

## Osmolality and pH in handmade enteral diets used in domiciliary enteral nutritional therapy

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### Abstract

Patients who need prolonged domiciliary enteral nutritional therapy may benefit from handmade diets. However, the preparation of such diets might cause insecurity with regard to their nutritional composition and physical-chemical properties. Current study analyzes the osmolality and Hydrogen-Ion concentration (pH) on handmade enteral diets. To this purpose, six formulas and two juices, prescribed on discharge from hospital, were analyzed physically and chemically. Osmolality and pH were respectively determined by cryoscopy and potentiometry. Most formulations were classified as isosmolar (with less than 400 mOsm/kg solvent), and only one was classified as slightly hyperosmolar, with rates ranging from 356.7 to 403.5 mOsm/kg solvent. On average, the standard formula presented higher osmolality than similar ones prepared for hyperglycemia. Among the juices, only one registered hyperosmolar concentration of 595.54 mOsm/kg solvent. All formulas presented pH rates classified as low acidity, ranging between 6.1 and 6.6, while the two juices had the lowest results, 4.73 and 4.66 each. The blend of ingredients used in handmade formulas and juices studied presented acceptable osmolality and pH rates for a safe administration and absence of gastrointestinal complications. Data showed here are consistent with an appropriate and healthy diet and contributed towards success in domiciliary enteral nutritional therapy.

**Keywords:** enteral nutrition; osmolar concentration; hydrogen-ion concentration (pH); food and nutrition safety.

**Practical Application:** This work evaluates physical-chemical markers of handmade enteral diets, important for its stability and for the success of enteral nutrition therapy.

### 1 Introduction

Domiciliary enteral nutritional therapy (DENT) is tube feeding within a domiciliary setting (De Luis et al., 2013), (Van Aanholt et al., 2011), prescribed for patients who are unable to comply to their nutritional needs orally, but who have an intact gastrointestinal tract (De Luis et al., 2013; Moreira et al., 2010). The method has a satisfactory cost-benefit ratio since it avoids infections due to extended hospitalization, with significantly low costs when compared to hospital nutritional therapy (Elia & Stratton, 2008). Moreover, it allows the patient to live with family members, besides having cultural benefits since the diet is prepared at home with conventional foods, featuring better tolerance, more comfort and improved life quality (Hurt et al., 2015). These factors contribute towards ensuring the right to healthy feeding to people with special feeding needs, as recommended in the guidelines of the Brazilian National Food and Nutrition Policy (PNAN) and National System on Food and Nutritional Safety (SISAN) (Brasil, 2012, 2011).

On discharge from hospital, patients who need prolonged DENT may benefit from non-industrialized enteral nutrition, or rather, from handmade or semi-handmade diets (Santos et al., 2013). These formulas are made with *in natura* food commonly used at home, with or without nutritional modules and food

products (Brasil, 2000). They usually have a lower cost when compared to industrialized ones. However, the ingredients and the preparation of these diets might cause a certain insecurity with regard to their nutritional composition and physical-chemical properties (Araújo & Menezes, 2006).

Thus, an important parameter that must be analyzed in non-industrialized diets is the number of osmotically active particles in the solutions, defined by osmolality: - expression of osmotic power of a solution measured in milli-osmols per kilogram of solvent (mOsm/kg). Osmolality is influenced by the amount of hydrolyzed nutrients in the diet, influencing the solute load, such as mono- and di-saccharides, minerals and electrolytes, hydrolyzed proteins, crystalline amino acids and medium-chain triglycerides (Halmos, 2013; Dupas-Langlet et al., 2013). Its analysis is important to assess the physiological acceptance capability of the diet and to avoid complications (Barrett et al., 2009).

Another essential physical-chemical characteristic to the stability of handmade enteral diets is the Hydrogen-Ion concentration (pH) whose control contributes towards the stability and flow control of the diet at the time of infusion,

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by providing a solubility environment to the nutrients. It is also crucial for the microbiological control of the solution (Klang et al., 2013; Pinto et al., 2015). Non-industrialized enteral diets with a pH rate favorable to microbiological growth may be an infection vector for patients undergoing enteral nutritional therapy if preventive hygiene measures are not applied during food handling (Blumenstein et al., 2014).

Current study collaborates in the development of suitable diets for food prescriptions after hospital discharge and contributes towards food safety and nutrition of vulnerable population groups.

