The Use of Fruit-Eze™ in the Management of Constipation in Children with Spina Bifida

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We were able to develop a study at J.W. Riley Hospital for Children to evaluate the effectiveness of Fruit-Eze™ , a commercially available fruit pectin, in the management of constipation in children with spina bifida. Our aim was to find the effects on frequency of stool, consistency of the stool, and individual bowel program. All children from the age of 9 months to 19 years had equal opportunity to participate in the study until a total of 60 subjects were enrolled. All subjects were examined by one of the study care providers. After consent was obtained subjects were given the Fruit-Eze™ with dosage instructions. Of the 60 enrolled 43 finished the study. A repeated measures design was used with each subject acting as their own control. Average stool frequency increased from 1.86 stools per week to 10.28 stools per week. 49% of patients reported their stools were hard prior to using the Fruit-Eze™. 55.6% of subjects described their stools as " soft to firm " while taking Fruit-Eze™. Both changes were significant ($p<.050$)). End dosage correlated positively with weight. Twenty-four subjects (56%) stopped participation at some time during the 12 weeks of data collection. The most common reason cited was " child's refusal secondary to taste."

The first efforts in developing treatment for the child born with spina bifida aperta or myelomeningocele were aimed at preserving life and minimizing the potentially devastating effects on the central nervous system (CNS) caused by hydrocephalus and meningitis. As increased knowledge and improved medical management have enabled these children to survive and live a normal life span, attention has turned to long-term management and issues affecting the individual's ability to be a functional, accepted member of society. Early surgical intervention and the use of ventriculoperitoneal shunts to control hydrocephalus now prevent much of the previous CNS damage. In fact, nearly two-thirds of children with myelomeningocele are of normal intelligence, successful in regular classrooms and capable of employment and significant contributions to society (Hunt & Holmes, 1975).

More recent efforts have been directed at management of the orthopedic problems related to paralysis, and management and prevention of renal problems related to the neurogenic bladder. The neurogenic bowel and the associated constipation has received less attention, no doubt as a result of the perception that constipation and bowel incontinence are not issues affecting life expectancy and functional abilities. In reality however, 90% of children with myelomeningocele will experience neurogenic bowel dysfunction (Shurtleff & Wicks, 1990). As a result, patients may experience constipation, impaction, fecal incontinence, odor, skin irritation and breakdown, urinary retention, rectal prolapse, rectal fissures, shunt malfunction, psychosocial difficulties, and low self-esteem (Passo,1980, Richardson et al, 1985, Younoszai, 1992, Gleeson, 1990). Hunt (1980) reported that chronic incontinence, especially fecal, causes greater distress to the child than any other associated concerns because of school and social problems. In a survey of 527 families of children with spina bifida in a Nordic collaborative study, both urinary and fecal incontinence were perceived as more stressful than impaired motor function (Lei et al, 1991).

A neurogenic bowel is the interruption of the continuity of the sensory and motor nerves to and from the brain as a result of an extrinsic spinal cord abnormality such as myelomeningocele. According to Shurtleff and Wicks (1986), "almost all such patients lack delicate anal canal sensation, perianal skin sensation and conscious motor nerve control over the external anal sphincter and levator ani" (p. 232). The result is generally one of two scenarios:

a. The patient tends to be constipated as a result of spastic external anal sphincter or an abnormal autonomic nerve development in the rectum causing rectal wall collapse and functional obstruction, or

b. The patient passes almost constant, small amounts of stool as a result of a weak or nonexistent anal sphincter (Shurtleff & Wicks, 1986).

Shurtleff & Wicks (1986) define constipation as "the accumulation of stool" and obstipation as "severe constipation to the point of colon dilatation leading to an abnormally large colon and "bypass" diarrhea interspersed with hard stools" (p. 227). Prevention of the neurogenic bowel can only be accomplished with prevention of the underlying anomaly, spina bifida. Until such time, prevention of constipation and its sequelae deserves our attention.

METHOD:

A repeated measures design was used with each subject acting as their own control. Changes or differences could then be examined for each subject.

Subjects were recruited from the Myelomeningocele Program at Riley Hospital for Children. Children selected were between the ages of 9 months and 19 years, had a diagnosis of spina bifida, had a history of constipation , and were be able to tolerate oral feedings. Children who were not able to tolerate oral feedings, ventilator dependent, diagnosed with a neural tube defect other than spina bifida, orally defensive, using an

effective bowel program or known to be allergic to any of the components of Fruit-Eze™ were excluded. Subjects were randomly contacted either by phone or as they attended a routine scheduled clinic appointment. A verbal explanation of the study and review of a brief letter of explanation was given to each subject and parent. Following a question and answer period with the subjects they were given an opportunity to participate in the study. Recruitment ended once 60 subjects had agreed to participate.

