

Effect of Protein Source and Iron Content of Infant Formula on Stool Characteristics

Edgardo E. Malacaman, Fadhil K. Abbousy, Donald Crooke, and *George Nauyok, Jr.

*Clinical Studies, Inc., Canton, Ohio, and *Ross Laboratories, Columbus, Ohio, U.S.A.*

Summary: Formula-fed, term infants were evaluated in two studies that assessed the influence on stool characteristics of protein source and iron content of the formula. Parental observations of infants' stool characteristics were recorded on standard forms. Green was the primary stool color for infants receiving whey-predominant formula containing iron at 12 mg/L. A low-iron (1.5 mg/L), whey-predominant formula produced yellow stools. A casein-predominant, iron-fortified (12 mg/L) formula produced

primarily yellow or brown stools, although many of the infants fed this formula also had green stools. Soft stools were common in infants fed either whey- or casein-predominant formulas. However, more infants receiving whey-predominant formulas passed watery or slimy stools than did infants receiving casein-predominant formulas. We conclude that green stools in the absence of signs of disease should be considered a normal variation of stool color. **Key Words:** Formula—Stool—Protein—Iron—Color—Consistency.

Parents tend to be concerned about their infant's stools. Changes in stool characteristics often prompt calls and visits to physicians. Although such changes may signal pathological conditions, many are apparently normal and caused by diet.

In our early studies with whey-predominant infant formulas, we noted that green stools were characteristic of infants receiving these formulas but were less common in infants receiving casein-predominant formulas. Therefore, in subsequent studies, we sought to define further the influences on stool characteristics of protein source and iron content in proprietary formulas. The studies were designed to provide normative information to pediatricians, who must frequently interpret questions about the color and consistency of infant's stools to anxious parents.

METHODS

We completed two clinical feeding studies with healthy, full-term infants. Each study was approved by an independent Institutional Review Board. Written consent was obtained from the parents of each infant after the study had been thoroughly explained.

No infant participated in both studies. Growth of the infants was monitored; however, this paper will report only the influence of feeding on stool characteristics.

The same standard report forms were used in both studies. One or both parents were instructed to record the primary stool color (yellow, green, brown, or black) and consistency (watery, slimy, soft, formed, or hard) for each bowel movement. Only one descriptor was permitted for color and one for consistency. Formulas used in study 1 contained iron at 12 mg/L and in study 2 at 1.5 mg/L.

Study 1

This study evaluated the effect of protein source on stool characteristics of young infants. Infants were randomly assigned at birth to be fed a whey-predominant formula (Similac with Whey + Iron, Ross Laboratories, Columbus, OH, U.S.A.) or a casein-predominant formula (Similac with Iron, Ross Laboratories). The whey-predominant formula contained ultrafiltered whey protein. Both formulas were provided in a ready-to-feed form that delivered 20 kcal/fl oz. Randomization favored the enrollment of infants into the whey-predominant feeding group. Forty-five infants were assigned to the whey-predominant for-

Address correspondence and reprint requests to G. Nauyok at Medical Department, Ross Laboratories, Columbus, OH 43216, U.S.A.

TABLE 1. Stool color of infants fed iron-fortified (12 mg/L) formulas

Formula	Week	n	Primary stool color			
			Green (%)	Yellow (%)	Brown (%)	Black or mixed (%)
Whey-predominant ^a	2	45	53	24	11	11
	4	42	74	17	5	5
	8	41	78	5	7	10
	12	40	68	5	12	15
	16	39	79	5	8	8
Casein-predominant ^b	2	18	28	44	28	0
	4	16	31	12	50	6
	8	13	38	23	38	0
	12	12	25	16	42	16
	16	12	42	8	42	8

^aSimilac with Whey + Iron (Ross), ready-to-feed form.^bSimilac with Iron (Ross), ready-to-feed form.**TABLE 2.** Stool color of infants fed low-iron (1.5 mg/L), whey-predominant formula^a

Week	n	Primary stool color			
		Green (%)	Yellow (%)	Brown (%)	Black or mixed (%)
2	9	0	67	33	0
4	9	0	67	11	22

^aSimilac with Whey (Ross Canada).

mula and 20 infants were assigned to the casein-predominant formula.

All parents agreed to provide formula ad libitum to their infants as the sole source of calories from birth to 16 weeks of age. Water and glucose water were the only other intake allowed. Neither the parents nor the investigators knew which formula was being fed.

Follow-up visits were at 2, 4, 8, 12, and 16 weeks of age. Before each visit, parents prepared a 3-day record of stool color and consistency.

Study 2

This study assessed the effect of iron level in the formula on an infant's stool characteristics. Nine infants received a low-iron (1.5 mg/L) formulation of Similac with Whey (Ross Laboratories, Montreal, Canada) from birth to 4 weeks of age. Parents were instructed to feed infants ad libitum and to avoid other foods except water or glucose water.