## 2 Material and methods

Current cross-section study determined osmolality and pH in handmade enteral diets, including the influence of sodium and potassium as physical-chemical indicators in the rise of osmotic load.

Six handmade enteral diets were analyzed, each comprising an enteral formula and juice, developed by our research group (Jansen et al., 2014), and prescribed to patients for home enteral nutrition therapy within the local public health system.

The diets were classified as: 1) standard diet (SD), with no nutrient restrictions and 2) hyperglycemia diet (HD), without the addition of sugar, and featured three different caloric levels, or rather, 1500, 1800 and 2100 kilocalories (Kcal). Chart 1 describes the diets which were based on the daily nutritional needs of a male adult weighing 70 kg and aged between 51-70 years. Rates were normocaloric, normoproteic, normoglycidic and

normolipidic, recommended by the Dietary Reference Intakes (DRI) (Institute of Medicine, 2006).

For the analysis of osmolality and pH, the ingredients were previously weighed with a BS3000A electronic scale (Bioprecisa™ - São Paulo, Brazil), maximum capacity 3 kg/0.1g and separated in identified recipients to facilitate preparation. Ingredients needing previous preparation or cooking, such as potatoes, eggs, oranges and carrots, were first cleaned, weighed and, in the case of vegetables, sanitized. Vegetables were washed under tap water, unit by unit, to remove residues and dirt. They were then immersed in a solution of 200 ppm chloride, suitable for food, for 20 minutes, following the manufacturer's instructions. The eggs were rinsed under tap water.

Potatoes and eggs were cooked separately: eggs were cooked for approximately 5 minutes after boiling point so that the yolk would have a firm consistency. Cinnamon was roasted in a medium fire for 3 minutes to eliminate eventual contamination. Liquids, such as milk and oils, were separated in volumetric cups. Ingredients were weighed, mixed and blended in a mixer until a homogeneous solution was obtained.

Since the juice in all diets has similar technical specifications with regard to amount of oranges and carrots and differed solely in the addition of the carbohydrate source (sugar or maltodextrin), only the juice presented in the 1800 Kcal SD and HD diets was prepared and analyzed, since it is the intermediary result from all caloric levels. Oranges were processed in an electric juicer for the extraction of the juice which was blended with the other ingredients, according to the recipe.

**Chart 1.** Formulation of handmade enteral diets studied.

Ingredients	Standard Diets (SD)			Hyperglycemia Diets (HD)		
	1500 Kcal	1800 Kcal	2100 Kcal	1500 Kcal	1800 Kcal	2100 Kcal
	<b>Formulas</b>					
Full fat milk (ml)	-----	500	500	-----	500	500
Skimmed milk (ml)	1000	500	500	1000	500	500
Egg (g)	45 (2x /week)	45 (2x /week)	45 (2x /week)	45 (2x /week)	45 (2x /week)	45 (2x /week)
Pure powder albumin (g)	17 (5x /week)	17 (7x /week)	29 (7x /week)	12 (7x /week)	17 (7x /week)	29 (5x /week) 23 (2x /week)
Oatmeal flour (g)	45	45	50	45	45	45
Enriched rice cream (g)	50	55	55	55	55	55
Potato (g)	280	280	280	280	280	280
Brazil nuts (g)	2	2	2	2	2	2
Canola oil (ml)	26	26	26	26	26	26
Soybean oil (ml)	13	13	26	13	13	26
Corn-based commercial cereal* (g)	5	15	25	5	15	15
Cinnamon powder (g)	12	12	12	12	12	12
Cristal sugar (g)	14	28	28	-	-	-
Maltodextrin without glucose (g)	-	-	-	25	25	50
Iodized salt (g)	2	2	2	2	2	2
	<b>Juice</b>					
Carrot, raw (g)	55	55	55	55	55	55
Bitter orange, juice (g)	180	180	180	180	180	180
Crystal sugar (g)	-----	14	28	-	-	-
Maltodextrin without glucose (g)	-	-	-	-----	17	33

\*Ingredients of enriched corn-based commercial cereal: corn flour, sugar, enriched with iron, phosphorous, calcium, zinc, folic acid, niacin, vitamins A, D, E, C, B1 and B6.

A total of three 80 mL samples were performed from each formula and juices. They were frozen at  $-20\text{ }^{\circ}\text{C}$  and analyzed in triplicate after samples were defrosted at room temperature.

