Evaluation of Infant Rehydration Solutions

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The information and suggestions presented in this research are only opinions and do not represent the policies or procedures of any laboratory or institution.

Summary

Infant dehydration can be a medical emergency and parents now understand that severe diarrhea, left untreated, can result in infant or child death. The physician needs to examine the patient in most cases and determine the serum sodium and potassium levels in order to decide on a course of treatment. Incorrect treatment of infant dehydration can result in organ damage and even death. In cases of severe dehydration, the child is admitted to the hospital where fluids and electrolytes are given intravenously.

In many cases of the 20 million episodes of diarrhea in the United States each year, the physician will recommend the use of an Oral Rehydration Solution [ORS]. These solutions represent a $100 million market. In addition to their use in treating diarrhea, infant rehydration fluids are also used to treat vomiting, although this can be difficult due to the nature of the condition. These solutions have also been embraced by the body building community to correct the extreme sodium and water losses generated prior to competition and to treat low sodium levels after long races. Pedialyte "the one most recommended by pediatricians" is the industry leader. Grocery and drug stores sell their in-store brand but they are marketed to be the exact formulation of Pedialyte at a 20% savings.

Research has shown that infant rehydration solutions should be hypotonic in order to allow for the most rapid rehydration and therefore, the quickest recovery from diarrhea. They also state that current retail infant rehydration solutions are hypotonic and have ***an osmolality of 250 mOsm/L for the unflavored solutions and 270 mOsm/L for the flavored solutions".***

What we can conclude from medical studies and publications is that in order to obtain the best medical outcome for the patient, the osmolality of the Oral Rehydration Solution should be hypotonic [less than 280 mOsm/L], and ideally in the range of [225-250 mOsm/L] and that the levels of sodium and dextrose should be balanced.

We evaluated the osmolality and taste of 30 popular infant rehydration solutions. Our research has determined that in fact most of the infant rehydration solutions currently being sold have an elevated osmolality. Depending on the level, this could actually worsen, not help the diarrhea. The general public and the medical community are unaware of this. Although 100% of the unflavored solutions we tested were hypotonic with osmolalities below 257 mOsm/L, one-third of all flavored solutions were clearly hypertonic. 26% had osmolalities over 310 mOsm/L and 9% had osmolalities exceeding 400 mOsm/L. These results differ from the much quoted statement that *Flavored Rehydration Solutions have an osmolality of 270 mOsm/L*. In fact, our results indicate that 70% of flavored solutions exceed this level. Large differences in taste [palatability] which can effect child compliance were also noted. Sixteen rehydration "freeze pops" were also examined. Their average osmolality was 307, with a range of 283-332.

Overview / Physiology

Diarrhea is one of the most common illnesses in children. In the United States it results in at least 200,000 hospitalizations and several hundred deaths per year, primarily from dehydration due to loss of fluids [1]. Infant dehydration can be a medical emergency and parents now understand that severe diarrhea, left untreated, can result in infant or child death. The physician needs to examine the patient in most cases and determine the serum sodium and potassium levels in order to decide on a course of treatment. Incorrect treatment of infant dehydration can result in organ damage and even death. In cases of severe dehydration, the child is admitted to the hospital where fluids and electrolytes are given intravenously.

Much has changed regarding treatment of diarrhea over the past 30 years. In the past, medicines were used indiscriminately to stop diarrhea without treating the cause. The World Health Organization [WHO], studying Cholera epidemics, pioneered drastic changes in the handling of diarrhea in the 1960's and 70's, resulting in the introduction of Oral Replacement Therapy [ORT] for diarrhea. By replacing lost fluids and electrolytes, through the use of ORT, millions of children worldwide have been saved over the past 25 years. Previous to this, it was thought that antibiotics should be given to kill the germ causing the diarrhea along with medicines to reduce the amount of stool [antidiarrheals]. The past 30 years has taught us that in most cases of watery diarrhea, properly administered electrolyte solutions will correct chemical imbalances and water loss. The disease is then allowed to run its course. [Watery diarrhea is different from bloody diarrhea which is called Dysentery].

