Transition Of Hypoallergenic Amino Acid Formulas During The Infant Formula Shortage: Impact On Clinical Outcomes

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BACKGROUND

- Amino acid-based (AA) formulas are hypoallergenic formulas that provide complete nutrition and are recommended for children with cow's milk protein allergy, multiple food allergies or those who experience an anaphylactic reaction to a food protein.
- AA formulas that contain medium chain triglycerides are also recommended for infants and children with fat malabsorption or maldigestion.
- In February 2022, Abbott Nutrition issued a voluntary recall of their powdered infant formulas[1] in the US. This led to formula shortages in which children with specialized nutritional needs were required to switch to alternative formulas.

OBJECTIVE

- This study compared gastrointestinal (GI) and allergy symptoms in children before and after switching between AA formulas during the formula recall.

METHODS

- This retrospective study (June 2021 to April 2023) used nationally representative US claims data from the Decision Resources Group Real World Evidence Data Repository (Clarivate). This covers 98% of US health plans, including medical and pharmacy claims.
- Patient characteristics, comorbidities and clinical characteristics were analyzed in children aged ≤18 years, in post-acute care, who initially received EleCare® or EleCare® Jr formulas (AAAF; Abbott Nutrition, US) and switched to Alfamino® Infant or Alfamino® Junior formulas (NAAF; Nestlé HealthCare Nutrition, US). These formulas provide complete nutrition and have similar nutrient profiles and osmolality, while presenting relevant differences in MCT content (AAAF: 33%, 33%; NAAF: 43%, 65% in Infant and Jr formulations, respectively).
- GI intolerance and allergy symptoms at pre-index and post-index were outcomes of interest. Index date was defined as the date of switch to NAAF. 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. Outcomes at pre- and post-switch periods were compared using a Chi-square test.

RESULTS

- Study included 402 children (40% female; mean [standard deviation (SD)] age 5.3 [4.7] years) from all US regions, that switched from AAAF to NAAF **(Table1).**

Table 1. Patient Characteristics (n=402)

Age†	N (%)
0-1 Year	49 (12)
1-3 Years	174 (43)
4-8 Years	102 (25)
9-13 Years	43 (11)
14-18 Years	34 (8)
Gender, Male	243 (60)
Region	
Midwest	73 (18)
West	98 (24)
South	174 (43)
Northeast	57 (14)
Comorbidities	
GI Conditions	205 (51)
Congenital Malformations	198 (49)
Developmental Delays	107 (27)
Pediatric Comorbidity Index, Weighted Score ≥ 4	196 (49)

† Age was calculated at the index date.

RESULTS (cont.)

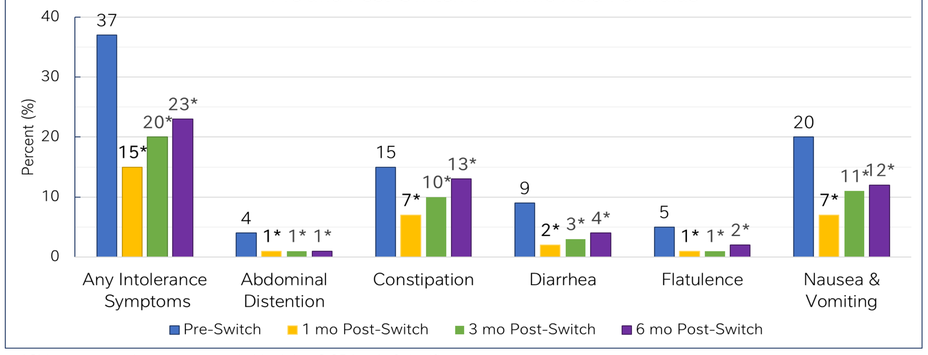
- The most common comorbidities pre-switch were GI conditions (51%), congenital conditions (49%) and developmental delays (27%).
- Among 355 patients (88%) with ≥1 comorbidity, the mean (SD) pediatric comorbidity index (PCI) score was 4.8 (3.4). Nearly half of children (49%) had PCI score of ≥4.
- Significantly fewer children experienced any GI intolerance symptoms at 1 month, 3 months and 6 months post-switch (AAAF to NAAF), compared with pre-switch ($p<0.001$) **(Figure 1).**
- Significant reductions in the percent of children reporting abdominal distention, diarrhea, flatulence, and nausea & vomiting were observed at all time-periods post-switch compared with pre-switch ($p<0.05$).
- At 1 month, 3 months and 6 months post-switch, significantly fewer patients experienced any allergy symptoms compared with pre-switch ($p<0.05$) **(Table 2).**
- A significant reduction in the percentage of children reporting hives and other allergic reactions was observed only at 1 month **(Table 2).**

CONCLUSIONS

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.

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

Figure 1. Percentage of Children Reporting GI Intolerance Symptoms, Pre and Post-Switch of Amino Acid Formulas



*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.

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REFERENCES

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