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Isolate Soy Protein with Dietary Fiber Formula in Children with Cow's Milk Protein Allergy: Case Report

Formula Isolat Protein Kedelai dan Serat Pangan untuk Anak dengan Alergi Protein Susu Sapi: Laporan Kasus

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ABSTRACT

Background: Cow's milk protein allergy (CMPA) represents the most frequently encountered food allergy in pediatric populations younger than three years. Clinical presentations vary widely, including gastrointestinal (GI), respiratory, and cutaneous manifestations.

Objectives: The purpose of this case report is to determine the effectiveness of an isolated soy protein formula, enriched with dietary fibre, as a dietary alternative for a child afflicted with cow's milk protein allergy (CMPA).

Methods: This study presents a case report concerning a 2-week-old infant who presented with gastrointestinal (GI) symptoms, specifically watery loose stools and vomiting. Given the family and socioeconomic circumstances, neither breast milk nor an amino acid or extensively hydrolyzed formula could be provided. Consequently, the infant received an isolated soy protein formula fortified with dietary fiber. This report further includes a review of the current literature on the utilization of dietary fiber in pediatric populations.

Results: The use of isolate soy protein with dietary fibre formula may offer a well-tolerated and nutritionally adequate alternative for children with CMPA, providing paediatricians, nutritionists, and the broader healthcare community with an additional dietary option.

Conclusions: The use of soy isolate protein formula with additional fibre suggests a beneficial effect to improve gut microbiota diversity and may improve stool consistency for both constipation and diarrhoea. However, further large-scale studies are needed to confirm its long-term effect, efficacy, and impact on growth and gut health.

INTRODUCTION

Cow's milk protein allergy (CMPA) is one of the most prevalent food allergies in children. The incidence ranging from 2% to 7.5% in the first year of life[1]. The prevalence rate in developing countries typically spans from 0.5% to 3% among infants aged one year[2]. Prevalence of CMPA in Indonesia remains unknown. Most CMPA reactions are mediated by Immunoglobulin E (IgE) with an incidence 1.5%, while the others are non-IgE type. CMPA clinical manifestations mediated by IgE include Cutaneous manifestations such as urticaria, angioedema, erythematous eruptions, and atopic eczema; gastrointestinal symptoms including emesis, abdominal discomfort, and loose stools; as well as respiratory signs like allergic rhinoconjunctivitis, bronchial hyperresponsiveness, and anaphylactic reactions[3]. The Indonesian Paediatric Society developed guidelines on CMPA diagnosis and treatment. Principle of therapy for cow's milk allergy is complete avoidance of all forms of cow's milk products but must provide balanced and appropriate nutrition for the growth development of the baby/childFor infants who are exclusively breastfed, mothers can safely continue breastfeeding by adhering to a diet that excludes cow's milk protein and its derivatives. In paediatric patients reliant on milk-based formulas, the utilization of extensively hydrolysed formulas (eHF) is advised to cases of mild to moderate allergy, whereas

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amino acid-based formulas are recommended for individuals presenting with severe allergic manifestations. In situations where hydrolyzed formula is not readily accessible, an isolated soy protein formula may be considered as an alternative. Nevertheless, it is imperative to provide thorough education regarding the potential for continued allergic reactions to soy protein isolate formulas[3]. According to the National Health and Nutrition Examination Survey 2003-2010, a number of 12% newborns in America aged 0 to 12 months use soy-based infant formula[4]. Indonesia is among the Asian countries demonstrating the highest consumption of soy-based products, many of which serve as breast milk substitute formulations[5]. European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) recommends the use of soy formula after the age of 6 months due to lower cost and better acceptance, and only if tolerance to soy protein has been shown through clinical challenge[6].

