


Is Saccharomyces boulardii Really Safe?

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Saccharomyces boulardii is a nonpathogenic yeast isolated from the skin of lychees grown in Indochina that has been widely prescribed in the last 30 years for prophylaxis and treatment of bacterial diarrhea [1,2].

Hypersensitivity reactions to S boulardii are rare, and, to the authors’ knowledge, only 2 cases have been reported in the literature [3,4].

We present a case of an exclusively breastfed 2-month-old girl, who presented with blood and mucus in stool. Enteritis (viral and bacterial) was excluded, and the mother was advised to begin a dairy-free diet. However, blood and mucus persisted despite the change to the mother’s diet. Rectosigmoidoscopy with biopsy revealed nodular lymphoid hyperplasia and histopathologic evidence of colitis characterized by edematous and hemorrhagic focal areas with eosinophil infiltration (more than 6 per high-power-field) and occasional lymphoid nodes, suggesting a diagnosis of allergic colitis. We therefore reinforced the importance of a dairy-free diet while breastfeeding.

The patient was a healthy, full-term infant delivered by cesarean birth, with normal growth for age. Blood and mucus persisted in stool, albeit at a lower intensity. At 3 months, the infant began to produce watery stool. S boulardii (UL 250 sachets) was prescribed. The child began to vomit profusely approximately 2 hours after ingestion, with spontaneous resolution within a few hours. Three weeks later, as gastrointestinal symptoms persisted (intermittent watery stools with blood and mucus), she was again treated with S boulardii, 2 hours after which she experienced an episode of uncontrollable vomiting, with severe prostration. She was seen at the emergency department, where she received replacement fluid therapy. The vomiting resolved on the same day, and no other signs of infection were observed.

At that time, she was referred to our Immunology Department. Skin prick tests and specific IgE for milk, casein, α-lactalbumin, and β-lactoglobulin were negative. We diagnosed non-IgE-mediated cow’s milk allergy and

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reinforced the importance for both mother and infant of a dairy-free diet. Cow’s milk was successfully introduced to the patient’s diet at the age of 12 months.

Despite the suspicion of *S. boulardii* hypersensitivity reactions, the parents refused an oral challenge test with this probiotic because their child had tolerated another probiotic (*Lactobacillus reuteri*).

*S. boulardii* is considered a safe probiotic, although hypersensitivity reactions—while rare—can occur [3,4].

The patient we report presented symptoms indicative of gastrointestinal allergy, such as that occurring in food protein-induced enterocolitis syndrome (FPIES), as in a previously published case of hypersensitivity to *S. boulardii* [3]. We excluded a possible IgE-mediated reaction owing to the absence of associated classic allergic skin or respiratory manifestations and the late onset of the reaction [4,5].

FPIES is a non-IgE-mediated food allergy characterized by profuse vomiting accompanied by pallor and lethargy within 1 to 4 hours (usually 2 hours) after ingestion of the offending food. It also can be followed by diarrhea in 5 to 8 hours in some patients and may last for up to 24 hours after exposure [5,6].

The diagnosis is based on the clinical history, recognition of clinical symptoms, exclusion of other etiologies, and a supervised oral challenge test. Although the challenge test is considered the gold standard, a history of severe, repeated reactions in a patient who becomes asymptomatic after elimination of the suspected culprit is sufficient to make a diagnosis [5,6].

We assessed causality in this suspected adverse drug reaction using the probability scale of Naranjo [7], in which a score of 10 was obtained, indicating a definitive diagnosis. Even though the patient’s parents refused an oral challenge test, the Naranjo score supports the link between exposure to *S. boulardii* and FPIES-like reaction [7].

According to international consensus guidelines [5], the major criterion and at least 3 minor criteria must be met for the diagnosis of FPIES. Our patient experienced profuse vomiting 2 hours after ingestion of *S. boulardii* and, when re-exposed, experienced a second episode of repetitive vomiting with extreme lethargy and need for replacement fluid therapy in the emergency department, thus fulfilling the requirements for the diagnosis of FPIES-like reaction. Based on the convincing clinical history with a repeated reaction to the same drug, complete resolution over a matter of hours, and the absence of infectious gastroenteritis, the reaction we describe can be considered an FPIES-like allergic reaction caused by *S. boulardii*.

We hope that our findings raise awareness of possible hypersensitivity reaction to *S. boulardii*.

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**Conflicts of Interest**

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**References**


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