Speed of fluid absorption from the intestine to the blood, and therefore rehydration, is directly related to solution osmolality and a 1:1 millimolar ratio of sodium and dextrose levels. Research has shown that hypotonic solutions and particularly those in the range of 225-245 mOsm/L are absorbed the fastest. Hypertonic solutions are absorbed slower and in fact may increase the diarrhea due to osmotic diuresis.

ORS [Oral Rehydration Solutions]

In many cases of the 20 million episodes of diarrhea in the United States each year, the physician will recommend the use of an Oral Rehydration Solution [ORS]. These solutions represent a multi-million dollar market. In addition to their use in treating diarrhea, infant rehydration fluids are also used to treat vomiting, although this can be difficult due to the nature of the condition. These solutions have also been embraced by the body building community to correct the extreme sodium and water losses generated prior to competition.

The Initial ORS solution, [ORS-90] developed and recommended by the WHO beginning in 1975, had sodium levels twice that of the solutions sold in American drug stores today. The high sodium was needed because of the very high amounts of sodium lost in Cholera. Initially only one solution was recommended because the organization recognized that it would be too difficult to promote and distribute several different formulations of ORS around the world. A liter of ORS-90 contained; Sodium 90 mmol [2070 mg], Potassium 20 mmol [782 mg], Chloride 80 mmol [2832 mg], Base (Bicarb) 30 mmol, and 20 gm of glucose, which is a 2% solution. The osmolality of ORS-90 is 311. [Previous solutions had used an 8% sugar concentration and the high osmolality produced by them actually worsened fluid loss].

Over the years, physicians began to report that when ORS-90 was used to treat non Cholera diarrhea, a certain percent of the patients developed elevated blood sodium levels. These studies prompted the WHO to recommend using a reduced sodium solution, [ORS-75], for non Cholera diarrhea.

ORS-75 contains per liter; A balanced millimolar concentration of Sodium and Glucose; Sodium 75 mmol [1725 mg], Glucose 75 mmol [13.5 gm, 1.35%], Potassium 20 mmol [782 mg], Chloride 65 mmol [2801 mg], and Base (Citrate) 10 mmol. The osmolality of ORS-75 is 245 mOsm/L. This solution was evaluated by leading physicians and the results published in the April 2001 journal of Pediatrics. In the article they reviewed several world wide clinical trials which had used reduced osmolality solutions in the treatment of non Cholera diarrhea. These studies had indicated that the use of reduced osmolality rehydration solutions, with sodium levels of 60 mmol/L [osmolality 225] or 75 mmol/L [osmolality 245] resulted in a significant reduction in the need of IV therapy. The journal of Pediatrics confirmed this in their study that although there was little difference in the amount of stool produced, there was a 33% reduction in the need for IV therapy, when ORS-75 solution was used instead of the original ORS-90 solution [2].

Significance

Although physicians can recommend the use of ORS-75 for rehydration, most American children will not accept the very salty taste of products containing 1725 mg of sodium per liter. Therefore although Rehydralyte, an ORS-75 type is available, little is sold. What is widely available and sells well are ORS solutions with lower salt levels that appear to be better tolerated by American infants and children.

What we can conclude from these medical studies is that in order to obtain the best medical outcome for the patient, the osmolality of the Oral Rehydration Solution should be hypotonic [less than 280 mOsm/L], and ideally in the range of [225-250 mOsm/L] and that the levels of sodium and dextrose should be in equimolar concentrations [2,6].

Pedialyte developed by Ross Pharmaceuticals and now owned by Abbott is the industry leader in the ORS American market. Pedialyte, has national competition from Liquilyte, a Gerber product and many in-store generic knock-offs. Most in-store brands [which are priced about 20% less than Pedialyte] have formulated their products to match the composition of Pedialyte and in fact list each ingredient in their product with a direct comparison to Pedialyte. [The bottle is also the same square shape as the Pedialyte bottle].

