THE EFFECT OF PROBIOTIC, OHHIRA OMX CAPSULES, IN THE TREATMENT OF ACUTE NON-BLOODY DIARRHEA IN INFANTS 3-24 MONTHS OF AGE

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INTRODUCTION

Diarrheal diseases remain to be one of the most important causes of morbidity and mortality in many areas of the world. They can cause health problems in all age groups however, their major effects are most evident in d viruses each year, mostly in developing countries. In the Philippines, diarrhea affected infants and young children. Millions of young children die from diarrhea caused by bacteria and 845,526 children with a rate of 1,085 per 100,000 children in the year 2000 based on the Department of Health census, making it the leading cause of morbidity and mortality among infants and children. In our institution, diarrhea is among the top four leading causes of consultation at the emergency department and accounts for 11.5 % of all admissions for the year 2004 making it one of the major concerns of pediatricians.

Diarrhea is characterized by excessive and frequent loose and/or watery bowel movements. It is defined by the WHO as at least 3 liquid stools in 24 hours. Accompanying symptoms include abdominal pain, fever, thirst and vomiting. Excessive or prolonged diarrhea can cause dehydration due to the water and electrolyte losses from the body. It can also affect intestinal absorption of nutrients because the digested food rushes through the intestines before nutrients can be extracted and absorbed.

The causes of diarrhea include ingestion of certain foods, lactose intolerance, food poisoning, the adverse effect of certain medications, infection, inflammation, irritation, or toxins produced by invading pathogenic bacteria. No matter what the cause is, when a child suffers from diarrhea, he lost vast amount of non-pathogenic bacteria at a very fast rate in a very short period of time. This condition affects the resident beneficial bacterial population of the bowel. Thus, an important goal for the control of the diarrhea is the prompt replacement of the friendly bacteria that the child lost. When the beneficial bacteria are reinforced with

effective probiotics, no matter what the cause of the diarrhea might be, the body is being given what it needs to restore health to the region.

With the growing interest in functional foods that promote health beyond providing basic nutrition, the market for probiotics is flourishing. Probiotics are live microbial food supplements that beneficially affect an individual by improving intestinal microbial balance. The consumers' overwhelming interest in and demand for functional foods including probiotics, make it imperative that health professionals especially pediatricians stay abreast of the latest research findings and available products.

A number of studies have found probiotic consumption to be useful in the treatment of many types of diarrhea including antibiotic-associated diarrhea in adults, traveller's diarrhea and diarrheal diseases in young children caused by rotaviruses. However, most of these studies were done abroad. Locally, a study done by Orendain, Franco and Gatcheco in 1999 showed that a probiotic (Infloran Berna) was effective in improving and in shortening the duration of diarrhea in children 2-5 years of age (mean duration:3.4 days vs control group: 4.12 days). A similar study was done in infants 6-24 months old by Oandasan, Gatcheco and Kapalungan in a tertiary hospital which revealed that the probiotic, Infloran Berna, was also effective in infants in the treatment of diarrhea. However, on-going researches continue to identify and improve probiotics preparation. A new probiotics, OMX capsule, is the only organically fermented probiotics in paste form available in the local market today. All other probiotics which are widely used today come in powdered form wherein the beneficial bacteria are in an arrested state of growth. However, the use of OMX probiotics in infants in the local setting has not yet been established. Since the full potential of probiotics can only be realized when their benefits can be established scientifically, this research aims to determine the efficacy of this product in infants for the infants are the ones who suffer the most severe complications of diarrhea.

OBJECTIVES

General Objective:

To determine the efficacy of lactobacillus and bifidobacteria (OMX capsules) in the treatment of acute non-bloody diarrhea in patients 3-24 months of age.