While acknowledging the crucial role of human milk in a child's health, growth, and development, it is equally important to note that oligosaccharides are the third most significant solute component in human milk, after lactose and fat. The oligosaccharides content in human milk varies with breastfeeding duration, circadian rhythms and the maternal genetic profile. Beyond breastfeeding duration and genetics, recent studies variations in human milk oligosaccharide composition associated with maternal diet, nutritional status, allergic diseases, pre-pregnancy BMI, mode of delivery, and infant characteristics such as sex and gestational age. Human milk oligosaccharides are currently attracting a lot of interest for their potential uses. Oligosaccharides serve as a source of soluble fiber and additionally exert prebiotic effects, primarily due to their bifidogenic activity which supports gastrointestinal health[7]. Through its ability to foster a healthier gut microbiome, dietary fiber, especially varieties with prebiotic functions, exhibits a bifidogenic effect. This positively impacts gastrointestinal (GI) health, including alleviating functional constipation and reducing the likelihood of or accelerating recovery from diarrhea, a significant GI challenge in childhood. Dietary fibres, acting as prebiotics, play a crucial role in modulating gut microbiota composition by promoting beneficial bacteria, which help regulate immune responses in CMPA patients. Early-life exposure to dietary fibres has been associated with immune system maturation and the potential induction of oral tolerance to allergens, suggesting a long-term role in allergy prevention. By shaping the gut microbiota, strengthening intestinal immunity, and mitigating allergic inflammation, dietary fibres emerge as a promising strategy in managing and potentially preventing CMPA[8]. Soluble fibre slows the movement of food through the digestive system, which can help with diarrhoea control, for example is inulin.

Constipation is a common paediatric condition, with prevalence rates reported between 0.7% and 29.6%[9]. The inclusion of dietary fibre has demonstrated therapeutic benefits in managing constipation among infants and young children. Increasing fiber intake not only aids in alleviating constipation-related symptoms but may also contribute to the overall improvement of dietary quality in paediatric populations[10]. In children with chronic constipation, enhanced fiber consumption has been associated with a significant reduction in both constipation and diarrhoea symptoms. Dietary fibre supports gastrointestinal function by promoting regular bowel movements and improving stool consistency[9,11]. Thus, providing soy protein isolate formula enriched with fibre, tailored to meet the nutritional requirements of children, plays a crucial role in supporting adequate dietary fibre intake[8]. This case report aims to evaluate the use of an isolate soy protein formula enriched with dietary fibre as a nutritional alternative in a child with CMPA, highlight the potential role in improving gut microbiota and alleviating constipation symptoms in paediatric patients with CMPA.

METHODS

This study case report details the presentation of a 2-week-old boy to the emergency room with severe dehydration. Chief complaints involved watery, yellowish loose stools (consistency score = 7) 5-6 times daily over the preceding five days, without evidence of fiber, blood, or mucus. The patient also reported six episodes of vomiting (15-20 ml each) per day and diminished urine output. The infant had been on formula milk since birth. A history of allergies in the biological parents was unobtainable given the child's adoption status.

The patient was given fluid correction and evaluated for signs of dehydration. He treated with probiotic 5 drops per times and zinc syrup 10 ml. The presenting symptoms were suspected due to cow's milk protein allergy, then the milk formula was replaced with soy protein isolate milk with added fibre. Soy-based formula is considered a safe alternative for children with CMPA, as it does not typically trigger significant allergic reactions. Moreover, it provides essential nutrients necessary for growth and development, ensuring that the dietary needs of affected children are met. Soy protein isolate formula with dietary fibre may cause gastrointestinal discomfort, including bloating, gas, or diarrhoea, particularly in children with sensitive digestion. In Indonesia, where soy consumption is high from an early age, the risk of soy allergy may be lower due to increased tolerance. However, close monitoring is required to ensure nutritional adequacy, tolerance, and growth.

The patient's condition improved within three days, with stool consistency reaching a score of 4. This clinical response corroborated the suspected diagnosis of cow's milk protein allergy (CMPA). The patient was discharged after 7 days and advised to continue consuming soy protein isolate milk with additional fibre (Bebe Soya). Two months post-diagnosis, the patient was re-evaluated, showing a body weight of 4.5 kg and complete resolution of vomiting and loose stools.

