Study Summary: TRANSITION of AAF DURING FORMULA SHORTAGE: IMPACT ON CLINICAL OUTCOMES

TRANSITION OF HYPOALLERGENIC AMINO ACID FORMULAS DURING THE INFANT FORMULA SHORTAGE: IMPACT ON CLINICAL OUTCOMES

Cekola P., Boccella J., Desai A., et al. JPGN 2023; 77(1): A 761, S552-553

Background

In February 2022, Abbott Nutrition issued a voluntary recall of their powdered infant formulas, which led to formula shortages in which children with specialized nutritional needs required alternative formulas, including amino acid-based formulas (AAF). [1]

AAF are hypoallergenic nutritionally complete formulas that are recommended for children with cow's milk protein allergy, children with multiple food allergies or those who experience an anaphylactic reaction to a food protein. AAF with medium chain triglycerides (MCT) are also recommended for infants with fat malabsorption or maldigestion.

Objective

This study compared gastrointestinal (GI) and allergy symptoms in children before and after switching between two AAF during the formula shortage.

Study Design

A retrospective study using nationally representative US claims data obtained from the Decision Resources Group Real World Evidence Data Repository (Clarivate), which covers 98% of US health plans, including medical and pharmacy claims. Patient characteristics, comorbidities, and clinical outcomes were assessed in children ≤ 18 years; with a history of receiving EleCare® or EleCare® Jr formulas (AAAF, Abbott Nutrition, US) and having switched to Alfamino® Infant or Alfamino® Junior formulas (NAAF, Nestlé HealthCare Nutrition, US); in postacute care settings between June 2021 and April 2023

Methods

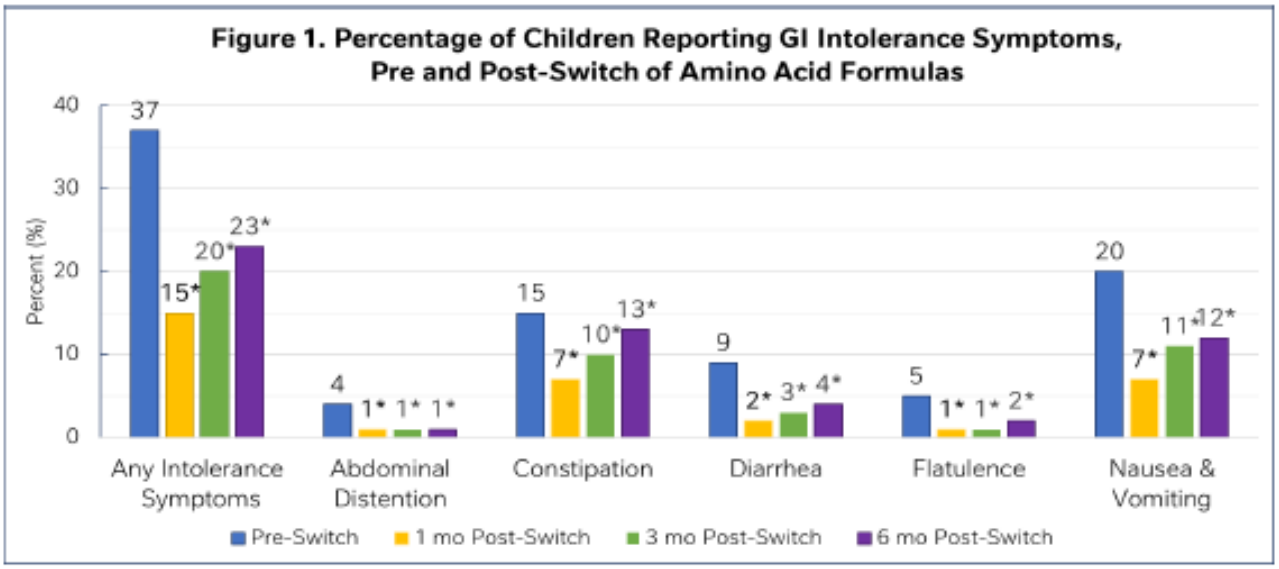
The index date was defined as the date when patients switched from AAAF to NAAF. The pre-switch period was defined as 6 months prior to the index date. Post-switch periods were 1 month, 3 months and 6 months after the index date. GI intolerance and allergy symptoms at pre- and post-switch periods were compared using a Chi-square test.

