Renastart Use in an Infant on Peritoneal Dialysis

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Adequate nutrition and growth is vital in pediatrics. Breast milk alone might not be able to satisfy the nutrition needs of an infant with renal disease. Similac PM 60/40 (Abbott Laboratories, Abbott Park, IL, U.S.A.) is a low-iron infant formula indicated for infants who would benefit from a lowered mineral intake. It is the only infant formula marketed in the United States for infants with renal impairment. The objective of the present case study was to examine whether Renastart, a pediatric renal formula (Nestlé Health Science, Florham Park, NJ, U.S.A.), could be used alongside expressed breast milk (EBM) to meet the nutritional needs of an infant with renal disease, while maintaining normal serum electrolytes.

A 9-month-old infant received EBM with Similac PM 60/40 treated with Kayexalate (Concordia Pharmaceuticals, Bridgetown, Barbados) because of hyperkalemia. That formulation was not well tolerated, and the infant's growth trajectory declined. The infant was then switched to EBM with Renastart. During this intervention, growth trends; formula volume; kilocalories and protein grams consumed per kilogram weight; episodes of emesis; serum Na, K+, Ca, and phosphorus; blood urea nitrogen; and creatinine were collected.

Results showed an increase of formula intake, an improvement in weight and linear growth, and normal serum levels of Na, K+, and Ca, but low serum phosphorus.

A combination of Renastart and EBM can be safely and effectively used to meet the needs of an infant with renal disease. Close monitoring of protein intake and electrolytes is necessary, and supplementation with phosphorus should be considered. Larger studies are needed to further confirm the benefits of Renastart in infants.

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Introduction

Adequate nutrition and growth is vital in pediatric patients, and especially in infants. Infants typically have higher energy and protein needs because of exponential growth during the first year of life (1). In the setting of renal disease, the energy and protein needs in this age group are even higher, especially while receiving peritoneal dialysis (PD) secondary to the protein losses associated with that modality (2).

Breast milk is the optimal form of infant nutrition (3). Unfortunately, an infant with renal disease requires close management of protein, potassium, phosphorus, and calcium to maintain normal levels. Conventional nutrition interventions might replace breast milk with an infant renal formula or a balance of expressed breast milk (EBM), renal infant formula, and modulars to maintain normal electrolytes. The only infant formula in the U.S. market that includes an indication for renal impairment is Similac PM 60/40 [SimPM (Abbott Laboratories, Abbott Park, IL, U.S.A.)].

Even with the use of a renal infant formula, some infants will continue to experience hyperkalemia and require Kayexalate (Concordia Pharmaceuticals, Bridgetown, Barbados), a potassium binder, to manage hyperkalemia. Kayexalate can induce anorexia, constipation, diarrhea, fecal impaction, nausea, vomiting, hypernatremia, hypocalcemia, hypokalemia, hypomagnesemia, and sodium retention (4). Infants have an immature gastrointestinal tract, and therefore oral use of Kayexalate is often not recommended. To prevent gut injury, pretreatment of formula with Kayexalate to manage hyperkalemia is a common practice. Although this method can help to manage hyperkalemia, Kayexalate works by binding to potassium while releasing sodium into the formula (5,6). Pretreated formula can be unpalatable, and if a

gastrostomy tube is available, formula can be given by that route to meet the infant's nutrition needs.

Renastart (Nestlé Health Science, Florham Park, NJ, U.S.A.) became available in the U.S. market in 2015 (7). It is recommended for ages 1 and up in the United States; however, in Europe it is marketed for the dietary management of renal failure from birth to 10 years. Renastart is whey-based and lower in protein, calcium, chloride, potassium, phosphorus, and vitamin A than standard pediatric formulas (8).

In the case presented here, Renastart was used as a fortifier for EBM in an infant on PD. The goal was to improve growth, overall nutrition intake, and tolerance to feeds, while maintaining normal serum electrolytes—potassium in particular—without the use of Kayexalate.

Case presentation

A 31-week male infant born July 2015 with a birth weight of 1.6 kg (10th – 50th percentile) and a length of 40 cm (10th – 50th percentile) had a history of *in utero* ischemic injury resulting in renal failure that required PD. He had a nasogastric feeding tube until a gastrostomy tube was placed in November 2015 to supplement oral intake.

Records indicated that the infant's intake consisted of EBM fortified with SimPM to a concentration of 30 kcal/30 mL from the age of 2.75 months. After presenting with hyperkalemia in November 2015, he was started on Kayexalate. Our protocol was to treat every 100 mL fortified EBM with 1 g Kayexalate. Fortified EBM was treated for 45 minutes and then decanted into a clean container; sludge was discarded. The infant's other medications included epoetin alfa, ferrous sulfate, sodium chloride, furosemide, and lansoprazole.

The infant refused to take a sufficient amount of fortified EBM by mouth, and attempts to supplement with additional fortified EBM by gastrostomy tube were unsuccessful secondary to frequent emesis. Weight gain was insufficient for catch-up.

