Pediatr Gastroenterol Hepatol Nutr. 2021 May;24(3):316-324
https://doi.org/10.5223/pghn.2021.24.3.316
pISSN 2234-8646·eISSN 2234-8840

Pediatric Gastroenterology, Hepatology & Nutrition
pghn

Original Article



# Growth Patterns of Indonesian Infants with Cow's Milk Allergy and Fed with Soy-Based Infant Formula

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**Received:** Sep 21, 2020
**1st Revised:** Nov 4, 2020
**2nd Revised:** Dec 17, 2020
**Accepted:** Jan 2, 2021

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## ABSTRACT

**Purpose:** The use of soy-based infant formula has increased widely in infants with cow's milk allergy (CMA). This study aimed to provide evidence on the growth pattern of CMA infants fed with soy-based infant formula in an Indonesian setting.
**Methods:** A multi-site, intervention study was conducted among full-term and normal birth weight CMA infants. Within six months, the subjects were provided with a soy-based infant formula. Weight, height, and head circumference were measured at baseline, weeks 4, 8, 12, 16, 20, and 24. Adverse events were recorded by scoring atopic dermatitis and symptom-based clinical scores.
**Results:** Based on the World Health Organization growth chart, we found that most of subjects had normal nutritional status for weight-for-age, length-for-age, weight-for-length, and head-circumference-for-age. There were statistically significant differences between baseline and end-line for weight-for-age, length-for-age, weight-for-length, and head circumference-for-age nutritional status. No allergic symptoms or intolerance toward soy formula were observed at the end of the intervention period.
**Conclusion:** These results show that infants fed with soy-based infant formula have a normal pattern of growth.

**Keywords:** Soy milk; Milk hypersensitivity; Body weight; Body height

## INTRODUCTION

Breast milk is undoubtedly the best food for infants. Nonetheless, there are infants who cannot be exclusively breastfed due to certain conditions. Consequently, these infants would receive infant formula, which is mainly adapted from cow's milk. Cow's milk allergy (CMA) appears to be the most common food allergy in early childhood, with an incidence of 2–3% in the first year of life [1]. Among Indonesian children, CMA is the second most common food allergy after egg product consumption. The estimated prevalence of CMA varies from 2% to 7.5% [2].

**Conflict of Interest**
The authors have no financial conflicts of interest.

The Indonesian Pediatric Society (IDAI) established guidelines on CMA management and recommended the use of extensively hydrolyzed formula (eHF) for mild to moderate allergy or amino acid-based formula for severe conditions. However, considering the high cost and availability of eHF, soy-based formulas could be used as an alternative source of feeding in infants who cannot tolerate cow's milk. Mothers should be well-informed about the choice of formula feeding for their children. There is a debate regarding the safety and potential allergen of soy formulas, and their nutritional adequacy [3]. Concerns have been raised in relation to the soy formula components, that is phytoestrogens/isoflavones, due to their potential negative effects on human development, reproduction, and endocrine function. Nonetheless, there is no conclusive evidence that phytoestrogens/isoflavones may harm human health [4].

Food allergy is commonly found among infants [5]. Cross-reactivity between cow's milk and soya milk has been found; nevertheless, the clinical co-allergy is still in question [3,6,7]. Guidelines by European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) consider the use of soy formula after the age of 6 months due to their lower cost and better acceptance, and only if tolerance to soy protein has been established by clinical challenge [8]. The American Academy of Pediatrics (AAP) allows the use of soya formula in place of cow's milk for term infants with indications of galactosemia and hereditary lactase deficiency and in situations where vegetarian diet is preferred. Additionally, AAP clearly states that soya formula is not designed for preterm infants [4].

In relation to nutritional adequacy, a study by Fomon [9] comparing soya formula with cow's milk among infants demonstrated no growth differences in the first 4 months [9,10]. Another study revealed a similar evidence that they found no differences in terms of growth pattern, serum albumin, and hemoglobin levels between infants who consumed soya milk and those were initially breastfed and then weaned to cow's milk formula in their first year of life [11]. A review by Vandenplas and Hegar [12] also highlighted the difference in opinions regarding the adverse effects of soy formula and possible option for infants who are unable to breastfeed and cannot tolerate cow's milk. There has not been any study in Indonesia that particularly discussed the effect of soya milk on infant growth development. In the Asian context, people commonly consume soya beans as milk or dessert throughout their lives. Therefore, the lifetime soya bean exposure pattern could differ between Asians and non-Asians. Nevertheless, the data are still limited to justify that the soy protein allergic incidence would be lower in Asian countries than in non-Asian countries.

