

Gastrointestinal Tolerance of an Amino Acid-Based Formula in Children After a Formula Switch: A Retrospective Study

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INTRODUCTION

- Amino acid-based formulas (AAF) are recommended for children who cannot tolerate intact or hydrolyzed protein due to cow's milk protein allergy, protein malabsorption, severe food allergies, short-bowel syndrome, eosinophilic gastrointestinal (GI) disorders or other conditions in which an amino acid-based diet is required.¹
- When specific AAFs are out-of-stock due to product recall or supply issues, clinicians need to be confident that switching to an alternate AAF will continue to support growth and tolerance in their patients.
- The aim of this real-world data study was to describe GI intolerance symptoms in children before and after switching from one AAF to another AAF, due to a formula recall.

METHODS

- Retrospective analysis of USA claims data from the Decision Resources Group Real World Evidence Data Repository² for patients treated between June 2021- April 2023
- Patient and clinical characteristics were analyzed in children 1-13 years who initially received a recalled AAF as their baseline formula, and switched to the study formula, Alfamino Junior (Nestlé HealthCare Nutrition, USA), in post-acute care settings (home care).
- GI intolerance data was reported for the 6-months pre-switch and 3-months post-switch periods, where switch was defined as the date of switch to the study formula. GI intolerance percentages were compared using the Chi-square test.

RESULTS

- 297 children aged 1-13, with a mean age of 5 years (SD: 3.3 years).
- 52% of children were 1-3 years and 60% were male from across the USA (Table 1)
- Within three months post-switch from the baseline enteral formula to the study formula, significantly fewer children experienced any GI intolerance symptoms (20%, N=59) compared with pre-switch (36%, N=108) (p<0.001).
- Overall, in those experiencing intolerance, significant reductions in abdominal distention, constipation, diarrhea, flatulence, and nausea/vomiting were observed within 3-months post-switch compared with pre-switch (p<0.05).
- Constipation and nausea/vomiting were the two most common intolerance symptoms reported, with over 16% of the study population noting these symptoms pre-switch and approximately 10% post-switch (Figure 1)

References: 1. Hulsey A, et al. 2022. J Clin Nutr Diet Vol.8 No.8:181. 2. Decision Resources Group (DRG) Real World Evidence US Data Repository.

Switching from one amino acid-based enteral formula to another was effective, with improved tolerance in 45% of community-based children

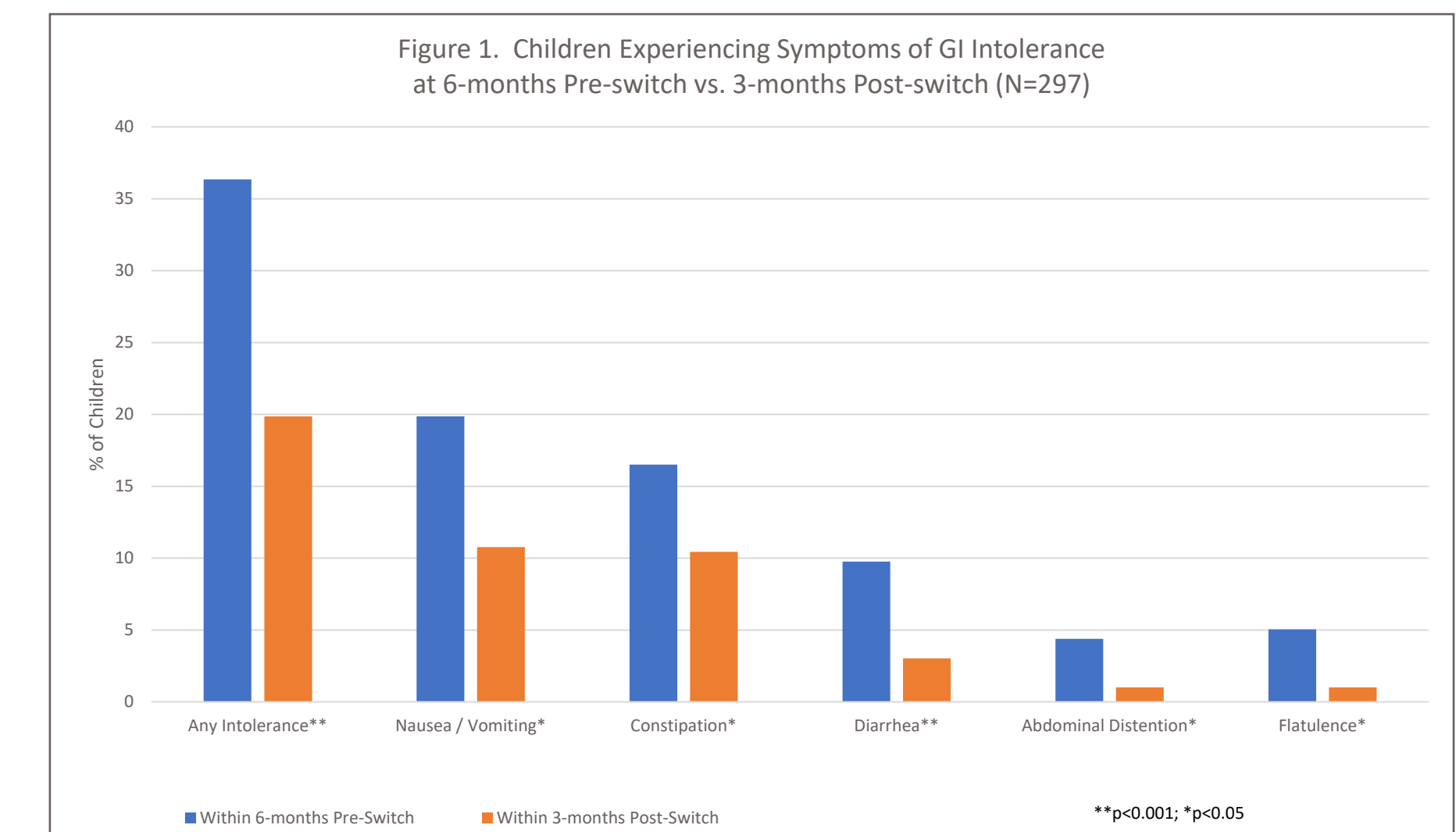
Presented at ASPEN 2024 Nutrition Science & Practice Conference, March 2-5. Tampa FL.

DISCUSSION / CONCLUSION

- This retrospective study found that post-acute care children successfully transitioned from one AAF to the study AAF, and almost half of the children with any GI intolerance had improved tolerance symptoms with the study enteral formula.
- Significant reductions in GI intolerance symptoms including abdominal distention, constipation, diarrhea, flatulence, and nausea/vomiting were reported within 3-months post-switch to the study enteral formula

Table 1: Demographic Characteristics

Age Group (Years)	#	MEAN (SD) - (YEARS)	%
TOTAL	297	5 (3.3)	-
1-3 Years	153	2.4 (0.8)	52%
4-8 Years	102	6.4 (1.3)	34%
9-13 Years	42	11.3 (1.5)	14%
Gender	#	MEAN (SD)	%
Female	119	-	40%
Male	178	-	60%



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