Apples to Osmoles? Differences in Osmolality Reporting for Enteral Formulas and Implications for Clinical Interpretation

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BACKGROUND

- Osmolality, the concentration of free particles per kg/H_2O[1], is a commonly reported characteristic of enteral nutrition (EN), with typical values between 280-875 mOsm/kg H_2O (Figure 1)
- Micro- and macronutrients, including from fruit and vegetable ingredients, contribute to EN osmolality[2]
- Despite the perception that hypertonic EN (i.e., >320 mOsm/kg H_2O), contributes to gastrointestinal (GI) symptoms, existing literature, GI physiology and clinical experience do not support the notion that higher EN osmolality alone causes GI intolerance/diarrhea[1,3,4]
- Yet, clinicians often utilize reported osmolality as one criterion when choosing EN, particularly for patients transitioning to peptide formulas, previously intolerant to standard EN
- However, variability of osmolality analytical methodologies and reporting practices across the EN industry may limit clinical relevance and utility of osmolality comparisons

OBJECTIVE

- This study aimed to compare osmolality of common pediatric and adult peptide-based EN formulas using standard methodologies[5-8] to assess variability across formulas with different ingredients, caloric densities, and manufacturers

METHODS

- Nine commercially available pediatric and adult plant-based peptide-based (PBP) formulas were identified:
  - FV-PBP: including fruit and vegetable ingredients (Compleat® Peptide formulas, Nestlé Healthcare Nutrition, US); n=4
  - W-PBP: without fruit and vegetable ingredients (Kate Farms® Peptide formulas, Kate Farms Inc, US); n=5
- Measured osmolality was determined using vapor pressure osmometry (Vapro® Vapor Pressure Osmometer, Wescor Model 5600)[5-8] (Figure 2):
  - Recommended for products with osmolality 100-3,000 mOsm/kg H_2O or increased viscosity
  - Adopted as an industry standard for medical foods internationally[6]
- Samples were tested in triplicate with averages compared to osmolality values published on manufacturer websites
- While not standard practice, samples diluted 1:1 with 200 mOsm/kg H_2O NaCl solution were measured to assess impact of dilution based on prior reporting[8]

RESULTS (FIGURE 3 AND 4)

- For FV-PBP, measured osmolality was 0.08-2.4% higher and 4-4.7% higher for pediatric and adult formulas, respectively
- For W-PBP, measured osmolality was 109-163% higher and 52-100% higher for pediatric and adult formulas, respectively
- Use of diluted samples increased the variability for FV-PBP but decreased variability for W-PBP to 32-49.3% and -1.8 to +9.8% for pediatric and adult formulas, respectively
- Differences in measured versus published osmolality were greater for products with higher caloric density

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Variability in osmolality analytical methodology and reporting practices underscore the need for standardization and clinician awareness

Figure 1. Basics of Osmolality

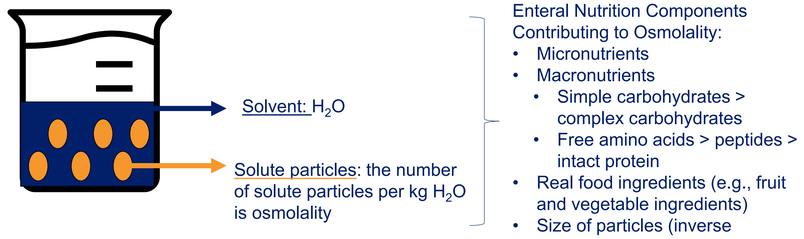


Figure 2. Basic Schematic of Vapor Pressure Osmometry (VPO)

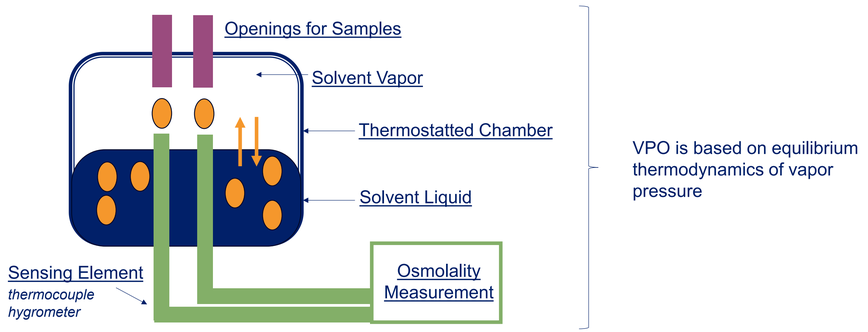


Figure 3. Comparison of Published Osmolality to Measured and Diluted Osmolality
Plant-Based Peptides