The soy formula is quite popular for infants with CMA, while eHF is not widely available and affordable by many Indonesians. Therefore, this study compared the growth status of CMA infants who consumed soy formula with the World Health Organization (WHO) growth standards. It aims to provide an overview of the growth status of the infants for a six-month period. Additionally, this study provides data on the infants' feeding tolerance towards soy formula consumption.

## MATERIALS AND METHODS

### Study design

This was a multisite intervention study among term infants who were fed soy formula after being diagnosed with CMA. A minimum sample size of 25 was arbitrarily chosen for this


https://doi.org/10.5223/pghn.2021.24.3.316

study. Term infants were recruited from hospitals or clinics in Jakarta, Bandung, Jogjakarta, and Surabaya, between January 2018 and September 2019. All sites were supervised by pediatricians. The study was approved by the Ethics Committee of the Faculty of Medicine, Universitas Padjadjaran, Bandung (945/UN6.C.10/PN/2017). Written informed consent was obtained from the parents of all the infants before enrollment.

## Subject selection criteria

The subjects enrolled in this study were full-term and normal birth weight infants, with a gestational age between 38 and 42 weeks and birth weight between 2,500 and 4,000 grams. Those included in the study were aged below three months old, had consumed formula milk for at least one month, and were diagnosed with mild to moderate clinical manifestation of CMA. The diagnosis was made by pediatricians in accordance with the CMA treatment algorithm, as published by the IDAI. Patients were suspected of mild to moderate CMA if they experienced the following symptoms: (1) frequent regurgitation, vomiting, diarrhea/constipation; (2) atopic dermatitis, angioedema, urticaria; (3) runny nose, chronic coughing, wheezing; and (4) colic for more than 3 weeks (with duration of more than 3 hours per day per week) [2]. Using the criteria for the symptoms, the patients were diagnosed as having mild to moderate CMA and therefore were recruited in this study. We excluded infants with severe conditions, such as failure to thrive due to chronic diarrhea/regurgitation/severe vomiting/refusal to feed, exudative/severe atopic dermatitis with hypoalbuminemia or iron deficiency anemia, acute laryngoedema or bronchial obstruction with breathing difficulty, and anaphylaxis. Infants with a history of severe anaphylaxis or severe congenital abnormalities were excluded from the study.

## Study feedings

Only one investigational product was used in this study. All infants were fed a soy-protein-based formula according to their age. Infant formulas were given to those aged below 6 months, and follow-on formulas for those aged between 6 and 12 months old. For infant formula, the soy formula contains (per 100 mL) 67 kcal energy, 2 g protein, 3.5 g fat, 7 g carbohydrate, 524 mg linoleic acid, 46 mg α-linoleic acid, 10.6 mg arachidonic acid (AA), 10.6 mg docosahexaenoic acid (DHA), 0.3 g dietary fiber, 19 vitamins and 12 minerals. For the following formula, the components (per 100 mL) included 140 kcal energy, 4 g protein, 5 g fat, 16 g carbohydrate, 819 mg linoleic acid, 73 mg α-linoleic acid, 16 mg AA, 16 mg DHA, 1 g dietary fiber, 16 vitamins and 11 minerals. Both products were designed for infants with CMA or lactose intolerance.

## Data collection

Upon enrollment, the parents of the subjects began feeding the study formula according to the age and weight of their children. Infants were examined at baseline (1–3 months of age) and at weeks 4, 8, 12, 16, 20, and 24 after the enrollment. Prior to the follow-up visit, parents were instructed to complete 3-day dietary records of the amount of soy milk consumption, adverse events, and concomitant medication. The growth status (weight, length, and head circumference), eczema severity, and soya milk allergy risk were assessed by a pediatrician at the time of entry into the study and at each follow-up visit. The severity of eczema was evaluated using scoring atopic dermatitis (SCORAD) and the soya milk allergy risk assessed through symptom-based clinical scores. SCORAD assessed atopic dermatitis in terms of the extent, intensity, and subjective symptoms of dermatitis. Patients with SCORAD <25 were considered to have mild symptoms, SCORAD between 25 and 50 was considered as moderate, and SCORAD >50 was considered to have severe symptoms. The symptom-based

clinical score is used to describe the symptoms related to the milk consumption, such as crying, regurgitation, stool assessment, skin and respiratory symptoms. A cut-off value of ≥12 would define an infant as having a risk of milk allergy. All adverse events throughout the study were recorded and treated accordingly by an on-site pediatrician.