The Pedialyte Formula

- Sodium: 45 mmol/L [1035 mg]
- Potassium: 20 mmol/L [782 mg]
- Chloride: 35 mmol/L [1243 mg]
- Citrate: 10 mmol/L (30 mEq/L) [1890 mg]
- Dextrose: 20 gm/L, Fructose 5 gm/L [2.5% Sugar] [139 mmol/L]
- Calories: 100

Method

We evaluated the osmolality, pH, specific gravity and electrolyte composition of 30 Infant rehydration and electrolyte maintenance solutions and 16 “freezer pops” sold over the counter in retail grocery and drug stores. Osmolality was measured with an Advanced 3D3 Osmometer, courtesy of Advanced Instruments, Norwood MA. Specific Gravity was measured with an American Optical T/S meter. pH was measured with a Fisher Scientific AR-15 Accumet Research pH meter. Taste was also evaluated. Although taste is a subjective test, sick infants and children are very fussy when it comes to taste. In order for the rehydration solution to work properly, a significant amount must be consumed.

Results

All results of the rehydration solution evaluations appear in [Table 1]. The results of the rehydration "freezer pop" evaluations appear in [Table 2]. The solutions rated best by both taste and osmolality appear at the top of each category followed by a [*].

Discussion

All infant rehydration solutions should be hypotonic in order to allow for the most rapid rehydration and therefore, the quickest recovery from diarrhea [3]. Most web sites, including www.drugs.com state the importance of using "hypotonic solutions" for infant dehydration. Many sources quote infant rehydration solutions as having an osmolality of "*250 mOsm/L for the unflavored solutions and 270 mOsm/L for the flavored solutions".*

We calculated the minimum osmolality using the stated electrolytes and sugars on the label to be 258 in all of these products. Several of the products have osmolalities below 258. The chemical properties of the ingredients indicate that this is impossible if the electrolytes and sugars are present in the amounts stated on the label. Although we did not determine the electrolyte or sugar levels in this research, we feel it is important that these levels are tested and confirmed at some time.

Although [7/7] 100% of the unflavored solutions were hypotonic with osmolalities below 257 mOsm/L, one-third of all flavored solutions were clearly hypertonic. 6/23 [26%] had osmolalities over 310 mOsm/L and 2/23 [9%] had osmolalities exceeding 400 mOsm/L. These results differ from the much quoted statement that "Flavored Rehydration Solutions have an osmolality of 270 mOsm/L". In fact, our results indicate that 70% of flavored solutions exceed this level. Large differences in taste [palatability] which can effect child compliance were also noted. Sixteen rehydration "freeze pops" were also examined. Their average osmolality was 307, range [283-332], median 307. By selecting the best rehydration solutions based on osmolality and compliance, treatment outcomes of diarrhea should improve.

Although all of the unflavored solutions are hypotonic, we found all but the Gerber Liquilyte to have a very disagreeable taste. The Gerber product uses Sucralose to provide just enough sweetness to make their unflavored solution palatable. By reducing the sugar level slightly in their rehydration solutions from 2.5% to 2.2%, Gerber was also able to reduce the osmolality 17 mOsm/L. Table 1 provides a comparison of the listed contents as well as our experimental results.

A careful examination of Table 1 reveals large differences in the measured osmolality of the flavored solutions. Although the top rated products in each flavor category are hypotonic, six products have osmolalities over 310 mOsm/L and two products have osmolalities over 400 mOsm/L. This is a critical piece of information which we feel is not generally known to the medical community or the general public. Solutions which are more concentrated than the blood can induce osmotic diuresis. In this process, fluid is drawn into the intestine from the blood, worsening the diarrhea. In our opinion, there is no need to use these higher osmolality products, especially since there are others in each category that taste better and have lower osmolalities.