Further, pH measurements were performed immediately before the cryoscopy trials by potentiometry, using a benchtop Tecnal<sup>™</sup> pH-meter TEC-2pH (Tecnal<sup>™</sup> – Piracicaba, SP, Brazil), precision 0.1 pH units, calibrated according to manufacturer's instructions, using standard solutions with pH = 4 and pH = 7. Data were expressed in pH absolute units on a 0-7 (neutral to acid) and 7-14 scale (neutral to basic).

Osmolality analysis was performed by the cryoscopic method, with a PZL 900 electronic cryoscope (PZL Equipments<sup>™</sup>, Londrina, PR, Brazil). For freezing point conversion, the equation  $\Delta t_c = K_c \times m$  was used, where  $\Delta t_c$  is the cryoscopic descent (difference between the initial freezing temperature of pure solvent and initial freezing temperature of the solution),  $K_c$  is the water cryoscopic constant ( $1.86\text{ }^{\circ}\text{C/mol/Kg}$ ) and  $m$  is the molal concentration of the solute (osmolality expressed in mOsm/kg solvent) (Henriques & Rosado, 1999).

Sodium and potassium were measured as electrolytes in the diets capable of significantly increasing osmolality. They were quantified in a ICP-OES equipment, Varian (720 ICP-OES, Varian Inc<sup>™</sup>, California, USA), with the following experimental conditions: Power: 1.20 KW, Plasma flow: 15.0 L/min, Auxiliary gas flow: 1.50 L/min, Nebulizer pressure: 200 Kpa, using the following spectral lines, respectively: 589.592 nm (Na) and 766.491 nm (K) (Association of Official Analytical Chemists, 2012). Chloride was not quantified due to the lack of significant detection levels either in the formula or in the juices.

Solutions were isosmolar with less than 400 mOsm/kg solvent; slightly hyperosmolar between 400 and 550 mOsm/kg solvent; hyperosmolar with osmolality higher than 550 mOsm/kg solvent (Henriques & Rosado, 1999).

Statistical analysis of data was performed with Sisvar<sup>™</sup> 5.4 package software (Lavras – MG – Brazil). One-way analysis of variance (ANOVA) was performed to test the significance of differences ( $p < 0.05$ ) between groups. When the difference was significant, Tukey's multiple comparison range test was used as a post hoc analysis. Correlation was performed between the variables electrolytes and osmolality to evaluate their relationship (significant correlation at  $p < 0.01$ ), while a principal component analysis was used to visualize the difference between treatments.

### 3 Results

Osmolar concentration of the formulas ranged between 356.7 (11.81) and 403.5 (12.22) mOsm/kg solvent, whereas standard formula predominantly presented a higher osmolality (Table 1).

It may be observed that in the case of the osmolality of juices (Table 2), only 1800-kcal SD presented a hyperosmolar concentration ( $\geq 550\text{ mOsm/kg solvent}$ ).

The impact of the substitution of sugar by maltodextrin on osmolality is significant for all the formulas ( $p < 0.05$ ) in spite of calorie level and in the juice ( $p < 0.05$ ). Only SD 1800 kcal juice was classified as a hyperosmolar solution. All formulas and juices analyzed featured pH with low acidity, as Table 1 shows. SD 1500 and 1800 kcal formulas were more neutral than their similar HD formulas ( $p < 0.05$ ). The acidity in SD formulas was equal at all calorie levels analyzed ( $p > 0.05$ ). Significant differences were observed in HD formula between 1800 and 2100 kcal, with a trend towards increasing neutrality.

In the case of solutes with osmotic activity ( $\text{Na}^+$  and  $\text{K}^+$ ), they showed an increase in concentration directly proportional to the level of increased calorie formula (Table 1). Sodium did not show any significant difference between SD and HD formulations at the same calorie level. On the other hand, potassium presented

**Table 1.** Sodium and Potassium concentration, Osmolality, pH and classification per osmotic effect and pH scale of handmade formulations studied.