### Statistical methods

The growth status of all subjects was recorded in weight-for-age, length-for-age, weight-for-length, and head circumference-for-age. These numerical data were compared between baseline and follow-up visits. The analysis was performed using a dependent t-test for normal distribution data or the Wilcoxon signed-ranked test for skewed data. A similar analysis would be applied to SCORAD and symptom-based clinical score data. All statistical tests were two-sided with $\alpha$ $p<0.05$ to determine statistical significance. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Co., Armonk, NY, USA). Adverse events were analyzed in terms of frequency (n) and percentage (%) and classified based on the severity level.

## RESULTS

### Subject characteristics

A total of 53 infants were enrolled in this study, and 39 (74%) completed the study. Fourteen subjects failed to complete all the follow-up visits: nine infants did not return in the fourth week visit, three in the eighth week, one in the 16th week visit, and one in the 20th week visit. The reasons included: dislike the milk flavor (2/14), return to breastfeeding (3/14), possibility of cross allergy (2/14), gestational age <36 weeks (1/14), not being diagnosed with cow's milk intolerance (1/14), and developed severe adverse events (5/14). All recruited subjects were term infants with mean birth weights of 3,146±362.53 grams. The mean age of mothers were 30.65±6.58 years old, and fathers were 33.04±5.71 years old. At enrolment, 55% of the subjects were fed full-formula, and the rest were mixed feeding of breastmilk and milk formula. Throughout the study, more infants were fed full-formula, about 87% (34/39) of them at week 24, and only 13% (5/39) of the infants were mixed fed. None of the patients was fully breastfed. In week 4, one infant received full breastfeeding and dropped out of from the study. **Table 1** below describes the characteristics of the subjects.

### Growth status

There was an increasing trend of growth status in all indicators, such as weight-for-age, length-for-age, weight-for-length, and head circumference-for-age. At baseline, using the weight-for-age parameter, we found that 77% (41/53) of infants had normal weight, 17% (9/53) were underweight, 4% (2/53) were severely underweight, and 2% (1/53) were overweight. At week 24, about 72% (28/39) of subjects with normal nutritional status showed no changes, 15% (6/39) showed improvement from underweight/severely underweight to normal, 8% (3/39) remains in the underweight category and 3% (1/39) had changes from normal to underweight status.

Most subjects were 85% (45/53) normal, 11% (6/53) had low length-for-age, and 4% (2/53) were considered tall at baseline. During the last measurement, the majority (34/39) were still normal, 10% (4/39) had low length-for-age, and 3% (1/39) were tall. For the weight-for-length indicator, 64% (34/53) were within the normal range, 23% (12/53) were in the wasting category, 7% (4/53) were severely wasted, 4% (2/53) were overweight and 2% (1/53) were obese.


https://doi.org/10.5223/pghn.2021.24.3.316

**Table 1.** Subjects' characteristics at baseline

| Variable | Frequency (n) | Percentage (%) |
|---|---|---|
| Sex | | |
| Male | 18 | 34 |
| Female | 35 | 66 |
| Age at enrollment (mo) | | |
| 1 | 21 | 40 |
| 2 | 20 | 38 |
| 3 | 12 | 22 |
| Parent's history for allergy* | | |
| Yes | 20 | 39 |
| No | 31 | 61 |
| Mother's education level† | | |
| Elementary level | 1 | 2 |
| Secondary level | 30 | 58 |
| Bachelor or above | 21 | 40 |
| Father's education level* | | |
| Elementary level | 3 | 6 |
| Secondary level | 32 | 63 |
| Bachelor or above | 16 | 31 |

*2 subjects' father demographic data are unavailable because the subject is a foster child (n=1) and the subject's father is unknown (n=1). †1 subject's mother demographic data are unavailable due because the subject is a foster child.

At the end of the study, we observed that approximately 59% (23/39) remained in the normal status, 28% (11/39) experienced a change in nutritional status from wasting or severe wasting to normal, 5% (2/39) from normal to overweight, and 3% (1/39) from normal to wasting.