The participants were divided into three groups based on age: 9 months to 5 years, 6 years to 12 years, and 13 years to 19 years. Every effort was made to enlist comparable numbers of subjects in each age group to provide a population distribution as close to normal as possible. A letter was sent to the parents to explain the study procedures and give them an appointment time to come in for the initial assessment. At this assessment, a history and physical examination was performed by clinic personnel. The assessment included: height, weight, diet history, medication, past and present bowel programs, and their outcome, stool consistency and frequency, allergies and physical examination. After the examination and history were completed, it was determined if the examination or history indicated the presence of an impaction and over flow stooling. A bowel prep was given to those subjects who showed evidence of significant retention based on abdominal and rectal examination. The bowel prep consisted of ; three Fleets enemas twelve hours apart with citrate of magnesia given after the first enema. Fruit-Eze™ was started one day after the bowel prep was completed and on the following day after the initial assessment was done if no bowel prep was required. The doses of Fruit-Eze™ were in the following amounts:

- 9 months to 2 years - one teaspoon per day
- 3 years to 5 years - two teaspoons per day
- 6 years to 12 years - one tablespoon per day
- 12 years to 19 years - two table spoons per day

If the child did not have a spontaneous stool within three days, parents were instructed to use digital stimulation and/or administer a glycerin suppository. If there was no stooling after five days parents gave one four ounce size tap water enema. The dose of Fruit-Eze™ was increased by one teaspoon per day for subjects 9 months to 5 years, and one tablespoon per day for subjects 6 years to 19 years. If the stools were soft for two weeks with a maximum dose of Fruit-Eze™, which is four tablespoons per day, but the child could not pass a stool secondary to poor colon tone, a bisacodyl suppository could be used.

Each parent received a stool consistency tool for the collection of data for the study (Appendix A). This tool was a weekly log of stool consistency, size of stool, frequency, interventions, dosage and timing of Fruit-Eze™ and stool patterns. The logs were returned to the investigators weekly for data collection. Parents were contacted by phone one week after initiating the data collection and monthly after that to make adjustments as required. The parents or the child could contact the investigators at any time during the study period if any concerns or questions arose. Collection of data and use of Fruit-Eze™ was to be for six months.

RESULTS:

Sixty patients agreed to participate in the study with 43 (72%) actually completing the assessment process and receiving samples of Fruit-Eze™. The age distribution of that group was as follows:

- 9 months to 5 years - 19 (43%)
- 6years to 12 years - 15 (35%)
- 12 years to 19 years - 9 (21 %)

Twenty-two patients (51 %) reported small amounts of fiber in their diet while only one patient reported high fiber intake. The average fluid intake was 24 ounces per

day. Fourteen patients (33 %) reported taking a senna preparation prior to beginning Fruit-Eze™ but stopped at the beginning of the study. Eleven subjects (26%) reported taking oxybutynin and nine subjects (21 %) reported receiving trimethoprim-sulfamethoxazole daily. The average stool frequency reported at the beginning of the study was 1.86 stools per week (Table 1) with 49% of subjects describing their stools as hard (Table 2). Sixteen subjects (37%) had abdominal radiographs (KUB) and used bowel cleansing procedures prior to starting Fruit-Eze™.

At the conclusion of the study, the average stool frequency reported was 10.28 stools per week (Table 3) with 55.6% of subjects describing their stools as soft or firm (Table 4). Only one subject reported an increased amount of fiber in their diet at the conclusion of the data collection. None of the subjects reported increased fluid intake or change in medications from the initial assessment.

Seven of the eleven subjects taking oxybutynin and four of the nine subjects receiving trimethoprim-sulfamethoxazole left the study before completion. The low frequency of common medications prevented detection of any correlation between medications used and the effects upon Fruit-Eze™.

Dosage range of Fruit-Eze™ at the conclusion of the data collection were as follows:

- 9 months to 2 years - 1-3 teaspoons
- 3 years to 5 years - 0.5-3 teaspoons
- 6 years to 12 years - 3-6 teaspoons
- 13 years to 19 years - 3-6 teaspoons

The cost of the Fruit-Eze™ would have been 10-60 cents per day. The cost of senna averaged 23 cents per day and the daily cost of bisacodyl was 96 cents.