RESULTS AND DISCUSSIONS

A survey conducted in Indonesia included a total of 277 healthcare practitioners, consisting of 147 paediatricians, 68 nurses, and 62 midwives. The survey indicated that healthcare practitioners across various specialties recommended soy-based formula for children

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who are unable to consume cow's milk. Nonetheless, extensively hydrolysed formula (eHF) or amino acid-based formula is generally considered the first-line recommendation. Respondents were also asked to identify specific components they believe should be incorporated into soy-based formulas. The most frequently suggested additions were arachidonic acid (AA) and docosahexaenoic acid (DHA) (43%), followed by dietary fibre (34%), specific amino acids (20%), and other components (3%), which included improvements in taste, as well as the inclusion of prebiotics, probiotics, synbiotics, vitamins, minerals, fats, and caloric content[5].

Soy-based infant formula (SIF) is formulated using soy protein isolate, providing approximately 2.2–2.6 grams of protein per 100 kilocalories—an amount greater than that found in standard milk-based formulas. Despite this difference, soy-based and milk-based formulas support comparable growth and developmental outcomes in infants, including similar serum albumin levels[12]. Modern SIF has been optimised with adjusted mineral content, and formulations incorporating hydrolysed phytate have demonstrated no adverse effects on growth or bone mineralization when compared to cow's milk-based formulas, nor do they increase the risk of malnutrition[13]. Soy protein isolate has a Protein Digestibility-Corrected Amino Acid Score (PDCAAS) of 1.0, which is the highest possible score and indicates that its protein quality is comparable to that of superior animal sources such as egg white and casein. Due to the purification processes involved in producing soy protein isolate, naturally occurring soy fibres are removed[14]. However, the inclusion of dietary fibres, particularly FOS and inulin in soy-based formulas may confer additional benefits to gastrointestinal health.

Dietary fibre contributes to a higher frequency of bowel movements and a reduce in the firmness of stool[15]. A meta-analysis of five studies with a population of 171 children and 24 adults revealed that the consumption of dietary fibre increases the frequency of bowel movements in cases of constipation. However, there were no significant differences observed in terms of stool consistency, painful defecation, laxative use, and treatment success[16]. A recent systematic review examining the impact of various types of fibres on functional constipation in children revealed that inulin improves the consistency, frequency, and transit time of stool and Oligosaccharides promote better bowel movement, alleviate painful defecation, and enhance stool consistency[17]. In addition to its bulking properties that aid in regulating bowel movements, dietary fibre undergoes fermentation by the gut microbiota, resulting in the production of various metabolites, notably short-chain fatty acids (SCFAs). These microbial byproducts exert effects that extend beyond the gastrointestinal tract, contributing to the regulation of metabolic processes and modulation of the immune system[18–21].

Infants with cow milk's protein allergy tend to have dysbiosis of gut microbiota that may affect their immune system development[22]. Inulin and fructooligosaccharides (FOS-inulin) are soluble, non-viscous, fermentable fibres that may increase gut's Bifidobacteria and decrease infection by gut pathogens, FOS-inulin also have no significant effect on laxative and constipation. A review from McRorie 2016 showed that Inulin has no effect on lowering LDL, total cholesterol and does not improve glycaemic control (fasting and postprandial glucose). A few studies showed inulin has triglyceride-lowering effects compared to placebo. No significant difference of inulin versus placebo in increasing stool output and stool softening. Fiber does not have a laxative effect by increasing intestinal motility, but instead improves regularity by changing stool viscosity. In the context of diarrhoea management, fibres are utilized for their potential to absorb water, increase stool bulk, and slow intestinal transit time. This approach may decrease both the incidence and intensity of diarrheal episodes[23]. FOS have demonstrated a significant capacity to increase the alpha-diversity of the gut microbiota and to stimulate the proliferation of beneficial bacteria, particularly *Bifidobacterium* and *Lactobacillus* species. Additionally, inulin supplementation has been associated with increased beta-diversity of the gut microbial community, notably enriching populations of *Prevotellaceae* and further stimulating the proliferation of *Bifidobacterium*. Conversely, inulin intake has been linked to a reduction in the abundance of *Desulfovibrio*, a genus associated with potentially harmful metabolic activities[24]. Prebiotics along with inulin-type fructooligosaccharides increase the growth of *Bifidobacterum* which results in more normal intestinal flora and less pathogens. This also leads to softer stools and reduces the duration of infectious diseases. FOS and inulin lead to enhances gastrointestinal health by promoting gut movement, preventing constipation, and acting as prebiotics, which support beneficial gut microbiota, thus providing a safe alternative for children with CMPA. It enhances digestion and nutrient absorption, potentially reducing symptoms like diarrhoea and improving overall growth and development in affected infants[25].

