 35^{+1} to 36^{+0} weeks and weight between 1,800 and 3,000 g at hospital discharge were randomly enrolled to receive either PDF or HPMCT starting from the discharge day. Intervention period lasted at least 28 days and until the infant's weight was at least 3,000 g or PCA was at least 40^{+0} weeks. Body weight, length, and head circumference were measured on days 0, 14, 28, 56, and 84 after hospital discharge. Formula intakes and adverse symptoms (abdominal distension, diarrhea, and constipation) were recorded by parents before each visit in diaries provided by the study group. Cost was calculated from estimated actual formula intakes.*

Results: *There were six and five infants enrolled into PDF and HPMCT group, respectively. Demographic data were not different between the two groups. There were no significant differences of growth rates in both groups at days 28, 56, and 84 after hospital discharge. Adverse effects and costs were not different either.*

Conclusion: *PDF and HPMCT might be comparably appropriate for feeding catching-up preterm infants after hospital discharge, as noted from growth rates, adverse effects, and costs. However, further studies involving biochemical and neurodevelopmental evaluation, with long-term follow-up in larger populations are needed to clearly compare both formulas.*

Keywords: *Preterm infants, Infant nutrition, Preterm nutrition, Preterm feeding, Post-discharge formula*

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Preterm infants have specific medical problems and need special care. Nutrition is one of the most important concerns. As most of intrauterine growth occurs in the third trimester of pregnancy, preterm infants often have low birth weight. Giving extra nutrients promotes their growth and neurodevelopment[1,2]. Infants without serious co-morbidities can grow well with fortified human milk or preterm infant formula[1]. Both diets have higher amount of energy, protein, and micronutrients, compared to unfortified human milk or standard infant formula in the same volume. Infants are usually discharged from hospital at postconceptional age (PCA) of about 35 to 36 weeks or with body weight of about 1,800 to 2,100 g[3].

Feeding preterm infants after hospital discharge is different. Full fortification of human milk and conventional preterm formula are usually superfluous at this stage but some of the infants still have low body weight for their PCA that non-fortified human milk or standard infant formula may not be enough for them to catch up. Therefore, a special formula designed for preterm infants after hospital discharge (post-discharge formula [PDF]) was introduced. This formula is intermediate in composition between preterm formula and standard term infant formula. It has higher energy and protein than standard infant formula, and contains extra calcium, phosphorus, vitamins, and trace minerals to allow better growth[4]. Studies show that preterm infants fed with PDF have significantly greater weight and length gains, higher

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bone mineral content, and better neurodevelopment, than infants who consumed standard infant formula[4,5]. PDF has been marketed in Thailand for some time, yet its availability is limited due to logistics and economics reasons. As a result, some preterm infants are given after hospital discharge other special formulas that may not be designed specifically for these infants. Data on use of such formulas in post-discharge preterm infants have rarely been explored.

We wanted to test in the present study whether a special formula having high energy, high protein, and medium-chain triglyceride (MCT), designed for infants and children with growth failure, is as appropriate as PDF for feeding preterm infants after hospital discharge. Growth rates of infants consuming either PDF or the high-protein, MCT-containing formula (HPMCT) were compared. Adverse effects and costs of both formulas were also evaluated.

Material and Method

Study design

This was a prospective randomized controlled trial. The study was approved by the Royal Thai Army Medical Department Institutional Review Board before being conducted. All procedures and measures were done in accordance with the Helsinki Declaration. Funding was partly provided by Research Support Committee of Department of Pediatrics, Phramongkutklao Hospital, Bangkok, Thailand. Investigational products were supported by their corresponding marketing companies as stated.

Study population

Enrollment criteria included preterm infants who had been hospitalized at Department of Pediatrics, Phramongkutklao Hospital, Bangkok, Thailand, and had PCA 35^{+1} to 36^{+0} weeks and weight between 1,800 and 3,000 g at hospital discharge. Subjects had to be able to feed orally and were not consuming more than 25 percent of total milk intake as human milk. Infants with obvious congenital anomalies, known chromosomal abnormalities, gastro-intestinal problems that limited feeding, and cow milk protein allergy would be excluded. Infants who had received PDF or HPMCT for longer than one week before hospital discharge were also excluded.