Using head circumference-for-age, we observed that 87% (46/53) of infants had normocephaly and 13% (7/53) had microcephaly. In the end line, there was significant improvement, with 95% (36/38) of the subjects having normal measurement and only 5% (2/38) still had microcephaly. One subject was excluded for head circumference-for-age measurement because the subject was diagnosed with microcephaly conditions that required further treatment.

**Fig. 1** plots the trend of growth data in each measurement time. The growth data (length in cm, weight in kg, and head circumference in cm) were compared between the baseline and each visit, and the mean differences were statistically significant (all *p*-values <0.05).

## Soy formula tolerance

At the beginning of the study, approximately 8% (4/53) of the infants did not well tolerate the soy formula well (data not shown). Throughout the study, some respondents dropped out for due to several reasons. At the end of the study, no patient fell into a severe condition. Using SCORAD, we calculated the risk of atopic dermatitis (**Table 2**). The median score at baseline was 6 (range, 0–70.2). At each timepoint of visits, there was improvement in the score, that is, the median (minimum–maximum) score was 0 (0–26.5) at week 4, 0 (0–33.3) at week 8, 0 (0–23.9) at week 12, 0 (0–30.0) at week 16, 0 (0–7.7) at week 20, and 0 (0–13.7) at week 24. We analyzed the differences between each timepoint and found that the differences were statistically significant (all *p*-values <0.05). We also assessed milk allergy risk among the infants using symptom-based clinical scores. At baseline, we evaluated the risk of allergy to cow's milk consumption. At week 4, the risks were assessed for the soy formula.

Wilcoxon signed-rank tests were conducted to compare the difference between the baseline and each timepoint visit for eczema severity and milk allergy. The results showed

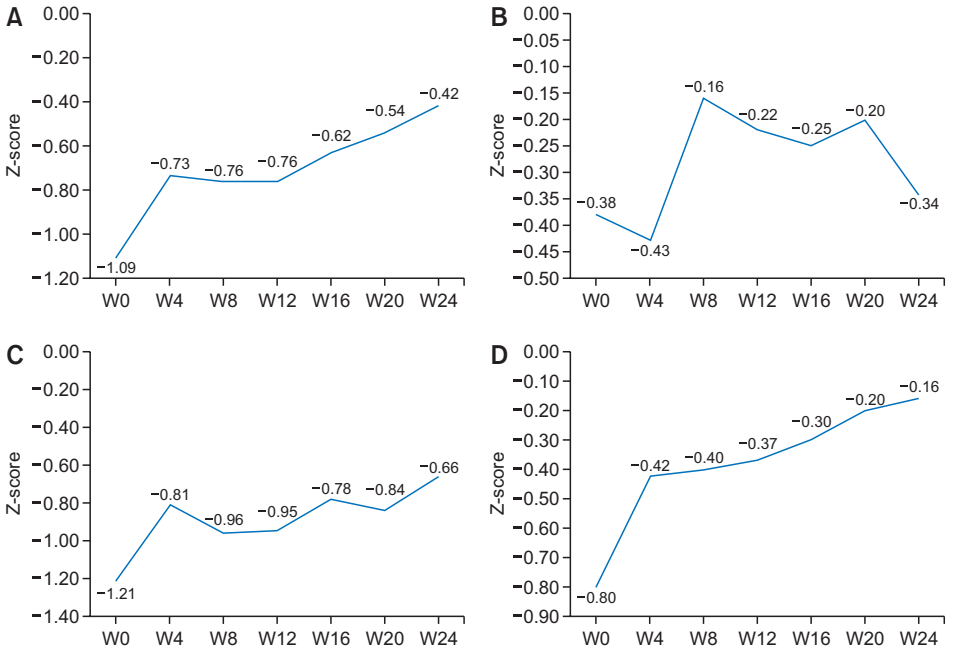


**Fig. 1.** Growth pattern of subjects. Panel A contains the Z-scores for weight-for-age. Panel B contains the Z-score for the length-for-age. Panel C contains the Z-score for the weight-for-length. Panel D contains the Z-score for the head circumference-for-age.
W: week.