Randomised controlled trial performed in children with functional constipation, demonstrated that fibre had significantly more defecation frequency than placebo. The dietary fibre mixture showed a higher median palatability score of 1.25 (1.00-1.67) than the placebo 1.00 (1.00-1.25), with a *p*-value of 0.007 indicating satisfactory compliance. Patients in the control group (placebo) had hardened stools, whereas patients in the dietary fibre mixture group had non hardened stools with RR 0.38 (0.2-0.73) 95% CI which is significant[26]. Another study found that one-month intervention involving dietary fibre combined with probiotics in children diagnosed with cerebral palsy significantly improved manual and spontaneous defecation and also the Bristol score. It has a good effect on both regular and liquid diets, but the duration of therapy needs to be longer on liquid diets. Indirectly, it has an impact on increased body weight[27]. Another recent meta-analysis found that fibre supplementation reduced the occurrence of diarrhoea in patients receiving enteral nutrition by 36% (RR=0.64[95% CI: 0.49–0.82, p-value=0.005; i^2=45%) compared to fibre-free formulas[28]. Therefore, dietary fiber demonstrates utility in addressing both constipation and diarrhea, facilitating the normalization of stool frequency and consistency.

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This study adds valuable insight. However, the findings are based on a single patient, making it difficult to draw general conclusions about the effectiveness of soy-based formula for all infants with CMPA. A larger cohort would be needed to validate these observations. Without a control group, it is not possible to directly compare the clinical outcomes and effectiveness of different formula types. The lack of family history due to adoption also limits genetic insights into allergic predisposition. Despite these limitations, this case highlights the potential role of isolate soy protein formula in managing CMPA in an Indonesian infant. Large-scale, controlled studies are needed to confirm its long-term safety, effectiveness, and suitability in similar populations. This case provides a practical, real-world example of managing suspected CMPA in an infant, helping paediatricians and nutritionists understand potential treatment options. The inclusion of dietary fibre in the formula may have contributed to improved gut health and stool consistency, an aspect often overlooked in CMPA management. In addition, this case emphasizes early recognition of formula intolerance and timely dietary adjustments, which are crucial in preventing severe dehydration and malnutrition in infants. While the short-term improvement in this case supports the use of isolate soy protein with dietary fibre formula in managing CMPA, the long-term effects of this intervention must be carefully evaluated through extended follow-up and larger studies to confirm the growth, metabolic, and allergy-related outcomes of this intervention, particularly in populations with high soy consumption like Indonesia.

CONCLUSIONS

The use of soy isolate protein formula with additional fibre in this case suggests a beneficial effect to improve gastrointestinal function such as improved bowel movements and stool consistency, which are crucial for the overall health and development of infants. Further research and clinical trials are necessary to explore the broader applications and positive effects of soy protein isolate formulas with dietary fibre usage in paediatric nutrition in long term.

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CONFLICT OF INTEREST AND FUNDING DISCLOSURE

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AUTHOR CONTRIBUTIONS

M.F., C.D., T.S., and D.P. involved in conceptualization; T.S., D.P., F.D.E., and E.K. writing the original draft preparation; M.F., C.D., T.S., D.P., and E.K. review and editing of the manuscript. Each author has read and approved the final version for publication.

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