Formula	Sodium (Na) mg*	Potassium (K) mg*	Osmolality* (mOsm/kg solvent)	Classifica tion**	pH (25 °C)*	Classifica tion***
SD 1500 Kcal	1531 ± 61 <sup>a</sup>	1916 ± 105 <sup>a</sup>	372 ± 13 <sup>c</sup>	Isosmolar	6.3 ± 0.2 <sup>a</sup>	Low Acidity
HD 1500 Kcal	1645 ± 78 <sup>a,b</sup>	2283 ± 119 <sup>b</sup>	357 ± 12 <sup>a</sup>	Isosmolar	6.6 ± 0.4 <sup>b</sup>	Low Acidity
SD 1800 Kcal	1722 ± 35 <sup>b</sup>	2364 ± 121 <sup>c</sup>	392 ± 12 <sup>e</sup>	Isosmolar	6.1 ± 0.2 <sup>a</sup>	Low Acidity
HD 1800 Kcal	1714 ± 40 <sup>b</sup>	2228 ± 71 <sup>b</sup>	370 ± 13 <sup>b</sup>	Isosmolar	6.5 ± 0.5 <sup>b</sup>	Low Acidity
SD 2100 Kcal	1998 ± 31 <sup>c</sup>	2726 ± 89 <sup>e</sup>	410 ± 13 <sup>f</sup>	Slightly Hyperosmolar	6.1 ± 0.3 <sup>a</sup>	Low Acidity
HD 2100 Kcal	1994 ± 70 <sup>c</sup>	2589 ± 70 <sup>d</sup>	391 ± 12 <sup>d</sup>	Isosmolar	6.3 ± 0.3 <sup>a</sup>	Low Acidity

SD = Standard diet; HD = Hyperglycemia diet. \* Different letters in each column indicate significant difference at  $p < 0.05$ ; \*\*According to Brasil (1999); \*\*\*According to Association of Official Analytical Chemists (2012).

**Table 2.** Sodium (Na) and Potassium (K) concentration, Osmolality, pH and classification per osmotic effect and pH scale of handmade juices studied.

Formula	Sodium (Na) mg*	Potassium (K) mg*	Osmolality* (mOsm/kg solvent)	Classifica tion**	pH (25 °C)*	Classifica tion***
SD 1800 Kcal	49 ± 0 <sup>a</sup>	394 ± 3 <sup>a</sup>	596 ± 33 <sup>a</sup>	Hyperosmolar	4.7 ± 0.2 <sup>a</sup>	Low Acidity
HD 1800 Kcal	47 ± 0 <sup>a</sup>	401 ± 3 <sup>a</sup>	475 ± 31 <sup>b</sup>	Slightly Hyperosmolar	4.7 ± 0.3 <sup>a</sup>	Low Acidity

SD = Standard diet; HD = Hyperglycemia diet. \* Different letters in each column indicate significant difference at  $p < 0.05$ ; \*\*According to Brasil (1999); \*\*\*According to Association of Official Analytical Chemists (2012).

a significantly lower concentration in hyperglycemia diet when compared to standard diet, regardless of calorie level.

When correlations were established between sodium and potassium concentrations and osmolality (Figure 1 and 2), the two electrolytes, present in significant amounts in the formulas, were capable of influencing osmolality. Significant positive correlations were found both for sodium ( $F = 18.73583$   $P = 0.000519$   $R^2 = 0.53938055$  - Figure 1) and for potassium ( $F = 15.01765$   $P = 0.001342$   $R^2 = 0.48416468$  - Figure 2). The charts in Figures 1 and 2 show very homogeneous dispersion levels and a very significant correlation for the ratio sodium/osmolality ( $r = 0.73$ ) and ratio potassium/osmolality ( $r = 0.69$ ).

Sodium concentration was very low and potassium had the same amount for SD and HD diets in the juices dispensed to complete total caloric value of diet. Osmolality is affected by total amount of solute, as Figure 3 shows.

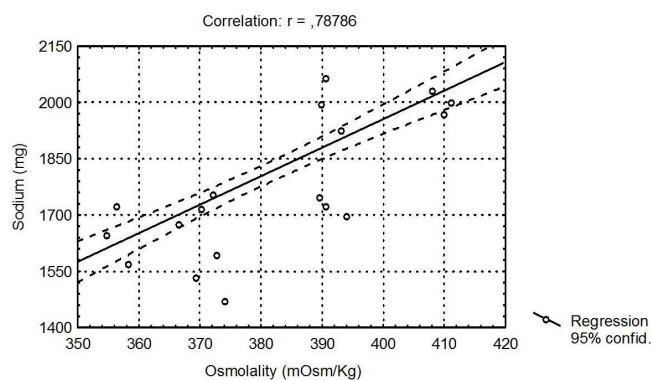
#### 4 Discussion

In current study, osmotic load curves demonstrated that the substitution of solutes, such as sucrose, by maltodextrin significantly reduced osmolality, which may be observed when SD and HD formulations are compared, regardless of calorie level.