Follow-up visits were at 2 and 4 weeks. Before the visits, parents completed the standard 3-day stool report forms.

TABLE 3. Stool consistency of infants fed iron-fortified (12 mg/L) formulas

Formula	Week	n	Primary stool consistency				
			Watery (%)	Slimy (%)	Soft (%)	Formed (%)	Hard or mixed (%)
Whey-predominant ^a	2	45	18	20	51	4	7
	4	42	21	36	36	0	7
	8	41	22	32	34	2	10
	12	40	22	30	38	5	5
	16	39	21	23	51	0	5
Casein-predominant ^b	2	18	6	11	56	11	17
	4	16	6	0	50	25	19
	8	13	8	8	62	8	15
	12	12	8	0	58	8	25
	16	12	0	0	83	0	16

^aSimilac with Whey + Iron (Ross), ready-to-feed form.^bSimilac with Iron (Ross), ready-to-feed form.

RESULTS

All infants in these two studies grew normally. The primary stool color of infants fed the whey-predominant, iron-fortified formula was green (Table 1). Infants fed the whey-predominant, low-iron formula had primarily yellow stools (Table 2).

Infants fed the whey-predominant, iron-fortified formula had stools that were soft, watery, or slimy (Table 3). A majority of infants (51%) consuming the whey-predominant, low-iron formula had soft stools at 2 weeks, and 54% of infants had soft stools at 4 weeks. The remaining infants had slimy or watery stools; firm or hard stools were uncommon.

The casein-predominant formula produced primarily yellow or brown stools, although up to 42% of infants had primarily green stools (Table 1).

Stool consistency of infants fed the casein-predominant formula was primarily soft (Table 3). A small percentage of infants had watery stools, but slimy stools were uncommon.

DISCUSSION

This study demonstrates that loose green stools are characteristic of healthy infants receiving iron-fortified, whey-predominant formulas. The characteristic green color of stools from infants fed whey-predominant formulas appears to be influenced by an interaction of whey proteins with iron. Infants fed the low-iron, whey-predominant formula produced primarily yellow stools that resembled those of infants fed the high-iron, casein-predominant formula.

An ultrafiltered whey protein was used in the whey-predominant formula tested. Iron-fortified, whey-predominant formulas using electrodialyzed whey (Enfamil, SMA) also cause loose green stools (unpublished data). Therefore, the association of iron-fortified, whey-predominant formulas with loose green stools appears to be unaffected by the method of whey processing.

The differences in stool characteristics of infants fed iron-fortified, whey- and casein-predominant formulas may be due to differences in the intestinal microflora associated with these feedings. Other in-

vestigators have reported that the intestinal microflora of infants is influenced by the protein component of milk-based feedings (1-3). These differences in microflora may be related to differences in the digestive products of casein and whey proteins (4,5). The results suggest that an interaction of whey protein and iron is needed to bring about the intestinal conditions that produce green stools. Rios et al. (6) reported that infants absorb about 4% of the iron from an iron-fortified, milk-based formula. Thus, a significant quantity of iron may reach the colon with the feeding of a formula containing iron at 12 mg/L.

In summary, green stools with a watery or slimy consistency are common for infants receiving commercially available, iron-fortified, whey-predominant formulas; green stools also are common for infants fed an iron-fortified, casein-predominant formula. Therefore, green stools in the absence of signs of disease should be considered a normal variation of stool color.

Acknowledgment: This study was supported by Ross Laboratories, Columbus, OH. The authors thank the nursing staff at Aultman Hospital and Timken Mercy Medical Center in Canton, OH. We also thank Wendy L. Bachhuber for editing the manuscript and Charles L. Paule, M.S., and William C. MacLean, Jr., M.D., for reviewing the manuscript.

REFERENCES

1. Hewitt JH, Rigby J. Effect of various milk feeds on numbers of *Escherichia coli* and *Bifidobacterium* in the stools of newborn infants. *J Hyg Camb* 1976;77:129-39.
2. Yoshioka H, Iseki K-I, Fujita K. Development and differences of intestinal flora in the neonatal period in breast-fed and bottle-fed infants. *Pediatrics* 1983;72:317-21.
3. Henley WL, Adams F, Ainbender E, et al. Studies in necrotizing enterocolitis (NEC): effects of formula on GI microbial flora [Abstract]. *Pediatr Res* 1978;12:436.
4. Ross CAC. Fecal excretion of amino-acids in infants. *Lancet* 1951;2:190-4.
5. Heine W, Zunft HJ, Muller-Beerthow W, Grutte FK. Lactose and protein absorption from breast milk and cow's milk preparations and its influence on the intestinal flora: investigations on two infants with an artificial anus. *Acta Paediatr Scand* 1977;66:699-703.
6. Rios E, Hunter RE, Cook J, et al. The absorption of iron as supplements in infant cereal and infant formulas. *Pediatrics* 1975;55:686-93.