663* *GROWTH AND TOLERANCE OF PEDIATRIC PATIENTS TRANSITIONED FROM A HYPOALLERGENIC FORMULA TO A PEA PROTEIN PLANT-BASED FORMULA.*

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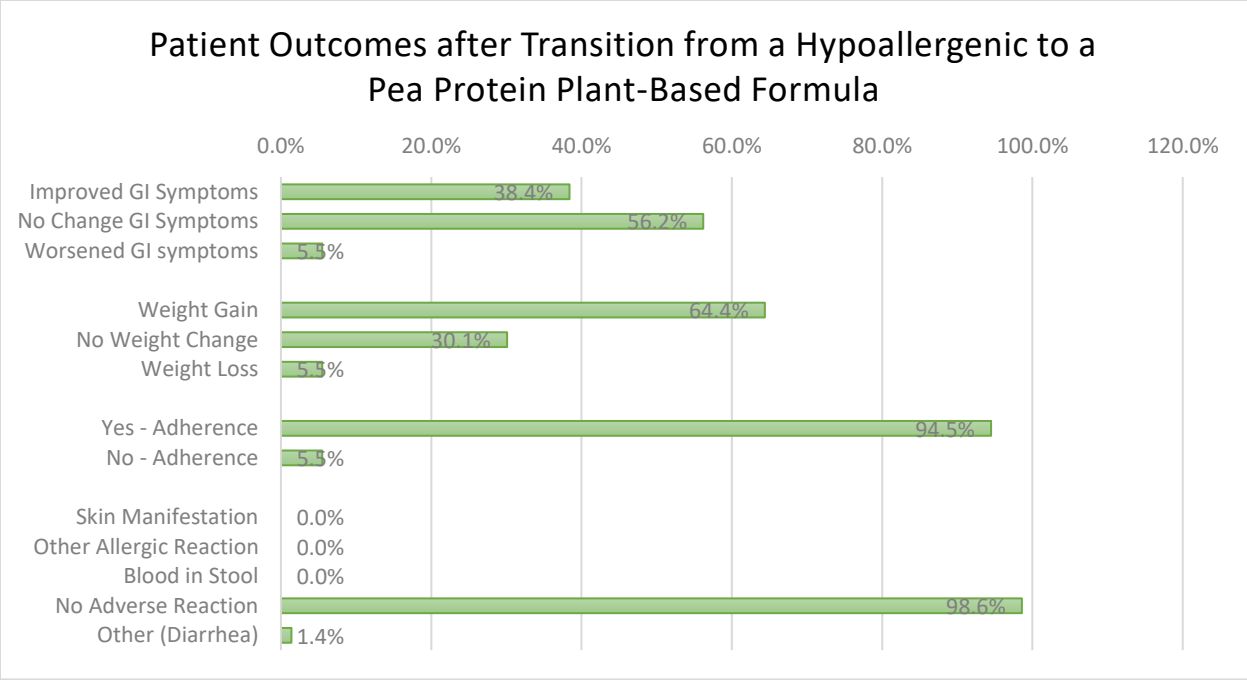
Background:
Research remains conflicted regarding the use of hypoallergenic versus peptide-based versus polymeric enteral formulas for optimal tolerance. No clinical consensus exists on when to use a hypoallergenic formula, outside of use in those with a cow's milk protein allergy (CMPA). Considerations for use can include clinical status, medical diagnosis, nutritional diagnosis, and the formula composition. In recent years, formulas composed of protein from yellow pea have emerged as an option for those with CMPA or other food allergies. Pea- protein plant-based formulas (PPPBF) provide a source of protein from intact or partially hydrolyzed (peptide) pea protein. To date there are no clinical studies examining clinical safety and efficacy of transitioning patients from a hypoallergenic formula to a PPPBF.

Methods:
This was a retrospective review of electronic medical records (EMR). Inclusion criteria consisted of pediatric patients 1-18 years old, transitioned from a hypoallergenic formula to PPPBF manufactured by Kate Farms™: Pediatric Peptide 1.0, Pediatric Peptide 1.5, or Pediatric Standard 1.2 within the past 12 months, oral or tube fed, supplemental or sole source nutrition, and who had progress notes available at required time points. De- identified data for individual patients was entered by the prescribing clinician into a REDcap survey of 23 items on demographics, clinical characteristics, growth, tolerance, adherence, and adverse reactions. This study was conducted under an exempt status by the IRB.

Results:
In total, clinicians completed 79 surveys on 79 unique pediatric patients, 6 surveys were excluded prior to final data analysis. Of the 73 patient surveys used for data analysis, 41.1% were female (n=30) and 58.9% were male (n=43), and the mean age was 56+46.74 months. Two-thirds of the patients had GI intolerance to other formulas (n=25, 34.5%) or CMPA/other food allergies (n=23, 31.5%) as the primary reason for use of hypoallergenic formula. The primary reason for transitioning was previous formula unavailable (n=42, 57.5%). GI tolerance after transition to a PPPBF was improved for 38.4% of patients (n=28), no change for 56.2% of patients (n=41) and worsened for 5.5% of patients (n=4). Of those with improved GI tolerance, clinicians reported improvement in abdominal pain, reflux, diarrhea, constipation, bloating, nausea, vomiting, and/or early satiety. For those (n=4) patients with worsened GI tolerance after transition, clinicians reported diarrhea and bloating. Weight was increased in 64.4% (n=47) and decreased in 5.5% (n=4) of patients after formula transition. One third of patients had weight stability (n=22, 30.1%). Adherence was 94.5% (n=69) with patients transitioned to PPPBF; defined as receiving at least 75% of the recommended amount. Safety was assessed with report of adverse reactions; 98.6% (n=72) of patients did not experience any adverse reaction, one patient was noted to have diarrhea.

Conclusion:
This retrospective chart review demonstrated pea protein plant-based formula as a safe and effective transition formula for this cohort of pediatric patients previously receiving a hypoallergenic formula. Transition from a hypoallergenic formula to a PPPBF resulted in improved or stable GI tolerance, weight gain or stability and demonstrated adherence. Findings from this study suggest that hypoallergenic formulas may be over-prescribed for certain medical conditions. A prospective clinical study is warranted to describe patient populations in which transition to PPPBF is effective and even preferred, and to further assess safety of this formula transition.

Al-Tawil Y, Ryan E, Patterson PJ, Wilson M, Millovich V. Growth and tolerance of pediatric patients transitioned from a hypoallergenic formula to a pea-protein plant-based formula. JPGN.2022;75(S1):S482-483



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