We did in advance randomization in blocks of four using a computer software and kept group randomization in opaque, sealed envelopes on which a number of participation order was marked. Parents of subject candidates were approached and informed, by an investigator, of the objectives and details of the study prior to the hospital discharge. Their written consents were obtained before proceeding. Then, infants' demographic data would be recorded and the infants would be allocated to receive either PDF or HPMCT depending on randomization. Beyond this process, however, parents and investigators were not blinded as to which formula an infant would be consuming.

Investigational formulas

Investigational products were supported by their corresponding marketing companies: PDF, under the brand Similac Neosure®, was supported by Abbott Laboratories Company Limited, Thailand, and HPMCT, under the brand Pan-enteral®, was supported by Thai Otsuka Pharmaceutical Company Limited, Thailand. The companies had no involvement other than providing investigational products and had no influence on the results of the study. Both formulas had compositions in ranges of infant formula recommended by expert organizations or regulatory agencies[6,7]. Some selected ingredients of both formulas are shown in Table 1. Appropriate amount of formula estimated to supply adequately until the next study visit would be given to parents before discharge.

Feeding protocol

We suggested parents to feed their infants the designated formula in a volume equivalent to energy about 100 to 120 kcal per kg of body weight per day. The exact amount was adjusted by the investigators to accommodate estimated needs of each infant. Parents were also instructed how to properly prepare the formula until investigators were certain that they understood it well. We also gave a diary in which they would record the amount of formula intakes, other diets including human milk, medication received, and adverse symptoms (abdominal distension, diarrhea, and constipation). Infants would be fed with investigational formulas for at least 28 days or until their weight was at least 3,000 g or PCA was at least 40^{+0} weeks. No infants would be fed with investigational formulas after the third study visits, i.e., around day 56 after discharge. Afterwards, appropriate diets for each infant would be suggested to the parents. Other than the stated criteria, investigational formula would be stopped if the infant had serious adverse symptoms as assessed by investigators, or if parents requested to use another formula or to leave the study.

Table 1. Selected compositions of investigational formulas

Compositions	Post-discharge formula[a]	High-protein, medium-chain triglyceride containing formula[b]	FAO/WHO Codex ranges[c]
Energy per 1,000 mL (kcal)	744	667[d]	600-700
Lactose (g per 100 kcal)	5.2	0	N/A[e]
Protein (g per 100 kcal)	2.6	3.0	1.8-3.0
Lipid (g per 100 kcal)	5.5	5.0	4.4-6.0
Medium-chain triglyceride (g per 100 kcal)	1.5	2.5	N/A
Calcium (mg per 100 kcal)	105	86	50-140
Phosphorus (mg per 100 kcal)	62	43	25-100
Vitamin D (IU per 100 kcal)	70	59	40-100
Iron (mg per 100 kcal)	1.8	1.0	≥0.45
Zinc (mg per 100 kcal)	1.2	0.7	0.5-1.5

FAO = Food and Agriculture Organization of the United Nations; WHO = World Health Organization
[a] Under the brand Similac Neosure®
[b] Under the brand Pan-enteral®
[c] From reference number 7
[d] Can be prepared to 1,000 kcal per 1,000 mL at osmolarity of 270 mosmol/L
[e] Stated as total carbohydrates 9.0-14.0 g per 100 kcal from lactose or glucose polymers

Measurements, data collection, and follow-ups

Anthropometric measurements using standard methods including body weight, length, and head circumference were recorded for the first time on the discharge day. Study appointments were then made on approximately days 14, 28, 56, and 84 after hospital discharge. At first visit (day 14), investigators repeated anthropometric measurements, asked about the infant's health and formula intakes as well as adverse symptoms, checked the recorded diary, evaluated protocol compliance, did general child care procedures, estimated the appropriate amount of formula for the next period, gave further supply of formula if needed, and re-instructed parents how to prepare the formula. Actual formula intakes and compliance were assessed from the diary and returned unprepared formula, which was weighed in grams. Cost of formula used was calculated from total amount of formula given subtracted with returned formula then multiplied by average market cost at the time of study per unit of formula. Anthropometry done at this visit was used to estimate appropriate feeding for the next 14 days but was not used to calculate growth rates.