Specific Objectives:

1. To describe the profile of infants 3-24 months of age with acute diarrhea of $\leq$ 2 days
2. To establish the efficacy of the probiotic OMX capsules given 2x a day for 5 days in acute diarrhea as assessed by a) the duration of the diarrhea; b) decrease in the frequency of stool, and; c) change in the consistency of stool
3. To determine the incidence of adverse effects associated with the probiotic capsule

METHODOLOGY

This was a randomized clinical trial. Randomization was done using fish bowl method. The study group consisted of 70 infants, male and female, 3-24 months of age with acute non-bloody diarrhea of ≤ 2days; who had no to some dehydration based on the WHO-CDD protocol . Excluded in this study were infants presenting with bloody diarrhea, those more than 24 months of age, those with previous intake of antibiotics and anti-diarrheal medications for the last 72 hours prior to consult, infants with diarrhea of more than 3 days, those with concomitant illness/es and those severely wasted infants as defined by Waterlowe Classification.

Upon the patients' consultation, a complete history and physical examination were undertaken. The age, sex, nutritional status, feeding history, medical history, associated signs and symptoms such as fever and vomiting and degree of dehydration based on the WHO criteria were recorded. Baseline CBC, urinalysis, and stool examination with stool pH were done on the day of consultation to rule out any bacterial infections that will need antibiotic. Only those with normal laboratory results were included. The patients who fulfilled the inclusion criteria were divided into 2 groups using the fish bowl method once they were with no dehydration and upon taking parents' written consent. Group A were given ORS and OMX capsules,1 capsule twice a day for 5 days while group B were given ORS alone, but both following Control of Diarrheal Diseases (CDD) protocol. For those admitted, the investigator noted the frequency and consistency of stools every day until the day of discharge. Associated symptoms were recorded on a day to day basis. Weight was recorded every day using Detecto weighing scale and was recorded in kilograms Resolution of the diarrhea was defined as passage of 2 consecutive formed stools or no stool output for the next 12 hours.

For those patients who were not admitted, the parent was the one who did the recording of the character and frequency of stool on a day to day basis. They were asked to make a follow up on the 3rd, 5th, 7th and 10th day of study periods regardless of the change in the consistency or frequency of stool days ahead.

Primary outcome variables were a decrease in the frequency of stool, a change in the consistency of stool to non-watery and shorter duration of diarrhea. Secondary outcome variables were weight gain or weights loss, recurrence of dehydration, occurrence of other diseases, unplanned need for intravenous fluid and occurrence of bloody diarrhea.

These factors were compared between those given the Ohhira OMX capsules and those who were given only ORS. Statistical analyses were performed with SPSS. Chi-square tests, t-tests, Fisher Exact test and Mann Whitney U tests were used to compare the data of these 2 groups. P value < 0.05 was considered significant. The magnitude of the effects were also computed like RR (relative risks), RRR (relative risk reduction), ARR (absolute risk reduction) and NNT (number needed to treat).

RESULTS

A total of 70 patients were included in the study. Table 1 shows the distribution of subjects according to group: 35 patients (50%) were given ORS and OMX probiotics for 5 days while 35 (50%) patients were given ORS only.

Table 1. Distribution of Subjects According to Group

Group	Frequency	Percentage
With probiotic	35	50.0
Without probiotic	35	50.0

Table 2A details the demographic characteristics of the infants at enrolment. Analysis of age, sex, weight, height, nutritional status, feeding history, medical history, associated signs and symptoms upon consultation, frequency of stool in 24 hours, medications given and degree of dehydration showed that the differences between the 2 groups were non-significant ($p>0.05$). The mean age of infants who had diarrhea was 12.5 months old, mostly males (57.1%), with normal nutritional status (85.7%) and majority were purely breastfed (44.3%). Most infants had no previous illnesses (95.7%); 2 patients had previous gastroenteritis while 1 patient had Pneumonia several months prior to consult. 30 patients had accompanying signs and symptoms, the most common of which is vomiting (34.3%) and fever (5.7%); 2 patients had both fever and vomiting. The demographic characteristics are comparable between the 2 groups.