**Table 2.** SCORAD and symptom-based clinical score of subjects

| Variable | W0 (n=53) | W4 (n=44) | W8 (n=41) | W12 (n=40) | W16 (n=39) | W20 (n=39) | W24 (n=39) |
|---|---|---|---|---|---|---|---|
| SCORAD | | | | | | | |
| Mild | 43 | 43 | 40 | 40 | 38 | 39 | 39 |
| Moderate | 8 | 1 | 1 | 0 | 1 | 0 | 0 |
| Severe | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Symptom-based clinical score | | | | | | | |
| Less likely related | 47 | 44 | 41 | 40 | 39 | 39 | 39 |
| Likely related/at risk | 6 | 0 | 0 | 0 | 0 | 0 | 0 |

SCORAD: scoring atopic dermatitis, W: week.
SCORAD mild score <25; moderate score 25–50; and severe score >50. Symptom-based clinical score for less likely related group is <12 and for likely related/at risk is ≥12.

a statistically significant difference in all comparisons, with *p*-values <0.05. We recorded the adverse events within six-month period and found nine cases of possibly related adverse events in the first four weeks, five cases in week 8, one case in week 12, no cases in weeks 16 and 20, and one case in week 24. Adverse events in week 4 included erythematous rash (2/9), diarrhea (1/9), loose stools (19), hard stools (1/9), itchy skin (1/9), cough (1/9), and vomit/nausea (1/9). At week 8, we found five cases with the following symptoms, i.e., cough, cold, itchy skin, fever, and underweight. In week 12, one case with underweight case was observed, while the other cases had improved. At the end of the study, we found only one case of diarrhea.

## DISCUSSION

The results of this study demonstrate that the growth pattern in term infants fed with soy formula was within the normal range. Hence, in this study, infant growth corresponded to normal limits, with a Z-score of height-for-age, length-for-age, weight-for-length, and


https://doi.org/10.5223/pghn.2021.24.3.316

head circumference-for-age were between -2 standard deviation (SD) and 2 SD. Similar to other studies, our findings showed normal growth patterns among infants who consumed soy formula [13]. Seppo et al. [14] compared soy formula with extensively hydrolyzed whey formula and found no differences in terms of anthropometric data. Han et al. [13] also observed a similar growth pattern in the first year of life between infants fed with human breast milk and formula milk.

In 2006, the WHO issued growth standards for infants and children [15]. These standards aim to provide universal standards for healthy infants worldwide. However, the use of these standards is questionable in the Asian context. Hui et al. [16] argued that it might not be appropriate across all populations, referencing to the Asian population. Dwipoerwantoro et al. [17] also mentioned that it might not reflect the growth patterns of Indonesian infants. Her study revealed that Indonesian infants had lower Z-scores for weight-for-age, length-for-age, and head circumference-for-age than WHO growth standards. Similarly, the results in our study showed that the mean Z-score of growth indicators was lower than the WHO growth standards, but similar or even higher than the Z-score for weight, length, weight-for-length, and head circumference of Indonesian infants referred to the Dwipoerwantoro study, who consumed either breast milk or formula milk. Nevertheless, the growth indicators were all within the normal range, from week 0 to week 24.

We acknowledge that our study merely observed the growth pattern of infants consuming soy milk, either mixed feeding with human milk or full formula. We did not compare with other types of formula for CMA infants, for example, eHF or amino acid-based formula, since we would like to offer CMA infants with more accessible and available options for feeding formula.

Within the six-month study period, approximately 76.47% of infants completed the study. Although more than 20% dropped out of the study, this study could provide an overview of the growth pattern of infants with CMA. We could be assured that infants fed soy formula would follow the growth chart standards.

In terms of soy milk tolerance, approximately 18.8% of infants had moderate to severe eczema at the time of enrollment. This probably refers to the symptoms of CMA. The AAP mentioned that about 10 to 14% of CMA infants would develop allergic reaction to soy protein [18]. In this study, only one infant still had dermatitis at weeks 4, 8, and 16. There has been a concern with cross-reactivity between soybean protein and cow's milk [19]. However, clear clinical evidences have not been conclusive at present [6,7].

Safety concerns regarding the isoflavone compound in soy formulations vary. Some experts worried that its estrogenic activity may influence the human reproductive function. Strom et al. [20] conducted a retrospective study and found no difference in reproductive maturity, cancer development and general health between infants who consumed soy-based formulas and cow's milk. Our study could not provide evidence on this issue since we only observed the infants for a six-month period. In addition, the adverse events found in this study were mostly related to gastrointestinal and skin reactions.

The present study indicates that soy formula supports the normal growth of term infants with CMA. The nutritional status and growth indicators were all within normal reference values. Additionally, the use of soy formula for CMA infants was still tolerable and appeared to be safe. However, further cohort studies over a longer period would be necessary to

observe the possibility of cross-reaction with CMA and potential adverse events related to phytoestrogen components.

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