Significantly fewer reported **GI intolerance** and **allergy symptoms** in children that **switched amino acid formulas** during nationwide formula shortage

Results

402 patients aged 0-18 years from all US regions; mean (standard deviation [SD]) age was 5.3 (4.7) years. Most common comorbidities pre-switch were GI conditions (51%), congenital conditions (49%) and developmental delays (27%). In 355 patients (88%) with ≥1 comorbidity, the mean (SD) pediatric comorbidity index (PCI) score was 4.8(3.4).

Significantly fewer children experienced any GI intolerance symptoms at 1 month, 3 months and 6 months post-switch (AAAF to NAAF), compared with pre-switch ($p < 0.001$). Significant reductions in percent of children reporting abdominal distention, diarrhea, flatulence, and nausea & vomiting were observed at all time-periods post-switch compared with pre-switch ($p<0.05$). **Figure 1**



*Chi-square test (pre- vs post-switch), alpha=0.05 level of significance

Table 2. Children Reporting GI Intolerance of Allergy Symptoms Pre- and Post-Switch of Amino Acid Formulas

	Pre-Switch	1 Month Post-Switch	p-Value†	3 Months Post-Switch	p-Value†	6 Months Post-Switch	p-Value†
Allergy Symptoms‡							
Any Allergy Symptom	20%	12%	**<0.001**	13%	**0.008**	15%	**0.033**
Anaphylaxis	2%	0%	0.094	1%	0.203	1%	0.203
Atopic Dermatitis	3%	1%	0.086	2%	0.507	3%	0.832
Eczema	1%	0%	0.255	0%	0.255	1%	0.737
Hives	1%	0%	**0.025**	0%	**0.025**	0.25%	0.101
Other Allergic Reactions	15%	10%	**0.019**	11%	0.075	11%	0.095
Rash	2%	0%	0.056	2%	1	3%	0.486

† Significant difference pre- vs post-switch shown in bold.
‡ Chi-square test (pre- vs post-switch), alpha=0.05 level of significance.
GI, gastrointestinal.

At 1 month, 3 months and 6 months post-switch, significantly fewer patients experienced any allergy symptoms compared with pre-switch ($p<0.05$). Allergies in the categories of hives and other allergic reactions showed significant reductions only at 1 month post-switch. **Table 2**

Conclusion

This study found that children in post-acute care settings successfully transitioned from AAAF (Elecare®) to NAAF (Alfamino®) Infant or Junior products with significantly fewer reported allergy symptoms and GI intolerance symptoms, including abdominal distention, constipation, diarrhea, flatulence, and nausea & vomiting up to 6 months post-formula switch.

During the nationwide powdered formula shortage, children who transitioned from AAAF to NAAF, showed significantly fewer GI intolerance and allergy symptoms. These findings suggest potential clinical benefits with a change from AAAF to NAAF.

References : *(1) The White House. 2022. FACT SHEET: President Biden Announces Additional Steps to Address Infant Formula Shortage. May 12, 2022; <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/fact-sheet-president-biden-announces-additional-steps-to-address-infant-formula-shortage; (2) Cekola P et al. (2023) NASPGHAN. Oct 4-7;77(1), S552*

Study summary prepared by Nestlé Healthcare Nutrition.

The poster presented at NASPGHAN 2023 may be accessed online: NASPGHAN Abstract 761

The complete abstract may be accessed online: NASPGHAN 2023.pdf (lww.com)