At subsequent visits, anthropometry and general childcare would still be done but steps involving investigational formula would be omitted, unless the infant had not reached the criteria to stop the formula. When the infant reached criteria to stop investigational formula, the product would be stopped and other appropriate diets would be recommended.

We also did telephone follow-ups at days 7, 21, 42, and 70 after hospital discharge, where we asked about diet intakes, adverse symptoms, and general health, and provided suggestions accordingly.

Statistical analysis

We calculated the sample size using G*power software version 3.0.5 by Franz Faul, Universtat Kiel, Germany. On assumption that desired weight gain rate was 200±50 g per week[3], in order to detect 25% of difference in weight gain rates with p-value ≤0.05 and power = 0.8, the calculated sample size would be 17 infants per group. Three infants were added to each group to compensate for possible follow-up losses, making up 20 subjects needed in each intervention group.

Weight, length, and head circumference gain rates at days 28, 56, and 84 after hospital discharge were primary outcomes. Percentages of adverse effects and cost of formula were secondary outcomes. Descriptive data were presented as mean, standard deviation (SD), median, interquartile range (IQR), or percentage. Median test was used to compare difference of numerical parameters. Chi-square or Fisher's exact test was used to compare dichotomous parameters.

Results

We were able to enroll during the approved study period only 11 preterm infants out of 40 required: 6 in PDF group and 5 in HPMCT group. Demographic data were not different between the groups and are shown in Table 2. Subjects were born at around 31st week of pregnancy with birthweight lower than 2,500 g. At enrollment, they were between 8 and 41 days of age. Co-morbidities and medications were not different either. Some of the infants were partially breastfed (less than 25 percent of total milk intake). None of them consumed other formulas or complementary foods.

Energy intakes suggested to both groups were comparable: medians of 110 kcal per kg of body weight per day for the PDF group and 100 kcal per kg of body weight per day for the HPMCT group during the first 14 days, and 120 kcal per kg of body weight per day for both groups during the next 14 days. Most infants, however, actually consumed significantly more than suggested: medians of 171 kcal per kg of body weight per day for the PDF group and 133 kcal per kg of body weight per day for the HPMCT group during the first 14 days, and 154 kcal per kg of body weight per day for the PDF group and 142 kcal per kg of body weight per day for the HPMCT group during the next 14 days. Nevertheless, actual energy intakes of both intervention groups were not different. Most infants stopped consuming investigational formulas at second visit (day 28 after discharge), except for two infants, one in each group, who continued the formula until day 35; at that point, they weighed more than 3,000 g.

Growth rates of infants consuming both formulas were not statistically different (Table 3), although PDF group seemed to gain weight and length better in the intervention period. Adverse symptoms were not reported in any subject.

Median costs of investigational formulas per gram of body weight gain in the first 28 days after discharge were not different, i.e., 1.69 Thai Baht per gram for PDF group and 1.06 Thai Baht per gram for HPMCT group (p-value = 0.242).

Discussion

The present study was aimed to answer the question: Are PDF and HPMCT equally appropriate for feeding preterm infants after hospital discharge? In order to answer it, we compared growth of preterm infants who were fed after discharge with either formula, and assessed the adverse effects of the formulas as well as their cost. Unfortunately, due to much smaller number of subjects than the calculated sample size, we could not clearly answer the question.