Several of the solutions are isotonic. An isotonic solution [280-295 mOsm/L] will have slightly delayed absorption because there is no osmotic concentration gradient present to accelerate absorption from the intestine to the bloodstream. Although in Australia, the food commission considers isotonic solutions to include any osmolality from 250-340 mOsm/L, we agree with the medical research that states that isotonic solutions are between 280-295 mOsm/L.

Several brands of Electrolyte Maintenance "Freezer Pops" were also studied and their results appear in Table 2. From the box labels it was determined that all freezer pop products evaluated have the exact same electrolyte and dextrose concentrations; Sodium 45 mmol/L [1035 mg], Potassium 20 mmol/L [782 mg], Chloride 35 mmol/L [1243 mg], Citrate 10 mmol/L [1890 mg] and Dextrose 139 mmol/L [25 gm]. In our opinion, the osmolalities of the freezer pops need to be reduced. None of the freezer pops are hypotonic. In fact, 12 of the 16 tested are hypertonic. We would suggest using a highly rated hypotonic solution first, switching to the freezer pops as a last resort if the child refuses to drink liquids. In addition to the elevated osmolalities, the freezer pops appear to have a substantial amount of dye in them compared to the rehydration solutions.

Many websites mention that homemade rehydration treatments are not appropriate for treating dehydration and sodium loss caused by diarrhea. They often quote chicken soup at 330 mOsm/L, apple juice at 700 mOsm/L or soda-based beverages as having too elevated osmolalities. Physicians have commented that both the osmolality and sodium levels are inappropriate in these "homemade" treatments. Sports drinks should also not be used as infant rehydration solutions. Their 465 mg/L sodium levels are too low, and their 6% sugar level and 350-430 mOsm/L osmolality is too high [4].

Specific Gravity

The specific gravity of infant rehydration solutions and rehydration "freeze pops" varied between 1.012 and 1.016. Although in general the specific gravity results agreed with the osmolality, this test does not provide a direct correlation with osmolality. Although hypotonic solutions had results of 1.012 to 1.013, and hypertonic solutions had results of 1.015 to 1.016, we found that specific gravity does not provide a reliable indicator of solute concentration.

pH

The unflavored solutions had an average pH of 4.90 with a pH range of 4.17 to 5.60. The twenty-three flavored solutions had an average pH of 4.20 with a pH range of 3.90 to 4.48. The average pH of the sixteen "Freezer Pops" was even lower at 3.92 with a pH range of 3.52 to 4.17. We were surprised that the solution pH values were this acidic. In addition to rehydration, these solutions are intended to help correct the acidic intestinal conditions occurring during the diarrhea.

Taste

We solutions and freezer pops were evaluated for taste. Although this was a subjective test it was included because physicians, nurses and parents we spoke with commented that children and infants often refuse to drink [or eat] the products because they did not like the taste. In an effort to make the solutions taste better parents sometimes mix the rehydration solution with apple juice. This should be avoided because it will result in a further elevation of solution osmolality.

Conclusion

The most appropriate product would have an acceptable taste and a hypotonic osmolality. That would be unflavored Gerber Liquilyte. If however the child refuses this unflavored product, any of the eight recommended flavored products, [indicated by an asterisk in Table 1] would be appropriate.

We support the need to produce and use Oral Rehydration Solutions which are both hypotonic and have an agreeable taste. Extensive medical research has demonstrated that solutions with these appropriate osmolalities provide the best benefit for the sick child. Our study has demonstrated large osmolality and taste differences between brands of infant rehydration solutions and rehydration freezer pops. This information should be of value in the treatment of watery diarrhea.

These results were presented at a large pediatric nurse's conference in April, 2005. Pediatricians and nurses we spoke with were surprised at the large osmolality and taste differences between brands. Many also stated that appropriate rehydration using these solutions absolutely requires compliance and compliance depends on taste.