The multidisciplinary renal team decided to discontinue SimPM as the fortifier for EBM, replacing it with Renastart (similar calories, decreased protein level, and lower amounts of vitamin A, calcium, chloride, and potassium). The EBM was concentrated back to the 30 kcal/30 mL concentration. Kayexalate was discontinued because of the low concentration of potassium in Renastart.

The infant was reviewed in clinic monthly by the dietitian to monitor and assess his growth, overall nutrition intake, gastrointestinal tolerance, and serum electrolytes. Oral intake, episodes of emesis, and number of bowel movements were recorded daily by the parents and shared with the dietitian at the monthly visits. Data were collected from April to September 2016 for review.

Results

Nutrition intake

Table I shows how the infant's intake of formula increased each month. During the initial switch, his intake increased by 5% during a 10-day period. From April 21 to May 19, his intake increased by 12% and then by 16%, 7%, 13%, and 13% respectively. Improvement in kilocalories consumed per kilogram body weight reveals that his overall intake of formula supported improved weight gain. His daily protein intake stayed about the same as it had been before the switch to Renastart as the fortifier, hovering between 1.5 g and 1.7 g per kilogram body weight.

The infant's emesis was a factor in his adequacy of nutrition and was also monitored for improvement. In Table I, the frequency of emesis can be seen to decline over a 3-month period to 0 – 2 times daily from 2 – 4 times daily while on EBM with SimPM. In August and September, his frequency of emesis ranged between 3 and 4 episodes daily.

Growth

The infant showed catch-up growth in both weight and length. In Table I, a gain of 28 g daily can be seen during the first 10 days after the switch to EBM with Renastart. Each month, his average weight gain varied between 13 g and 29 g daily. Figure 1(A) shows his weight trend as plotted on his growth chart. He was gaining weight appropriately for age, but fell into the 3rd percentile. Within the box in Figure 1(A), the infant's weight gain between 9 months and 10 months was slower than expected; however, in the months following, consistent catch-up growth was observed. By 13 months, the infant crossed the 3rd percentile channel, and during the following month, he crossed the 15th percentile channel.

Figure 1(B) shows the growth chart for length. Overall, the infant's length remained below the 3rd percentile channel before and during the switch to

TABLE I Growth and intake data

Date	*Infant weight (kg)*	*Formula*				
		Type	*Quantity (mL)*	*Energy (Kcal/kg)*	*Protein (g/kg)*	*Emesis (n/day)*
Apr 11, 2016	6.34	EBM with Similac PM 60/40[a]	480	76	1.6	2–4
Apr 21, 2016	6.62	EBM with Renastart[b]	506	76	1.5	1–2
May 19, 2016	6.74	EBM with Renastart	565	84	1.6	1–2
Jun 21, 2016	7.16	EBM with Renastart	656	92	1.7	0–2
Jul 19, 2016	7.55	EBM with Renastart	702	87	1.5	0–2
Aug 16, 2016	8.19	EBM with Renastart	793	97	1.7	3
Sep 13, 2016	9	EBM with Renastart	900	100	1.6	3–4

EBM = expressed breastmilk.
[a] Abbott Laboratories, Abbott Park, IL, U.S.A.
[b] Nestlé Health Science, Florham Park, NJ, U.S.A.

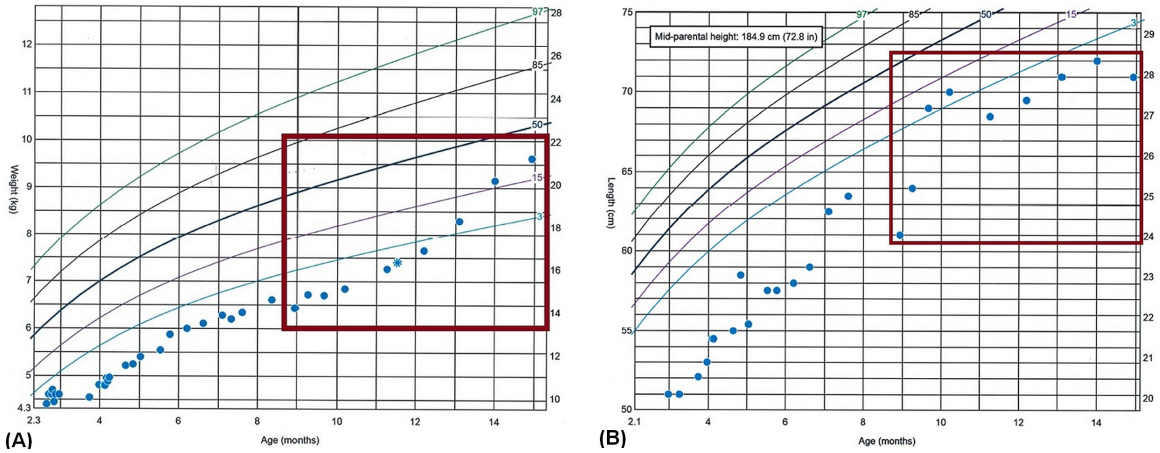

FIGURE 1 World Health Organization growth chart (A) for weight and (B) for length, 0–2 years. The box indicates the period of the intervention.