PDF has been proved to make post-discharge preterm infants grow better than unfortified human milk or standard infant formula[4,5,8] but its availability may be limited in some areas of our country. In our opinion, having options is always better than none. HPMCT is a local product that has been available in Thailand for longer than two decades. To our awareness, it is available only in Thailand and

Table 2. Characteristics data of study subjects

Characteristics	Post-discharge formula group (n = 6)	High-protein, medium-chain triglyceride containing formula group (n = 5)	p-value[a]
Male (percent)	83.3	60.0	0.545
Gestational age at birth (weeks)[b]	31.5 (30.6, 34.0)	31.0 (30.0, 32.5)	1.000
Birthweight (g)[b]	1,828.0 (1,538.5, 2,139.5)	1,550.0 (1,381.0, 1,965.0)	1.000
APGAR at 5-minute[b]	9.0 (8.0, 9.0)	9.0 (7.5, 9.0)	1.000
Age at hospital discharge (days)[b]	26.0 (10.3, 35.0)	21.0 (13.0, 32.5)	1.000
Co-morbidities (percent)			
Anemia	33.3	40.0	1.000
G-6-PD deficiency	16.7	20.0	1.000
Transient tachypnea of the newborn	50.0	60.0	1.000
Apnea in prematurity	33.3	20.0	1.000
Neonatal jaundice	83.3	60.0	0.545
Osteopenia of prematurity	0	20.0	0.455
Partially breastfed (percent)	33.3	20.0	1.000

G-6-PD = glucose-6-phosphatase dehydrogenase

[a] Difference tested with Fisher's exact test or median test as appropriate

[b] Shown as median (25th percentile, 75th percentile)

Table 3. Growth rates of study subjects

Growth rates	Post-discharge formula group (n = 6)	High-protein, medium-chain triglyceride containing formula group (n = 5)	*p*-value[a]
Weight gain rates since the day of discharge (g per week)[b]			
At day 28 after discharge	257.9 (216.5, 298.9)	226.5 (207.3, 319.8)	1.000
At day 56 after discharge	249.0 (207.3, 287.4)	306.3 (225.4, 314.0)	0.567
At day 84 after discharge	236.8 (194.4, 268.7)	258.3 (233.6, 316.3)	0.567
Length gain rates since the day of discharge (cm per four weeks)[b]			
At day 28 after discharge	4.4 (2.6, 5.8)	3.5 (2.0, 7.0)	1.000
At day 56 after discharge	3.8 (3.4, 4.5)	4.5 (2.9, 5.8)	0.567
At day 84 after discharge	3.5 (3.3, 4.2)	4.5 (3.1, 5.1)	0.567
Head circumference gain rates since the day of discharge (cm per four weeks)[b]			
At day 28 after discharge	3.3 (2.8, 4.0)	3.0 (3.0, 4.1)	1.000
At day 56 after discharge	2.6 (2.2, 3.1)	2.5 (2.5, 3.1)	1.000
At day 84 after discharge	2.3 (1.9, 2.7)	2.3 (2.3, 2.8)	1.000

[a] Difference tested with median test
[b] Shown as median (25^{th} percentile, 75^{th} percentile)

neighboring countries. It was originally designed for infants and children who have poor growth and nutrient malabsorption, not specifically for catching-up preterm infants. Theoretically, PDF and HPMCT should provide adequate nutrients to post-discharge preterm infants and support their growth equally well. As shown in Table 1, compositions of both formulas are similar and mostly in ranges recommended for infant formula. Catching-up preterm infants need high energy. Both formulas can be prepared to give higher energy density without adverse effects, particularly too high osmolarity, which may induce feeding intolerance. Catching-up preterm infants also need high protein[9-11]. Both formulas have higher protein contents than that of standard infant formula. The protein content of HPMCT is slightly higher than that of PDF but it is not beyond the upper limit for infant formula. Some may be concerned by the potential renal solute load (PRSL) of high-protein diets and its possible drawbacks on infants' kidneys and brain[12-14]. According to our calculation, PRSL of PDF is about 24.0 mosmol per 100 kcal and that of HPMCT is about 25.6 mosmol per 100 kcal; both are lower than previously recommended PRSL for infant formula of 33.0 mosmol per 100 kcal[15]. MCT is easily digested and absorbed than long-chain triglyceride[16,17], and is beneficial to growing preterm infants whose fat digestion and absorption may still be suboptimum. It also promotes growth of preterm infants[18]. Both PDF and HPMCT contain MCT as a fraction of their lipids.