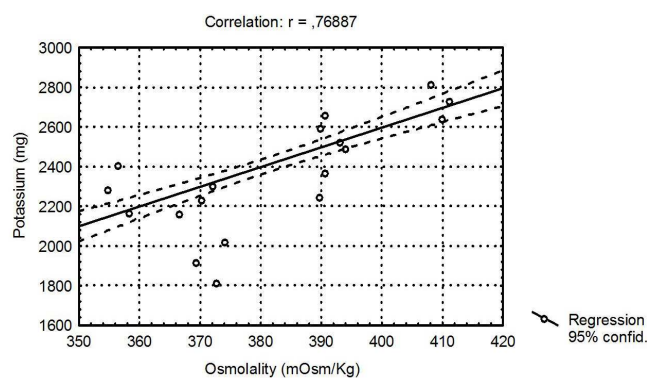
When the influence of electrolytes is analyzed, sodium, similarly to potassium, tends to significantly increase as calorie levels rise, regardless of the type of diet. In the case of sodium, this increase cannot be attributed to high amounts of table salt, which does not vary between diets and different calorie levels. Consequently and considering the very low amount of the chloride in the diets ( $< 1$  ppm), the main ions with osmotic effect were truly sodium and potassium. The addition of other components with osmotic effect in complex solutions, such as SD and HD formulations, seems to establish stationary variation ranges from a certain solute concentration. In fact, this effect has already been reported in a previous study by Henriques & Rosado (1999). The above does not apply to the juices, whose nutritional composition is simple and the change in osmolality was higher than 100 mOsm/kg.

Santos et al. (2013) analyzed the osmolality of formulas with maltodextrin between 440 and 450 mOsm/kg, a solute with lower osmotic impact than saccharose (Santos et al., 2013). Studies performed by the curve analysis built from the application of a linear regression model have shown that maltodextrin osmolality is four times lower than D-glucose (the monosaccharide that composes sucrose) (Henriques & Rosado, 1999). This result showed that the use of maltodextrin adjusts the energetic rate of carbohydrates without compromising the osmolality of diets.

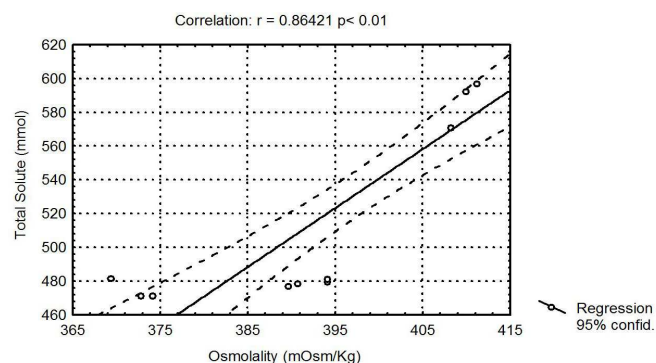
High osmolality of SD 2100 kcal formula, classified as slightly hyperosmolar, cannot be due merely to a greater amount of sucrose in the formulations, since the formulation SD 1800 kcal showed a similar concentration. Thus, electrolytes, especially potassium, cause the high osmolality of SD 2100 (Araújo & Menezes, 2006). Nonetheless, these findings do not imply in gastrointestinal complications if we consider that, mainly in domiciliary regimen, the tube's gastric positioning is the most common. The location where the diet formula will be infused



**Figure 1.** Correlation analysis between the sodium ( $\text{Na}^+$ ) concentration and osmolality in the handmade formulas studied - standard diet (SD) and hyperglycemia diet (HD).



**Figure 2.** Correlation analysis between the potassium ( $\text{K}^+$ ) concentration and osmolality in the handmade formulas studied - standard diet (SD) and hyperglycemia diet (HD).



**Figure 3.** Correlation analysis between the Total Solute Concentration and osmolality in the handmade juices studied - standard diet (SD) and hyperglycemia diet (HD).

affects the selection since the application by post-pyloric tube requires the use of isosmolar or slightly hyperosmolar diets. On the other hand, the gastric positioning allows greater flexibility and hyperosmolar formulas may be used since they may be diluted by gastric secretions (Barrett et al., 2009). The infusion method is also relevant since it determines the diet's volume and administration time, reflecting in the physiological acceptance, mainly when

accompanied by hyperosmolar diets (Von Atzingen et al., 2007; Blumenstein et al., 2014; Chowdhury et al., 2016).