Twenty-four subjects (56%) stopped participation at some point prior to 12 weeks. Sixteen subjects (37 %) completed 12 weeks of the data collection process. Numerous attempts were made to contact each family in the study to adjust dosages and

obtain data with mixed results. Many subjects were not consistent in collecting and returning data to the investigators weekly. After collection of 12 weeks of data the study was ended with a significant number of subjects leaving the study. Statistical analysis was completed after a final survey was sent to all participants to gain any additional information from those subjects who had used the Fruit-Eze™ but did not return the data sheets.

Those subjects and parents who completed the data collection in general felt the fruit pectin was effective in softening their stools and increasing their frequency. Twenty two of the subjects who ended participation in the study cited the child's refusal to consume the Fruit-Eze™ secondary to the taste. Two subjects ended participation secondary to their stools becoming too loose and frequent.

STATISTICAL ANALYSIS:

The sample size used in this study was relatively small, but significantly larger than Day and Monsma (1995) and large enough to assume the population distribution to be normal (Gravetter & Wallnau, 1992). The use of a repeated measures design reduces the amount of error variability and enables detection of treatment effect in smaller samples.

Analysis of stool consistency from beginning to end using a paired samples t test shows a significant change [$t(17)=2.878$, $p<.05$, two tailed]. The change in frequency of stools was also significant ($p<.01$) using a paired samples t test (Table 5). This supports the patient's perceptions of significant effect of the fruit pectin product.

Weight was positively correlated with end dose ($r=451$) using pearson R coefficient, but only approached significance ($p= .06$; Table 6). No significant correlation was found between age and effect. This is in agreement with common clinical findings.

DISCUSSION:

The perceptions of the subjects and parents support the effectiveness of the product.

Further study of this product with larger samples would significantly enhance the data to further support the effectiveness of Fruit-Eze™. Compliance with data collection could be improved by use of less frequent surveys for example every 1-3 months rather than weekly. The research questions can best be answered by comparison of the change in frequency and consistency from beginning to end, and weekly assessment is necessary only for the purpose of evaluating for any dosage change. To increase independence and avoid difficulties in contacting busy families, it would be best to convey to the parent a set of criteria for changing dosage of Fruit-Eze™. There is significant need for education to increase the understanding of the need for use of adequate fluids and fiber. Even with attempts to educate the subjects and their parents, there was no change in the amount of fluids or fiber consumed other than the Fruit-Eze™.

Further research should be aimed at developing more palatable preparations and effective means of educating children with spina bifida and their families on effective ways to increase fluid and fiber intake as well as compliance with treatment regimens related to constipation.

CONCLUSION:

The fruit pectin was effective within the dosage range used but has similar difficulties as medications to assist in constipation; including poor palatability for children, daily use and compliance. The difficulties found in data collection indicate a need for the child and their parents to recognize the need for consistent intervention to treat the constipation associated with a neurogenic bowel.

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Table 1

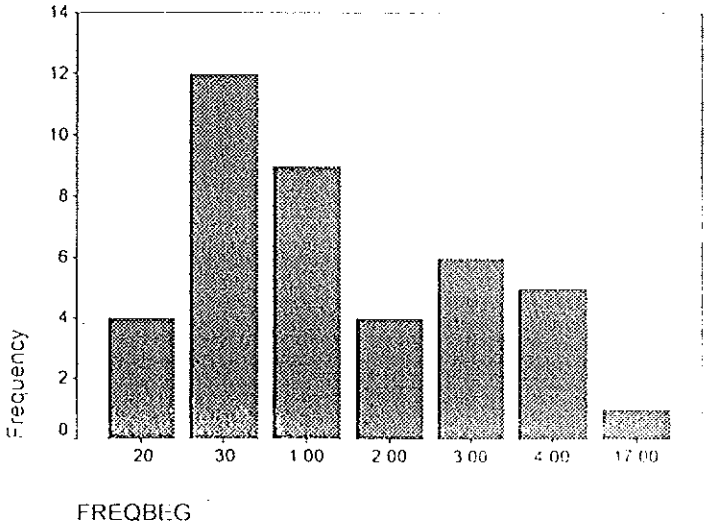
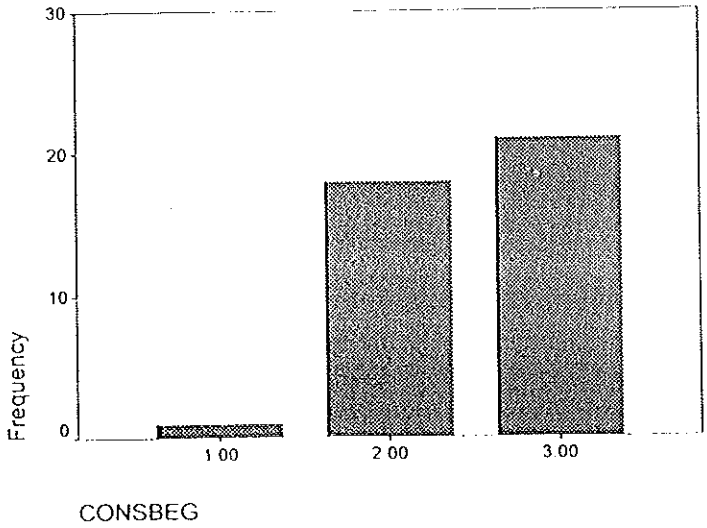