A noticeable difference between both formulas is lactose content. HPMCT contains no lactose whereas PDF contains lower lactose than standard infant formula. Some growing preterm infants have poor lactase activity and may require low-lactose or even no-lactose formulas[19,20]. Another difference is calcium content, which is 22% higher in PDF than in HPMCT. To promote bone growth, preterm infants need higher calcium than term infants. The precise levels of calcium needed for post-discharge preterm infants, however, have not been established[21]. HPMCT contains 86 mg per 100 kcal of calcium, which is higher than most standard infant formula, so we believe that it should provide enough calcium for most post-discharge premature infants.

Ideally, catching-up preterm infants should gain body weight at rates about 200±50 g per week, especially in first weeks of post-discharge[22]. As shown in Table 3, all subjects had body weight gain up to day 84 after hospital discharge equal to or beyond that. Thus, it is safe to conclude that both PDF and HPMCT could promote desirable post-discharge growth for preterm infants, albeit in a small sample size. We did not find difference in growth rates of infants fed with both formulas. One possible explanation could be that subjects in both groups had comparable energy intakes from investigational formulas, mostly within 28 days after discharge. After that period, i.e., after day 28 until day 84, however, nutritional effects of investigational formulas must be less obvious as most of the infants had stopped investigational formulas and were fed on other appropriate diets as per investigators' suggestions. Nevertheless, inadequate power to differentiate must be taken into account, as we wanted at least 17 infants

in each intervention group but we could enroll only 11 infants altogether. Post-hoc calculated power is only 0.31, which is lower than acceptable.

Despite statistical similarity in growth rates, subjects in PDF group seemed to have better growth rates in the 28-day period after discharge but slow down after that (Table 3). The finding was corresponding with slightly higher energy intakes of the PDF group during intervention period, albeit not statistically significant. On the other hand, better growth afterwards of HPMCT group may or may not be a result of HPMCT per se, because most subjects were fed with other diets after 28 days as mentioned earlier. We unfortunately did not record subjects' diets after intervention period, so a solid explanation could not be made. Again, lack of power makes explanation even more difficult.

Adverse effects and cost of formula are important in selecting diets for infants too. No adverse symptoms (abdominal distension, diarrhea, and constipation) were reported in both groups. This may also be a result of the small sample size. MCT has been known to cause gastro-intestinal adverse effects although the effects are less pronounced when it is consumed as a part of diets[16,23]. Both investigational formulas contain MCT, with higher amount of MCT in HPMCT than in PDF. According to our review, there were no particular adverse effects specifically related to either formula. As for cost, PDF seemed to cost about 60 percent higher than HPMCT per gram of body weight gain but the difference was not statistically significant. Due to inadequate power, we could only speculate that HPMCT might be a less expensive alternative to PDF.

Besides the limitation of small sample size, we did not include biochemical studies; e.g., serum electrolytes, calcium, phosphorus and alkaline phosphatase, blood urea nitrogen, and albumin. This prevented us from detecting any subclinical metabolic changes, which might be adverse effects of the formulas. For example, osteopenia of prematurity hardly has symptoms; it is mostly diagnosed with abnormal levels of calcium, phosphorus, and alkaline phosphatase, with or without imaging studies[24,25]. We did not test, apart from physical growth, neurodevelopment either. Evidences suggest that infants fed with PDF have better neurodevelopment than those fed with standard infant formula[26].

Being aware of limitations of the present study, we suggest that further studies with long-term follow-up in larger population should be done in order to compare both formulas. We also suggest doing biochemical studies and neurodevelopmental evaluation. In the meantime, however, we think HPMCT is an appropriate and less expensive alternative to PDF in case that PDF is not available.

In conclusion, PDF and HPMCT might be comparably appropriate for feeding catching-up preterm infants after hospital discharge with no detectable difference in growth rates of infants fed with either formula. Although generalization should not be made due to many limitations of this study, the findings may serve as preliminary data for future studies regarding this topic.

What is already known on this topic?