EBM with Renastart. A closer look shows that his length trajectory appears to have improved from 11 months to 14 months. The outliers at 10 months and 15 months were likely to have been measurement errors.

Electrolyte balance

Table II shows the trends of the infant's electrolytes each month. His sodium dropped from 145 mmol/L after the switch to EBM with Renastart. Hyperkalemia did not return when Kayexalate was discontinued and the fortifier was switched to Renastart. His serum albumin rose from 3.5 g/dL to between about 3.8 g/dL and 4.1 g/dL. Calcium had been normal before the formula change, and it rose above 10 mg/dL during the last 3 months on EBM with Renastart. His serum phosphorus ranged from 3.6 mg/dL to 4.4 mg/dL, which is lower than desirable for an infant. His blood urea nitrogen and creatinine remained stable.

Discussion

The aim for this case report was to determine whether Renastart can be used in combination with EBM to meet the needs of an infant with renal disease. After a switch to Renastart rather than SimPM for fortifying

TABLE II Serum electrolytes

Date	*Na (mmol/L)*	*K+ (mmol/L)*	*Albumin (g/dL)*	*Adjusted Ca (mg/dL)*	*Phosphorus (mg/dL)*	*BUN (mg/dL)*	*Creatinine (mg/dL)*
Apr 11, 2016	145	3.3	3.5	9.8	4	21	3.12
Apr 21, 2016	140	3.8	3.8	9.1	3.8	17	3.31
May 19, 2016	137	3.8	4.1	10.2	3.6	22	3.44
Jun 21, 2016	138	3.1	3.9	9.9	3.6	22	4.04
Jul 19, 2016	135	2.9	3.7	10.4	3.6	23	3.74
Aug 16, 2016	138	4.6	4.1	10.3	4.4	36	4.07
Sep 13, 2016	138	3.6	3.8	10.2	3.6	31	4.07

BUN = blood urea nitrogen.

EBM, the infant reported here showed catch-up weight gain, allowing him to shift from below the 3rd percentile to the 15th – 50th percentile channel over a 5-month period. His linear growth appeared to show improvement, but did not cross the 3rd percentile during the observation period.

The infant's frequency of emesis appeared to improve with the switch to Renastart, but did not resolve. In August and September, his frequency of emesis worsened. Around that time, mom had initiated feeding therapy for her infant secondary to oral aversion or sensitivity to pureed food. During therapy sessions, he gagged and vomited, and mom was taught how to desensitize his oral sensitivity for out-of-therapy sessions. The increased frequency of vomiting was attributable to this oral sensitivity to solids.

The infant's serum electrolytes were monitored, and his sodium dropped after the switch to EBM with Renastart. His previous sodium level on April 11 was 145 mmol/L, which could have meant he was dehydrated from emesis and poor intake. Another potential reason for the higher sodium level on April 11 was the use of Kayexalate to treat his EBM. Kayexalate binds potassium by exchanging it for sodium. His sodium intake could have been high on April 11 because the EBM would have had a higher sodium content after treatment with the Kayexalate. The EBM with Renastart maintained normal serum sodium values. Even with the discontinuation of the Kayexalate, this infant was able to maintain normal serum potassium. His calcium levels were normal to high-normal, but serum phosphorus was lower than desirable for his age. Phosphate supplementation was therefore started. His blood urea nitrogen and creatinine remained relatively stable during the transition period.

Conclusions

Although Renastart is not approved by the Food and Drug Administration for infant use, there has been considerable experience with such use in Europe. That knowledge led our team to trial Renastart as a fortifier in EBM in the hopes of promoting better nutrition intake and growth when our conventional practice of using SimPM failed. In this case, the infant improved his total intake of fortified EBM, leading to catch-up weight gain and linear growth. His electrolytes, except for phosphorus, were within normal limits, likely because Renastart has a low phosphate content. Phosphate supplementation was started. Protein intake was within Kidney Disease Outcomes Quality Initiative guidelines (2), but additional protein might have further improved linear growth.

Based on this case report, an infant with renal disease could use Renastart in combination with EBM to meet nutrition needs. However, close monitoring from a dietitian is necessary to ensure that overall nutrition and micronutrient requirements are met, and that appropriate adjustments are made to reach a protein intake that will promote growth and maintain normal serum electrolytes. Larger studies would be beneficial to assess whether the outcomes reported here are reproducible.

Disclosures

I understand that *Advances in Peritoneal Dialysis* requires disclosure of any conflicts of interest, and I declare that I have no conflicts to disclose.

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