Table 1 Pediatric Electrolyte Solution Evaluation

Product Type/Name	Taste	Cal	Na mg (mmol)	K mg (mmol)	Sugar gm (mmol)	Osmol	Sp Gr	pH
Unflavored								
Gerber *	C+	88	1035 mg (45)	782 mg (20)	22 gm (122)	256	1.012	4.18
Pedialyte	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	254	1.013	5.73
Eckerd	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	245	1.012	4.32
Parent's Choice [Walmart]	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	253	1.013	4.17
CVS	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	242	1.012	5.60
Wegmans	F	100	1035 mg (45)	782 mg (20)	25 gm (139)	242	1.013	5.55
Rite Aid	F	100	1035 mg (45)	782 mg (20)	25 gm (139)	255	1.013	4.74
Fruit Flavor								
Eckerd *	B	100	1035 mg (45)	782 mg (20)	25 gm (139)	269	1.013	4.26
Gerber [Instant Mix] *	B	88	1035 mg (45)	782 mg (20)	22 gm (122)	260	1.013	4.14
Parent's Choice [Walmart]	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	262	1.013	4.18
Rite Aid	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	296	1.014	4.10
CVS	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	297	1.014	3.90
Pedialyte	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	315	1.015	4.21
Wegmans	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	326	1.015	3.91
Apple								
Gerber *	B+	88	1035 mg (45)	782 mg (20)	22 gm (122)	272	1.013	4.15
Gerber [Instant Mix] *	B	88	1035 mg (45)	782 mg (20)	22 gm (122)	262	1.013	4.17
Pedialyte	C+	100	1035 mg (45)	782 mg (20)	25 gm (139)	279	1.014	4.25
CVS	C+	100	1035 mg (45)	782 mg (20)	25 gm (139)	410	1.016	4.36
Rite Aid	C+	100	1035 mg (45)	782 mg (20)	25 gm (139)	419	1.016	4.07
Bubble Gum								
Eckerd *	B	100	1035 mg (45)	782 mg (20)	25 gm (139)	269	1.013	4.25
Pedialyte	C+	100	1035 mg (45)	782 mg (20)	25 gm (139)	273	1.014	4.20
Rite Aid	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	297	1.014	4.18
CVS	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	314	1.014	4.45
Grape								
Eckerd *	B	100	1035 mg (45)	782 mg (20)	25 gm (139)	260	1.013	4.26
Parent's Choice [Walmart] *	B	100	1035 mg (45)	782 mg (20)	25 gm (139)	259	1.013	4.19
Pedialyte	D	100	1035 mg (45)	782 mg (20)	25 gm (139)	281	1.014	4.26
CVS	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	312	1.014	4.48
Rite Aid	C	100	1035 mg (45)	782 mg (20)	25 gm (139)	323	1.015	4.34
Cherry								
Pedialyte *	B	100	1035 mg (45)	782 mg (20)	25 gm (139)	279	1.014	4.28
CVS	C+	100	1035 mg (45)	782 mg (20)	25 gm (139)	327	1.015	3.97

All Results are Per Liter of Solution. [* Recommended Brand in Each Flavor Category - Opinion]

Table 2 – Electrolyte Maintenance "Freezer Pops"

Product Type/Name	Taste	Osmol	Sp Gr	pH
Rasberry				
Pedialyte	C+	299	1.016	3.56
CVS	C-	286	1.015	4.17
ReVital	B	314	1.015	3.96
Rite Aid	C	321	1.016	3.98
Orange				
CVS	C-	283	1.015	4.17
Pedialyte	C	301	1.016	3.52
ReVital	C	323	1.015	3.99
Rite Aid	C+	330	1.016	3.97
Cherry				
CVS	C+	286	1.015	4.17
Pedialyte	B	299	1.016	3.52
ReVital	B	313	1.016	4.00
Rite Aid	B	314	1.016	4.00
Grape				
CVS	C+	285	1.015	4.16
Pedialyte	C	301	1.016	3.52
Rite Aid	C-	328	1.016	3.99
Lime				
ReVital	B	332	1.015	3.99

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