Non-fortified human milk or standard infant formula are inadequate to provide nutrients for growth and development of preterm infants after hospital discharge, whereas fully fortified human milk or preterm formula may have excessive nutrients beyond their needs. PDF provides appropriate nutrients for these infants and has been proved to promote better growth and neurodevelopment than non-fortified human milk or standard infant formula. Its availability, however, is limited and optional diets may be required.

What this study adds?

HPMCT, when compared to PDF, provided similar growth to post-discharge preterm infants without detectable adverse effects and might be considered as an option for feeding these infants.

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Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบอัตราการเติบโตหลังจำหน่ายกลับบ้านของทารกเกิดก่อนกำหนดที่เลี้ยงด้วยอาหารทางการแพทย์ชนิด post-discharge formula กับอาหารทางการแพทย์ที่มีโปรตีนสูงและมีไขมันสายยาวปานกลาง

ชนิกานต์ เอกเจริญ, เรืองวิทย์ ตันติแพทยางกูร

วัตถุประสงค์: *เพื่อศึกษาว่าอาหารทางการแพทย์ที่มีโปรตีนสูงและมีไขมันสายยาวปานกลาง (HPMCT) เหมาะที่จะใช้เป็นอาหารเลี้ยงทารกเกิดก่อนกำหนดหลังกลับบ้านเหมือนกับอาหารทางการแพทย์ชนิด post-discharge formula (PDF) หรือไม่ โดยเปรียบเทียบอัตราการเติบโต ผลข้างเคียง และราคา*

วัสดุและวิธีการ: *การศึกษานี้เป็น randomized controlled trial ขนาดกลุ่มตัวอย่างที่คำนวณได้คือ 20 คน ในกลุ่มศึกษาแต่ละกลุ่ม กลุ่มตัวอย่างเป็นทารกเกิดก่อนกำหนดที่มีอายุหลังการปฏิสนธิ (PCA) 35^{+1} ถึง 36^{+0} สัปดาห์ และมีน้ำหนักตัว 1,800 ถึง 3,000 กรัม ซึ่งจะถูกสุ่มเพื่อรับ PDF หรือ HPMCT ในวันกลับบ้าน ทารกจะได้รับอาหารวิจัยนี้จนกว่าจะมีน้ำหนักตัวไม่ต่ำกว่า 3,000 กรัม หรือ PCA ไม่ต่ำกว่า 40^{+0} สัปดาห์ และเป็นเวลาอย่างน้อย 28 วัน ผู้นิพนธ์ติดตามน้ำหนักตัว ความยาวและเส้นรอบวงศีรษะในวันกลับบ้าน และในวันที่ 14, 28, 56 และ 84 หลังกลับบ้าน ผู้ปกครองจะจดปริมาณอาหารที่ทารกรับประทานและอาการข้างเคียง (ได้แก่ ท้องอืด ท้องเสีย หรือ ท้องผูก) ในสมุดบันทึก ราคาอาหารจะคำนวณจากปริมาณอาหารที่ทารกรับประทานจริง*

ผลการศึกษา: *มีทารกร่วมการศึกษาในกลุ่ม PDF 6 คน และในกลุ่ม HPMCT 5 คน ลักษณะทางประชากรของทั้งสองกลุ่มไม่แตกต่างกัน อัตราการเติบโตในวันที่ 28, 56 และ 84 หลังกลับบ้าน อาการข้างเคียง และราคาอาหารไม่แตกต่างกัน*

สรุป: *อาหารทางการแพทย์ PDF และ HPMCT อาจมีความเหมาะสมใกล้เคียงกันในการนำมาเลี้ยงทารกเกิดก่อนกำหนดที่กลับบ้านแล้ว เมื่อดูจากอัตราการเติบโต ผลข้างเคียง และราคา แต่น่าจะมีการศึกษาเพิ่มเติมในกลุ่มประชากรที่มากกว่านี้ และศึกษาการเปลี่ยนแปลงทางชีวเคมีและพัฒนาการทางสมองด้วย เพื่อจะเปรียบเทียบอาหารทั้งสองชนิดได้ชัดเจนยิ่งขึ้น*