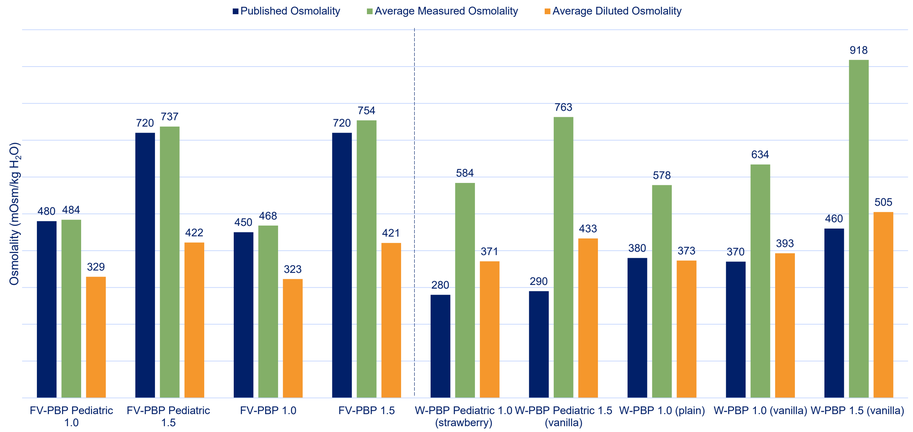


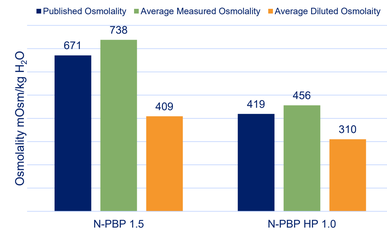
Figure 4. Percent Difference Between Published, Mean and Diluted Osmolality

	% Difference between Published and Mean Osmolality	% Difference between Published and Diluted Osmolality		% Difference between Published and Mean Osmolality	% Difference between Published and Diluted Osmolality
FV-PBP Pediatric 1.0	+0.08%	-31%	W-PBP Pediatric 1.0 (strawberry)	+109%	+32%
FV-PBP Pediatric 1.5	+2.4%	-41.4%	W-PBP Pediatric 1.5 (vanilla)	+163%	+49.3%
FV-PBP 1.0	+4%	-28.2%	W-PBP 1.0 (plain)	+52%	-1.8%
FV-PBP 1.5	+4.7%	-42%	W-PBP 1.0 (vanilla)	+71%	+6.2%
			W-PBP 1.5 (vanilla)	+100%	+9.8%

POST-HOC SECONDARY ANALYSIS AND RESULTS

- A post-hoc secondary analysis was performed using the same methodology as described to evaluate non-plant-based peptide formulas (N-PBP) (Abbott Nutrition; Vital® 1.5 and Vital® HP 1.0)
- For N-PBP, measured osmolality was 8.8 (N-PBP HP 1.0) to 10% (N-PBP 1.5) higher than published osmolality
- Use of diluted samples increased the variability, -39 (N-PBP 1.5) to -26% (N-PBP HP 1.0)

Figure 5. Comparison of Published Osmolality to Measured and Diluted Osmolality
Non-Plant-Based Peptides



DISCUSSION

- Notable differences were observed for W-PBP, with measured osmolality more than two-times (≥100%) higher than published osmolality values in three of five samples
  - Although minor discrepancies may be expected due to analytical variability, formula homogeneity, storage conditions, and changes that may occur over the shelf life, differences of 200-400 mOsm/Kg H_2O would not be anticipated; diluted osmolality narrowed discrepancies but does not represent formula as fed
- For FV-PBP, measured osmolality compared to published osmolality was within 5% for all formulas, suggesting good agreement
- In a post-hoc secondary analysis, measured osmolality compared to published osmolality was within 10% for non-plant-based peptide formulas

CONCLUSIONS

- This analysis underscores the need for standardized methodology and reporting practices to enable meaningful comparisons of osmolality across EN formulas
- Clinicians should remain aware of these differences when using osmolality as a criterion for EN formula selection

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