The diets analyzed in current study contain cow milk as their predominant fluid base, whose main sugar is lactose (present in 4-6% concentrations). This sugar, composed of glucose and galactose molecules, also has an osmotic effect. Its presence in an intact form in the intestinal lumen increases osmolality and allows fermentative processes by intestinal bacteria. Since disaccharide is a food factor widely known to cause gastrointestinal discomfort, it should be duly taken into account during the prescription and elaboration of enteral formulas due to its significant osmolality, mainly in individuals with small lactase production (Halmos, 2013; Dupas-Langlet et al., 2013). In intolerant or lactose-sensitive patients, the milk of the formulas may be substituted by lactose-free milk, without any loss in the diets' nutritional value.

The high osmolar concentration of 1800 kcal SD juice may compromise its infusion by post-pyloric tube. Enteral diets above 600 mOsm/kg water demand special care with regard to their administration, following parameters by the Brazilian Health Surveillance Agency (Brasil, 1999). Since 1800-kcal SD juices are hyperosmolar, their administration requires special attention for handling time and infusion volume. As a strategy, gravitational administration rather than infusion in bolus may be recommended so that a smaller volume is offered during a longer period, avoiding an intense osmotic effect on the intestinal lumen coupled to osmotic diarrhea (Barrett et al., 2009).

In the case of pH of the enteral formulas studied, all formulas and juice had low acidity rates. The significant pH variations in 1500 kcal HD and 1800 kcal HD diets may be more related to the solutions stability than to the diets' composition. In fact, pH may influence the growth of pathogenic microorganisms and their deterioration in handmade enteral diets (Silvia et al., 2007). Rates close to neutrality (6.5 to 7.5) are more favorable for the growth of most of them (Von Atzingen et al., 2007; Pinto et al., 2015).

As pH rate is one of the food's intrinsic factors that may cause handmade enteral diets an excellent culture for microbial growth, it is important to control the extrinsic conditions for the safety of product quality, reduce contamination risks and patient's infection. Therefore, the adoption of good practices in the manipulation by the caregiver or by the person responsible for the preparation of the formula is crucial throughout the process involving the manufacture of the diet (Santos et al., 2013; Von Atzingen et al., 2007; Blumenstein et al., 2014; Brasil, 1999).

In addition, pH rates lower than 4.6 may obstruct the feeding tubes, since they contribute towards the coagulation of proteins. When pH is lower than 3.5 it may interfere in gastric motility and contribute towards a slower gastric emptying (Araújo & Menezes, 2006; Klang et al., 2013; Blumenstein et al., 2014).

Current results demonstrate that diets and juices developed have a pH that is compatible with non-interference on gastric motility and with low risks in catheter obstruction, when such a parameter is considered alone.

Despite a more acid pH of the complementary juices, their volume corresponds to approximately 10% of the total diet daily administered whose near neutrality rates ensure greater safety in the stability and in the prevention of potential risks of microbial development and emergence of fermentation products (Von Atzingen et al., 2007).

The diets proposed have a considerable analytical composition data of macro- and micro-nutrients and not only data from centesimal composition food tables. Measurements performed throughout current study revealed best performance in stability, fluidity and concentration balance parameters, at approximately 1800 Kcal, consistent with the data found in other investigations with handmade enteral diets (Sousa et al., 2014).

The two parameters studied showed that, coupled to nutrients' quantitative centesimal analyses (which are part of the handmade diets), osmolality and pH are crucially determinants in DENT quality and in food safety in special situations.

## 5 Conclusions

The study of the physical-chemical parameters of handmade enteral diets prescribed for home care has shown that osmolar differences might be observed with the substitution of sucrose by maltodextrin and influenced by increased potassium concentration in the different calorie levels studied. Further, correlation studies between electrolytes and osmolality have shown that, coupled to carbohydrates, the dissociation of salts in the solution boosts the osmotic effect of the diet as the caloric levels are increased, due to the rise in the amount of sodium and potassium ions. Although the formulations contain important elements for an increase in osmolar concentration, such as sucrose and electrolytes (sodium and potassium), the balance between the amount and quality of ingredients used contribute towards osmolality and pH rates within the recommendation range. These characteristics have contributed towards the final quality of the diets and their maintenance within the physiological acceptance standards necessary to reduce gastrointestinal complications. Since a large number of patients are benefitted, the success of the domiciliary enteral nutritional therapy is guaranteed and the right to healthy food for patients with special food necessities is ensured.

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