Table 2



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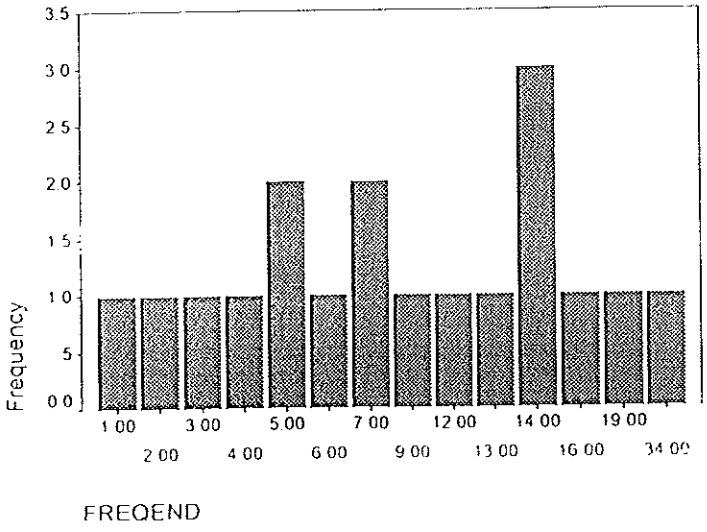
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Table 4

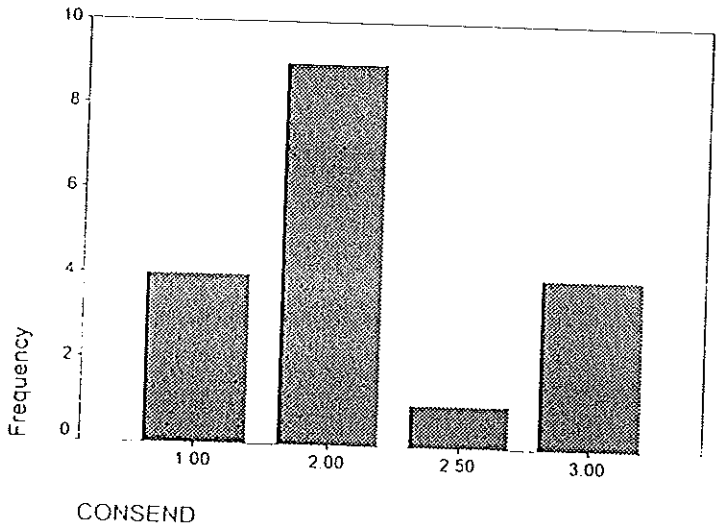

Table 5
Paired Samples Test

		Paired Differences					t
					95% Confidence Interval of the Difference		
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	
Pair 1	CONSBEG - CONSEND	.4722	.6960	.1641	.1261	.8184	2.878
Pair 2	FREQBEG - FREQEND	-8.1667	7.8989	1.8618	-12.0947	-4.2386	-4.386

		df	Sig. (2-tailed)
Pair 1	CONSBEG - CONSEND	17	.010
Pair 2	FREQBEG - FREQEND	17	.000

Table 6

		ENDDOSE	WT
Pearson Correlation	ENDDOSE	1.000	.451
	WT	.451	1.000
Sig. (2-tailed)	ENDDOSE	.	.060
	WT	.060	.
N	ENDDOSE	18	18
	WT	18	43