Table 2A. Comparison of Different Demographic Characteristics According to Groups

	Groups		Total	P value
	With Probiotic (n=35)	Without Probiotic (n=35)		
Age (in months)				
Mean +/- SD	13.4 +/- 7.28	11.54 +/- 5.91	12.50 +/- 6.65	>0.05 (NS)
Median	3 - 24	4 - 24	3 - 24	(t-test)
Sex				
Female	13 (37.1%)	17 (48.6%)	30 (42.9%)	>0.05 (NS)
Male	22 (62.9%)	18 (51.4%)	40 (57.1%)	(chi-square test)
Weight (in kg)				
Mean +/- SD	9.20 +/- 2.23	8.70 +/- 1.76	8.95 +/- 2.01	>0.05 (NS)
Median	5 – 13.5	6 - 13	5 – 13.5	(t-test)
Height (in cm)				
Mean +/- SD	75.11 +/- 8.66	74.28 +/- 7.09	74.70 +/- 7.87	>0.05 (NS)
Median	56 - 90	64 - 88	56 - 90	(t-test)
Nutritional Status				
No Wasting No Stunting	30	30	60	>0.05 (NS)
Mild Wasting No Stunting	4	2	6	(chi-square test)
Mod Wasting No Stunting	1	3	4	
Feeding History				
Purely Breast fed	14	17	31	>0.05 (NS)
BF to Formula	4	0	4	>0.05 (NS)*
BF to Mixed fed	4	3	7	>0.05 (NS)*
Formula Fed	4	2	6	>0.05 (NS)*
Mixed Fed	5	11	16	>0.05 (NS)
Mixed to Formula	4	2	6	>0.05 (NS)*
Medical History				
With	2	1	3	>0.05 (NS)
Without	33	34	67	(Fisher Exact test)
Associated Sign and Symptoms				
With	17	13	30	>0.05 (NS)
Without	18	22	40	(chi-square test)

* Fisher Exact test

The mean (SD) duration of diarrhea prior to consult was 17.36 (13.36) hours. On the other hand, the mean (SD) frequency of stool in 24 hours prior to consult was 6 (2). 50% (35) of the subjects were given ORS prior to consult while 50% (35) of infants were not given anything. 54.3% (38) had some dehydration upon consultation while 45.7% (32) had no signs of dehydration (Table 2B).

Table 2B. Duration of Diarrhea PTC, Frequency of Stool in 24 Hours, Medications Given and Degree of DHN According to Groups

	Groups		Total	P value
	With Probiotic (n=35)	Without Probiotic (n=35)		
Duration of Diarrhea PTC (in hours)				
Mean +/- SD	19.31 +/- 14.78	15.41 +/- 11.66	17.36 +/- 13.36	>0.05 (NS)
Median	5 - 48	1.5 - 48	1.5 - 48	(t-test)
Frequency of Stool in 24 hours				
Mean +/- SD	6 +/- 2	6 +/- 2	6 +/- 2	>0.05 (NS)
Median	4 - >10	4 – 13	4 – 13	(t-test)
Medications Given				
With	19	16	35	>0.05 (NS)
Without	16	19	35	(chi-square test)
Degree of DHN				
Some	18	20	38	>0.05 (NS)
None	17	15	32	(chi-square test)

Comparison of the number or frequency of watery stool on day 1 showed that there were no significant differences between the probiotic and non-probiotic groups ($p>0.05$) on the first day of treatment (Table 3A). However, on the second day of treatment (Table 3B) there was a significant difference in the frequency of stool between the 2 groups, although the median frequency was still 3X in the probiotic group and 5X in the non-probiotic group. On the fourth day of treatment, the median frequency for the probiotic group was 2 and 3 for the non-probiotic group which was statistically significant (Table 3C).

Comparison on the frequency of watery stool on day 4 (Table 3D) showed that 30 patients (85.7%) in the non-probiotic group still had $\geq$ 3 loose stools on the 4th day of treatment while there were 9 patients (25.7%) in the probiotic group who still had $\geq$3 loose stools on day 4 with an ARR of 0.60 (ARR=0.86-0.26),RR of 0.30 (RR = 0.26 ÷ 0.86), RRR of 70% (RRR= 1- 0.26/0.86 x 100), and an NNT of 1.67 (NNT = 1/ARR).

Table 3A. Comparison of the Number or Frequency of Watery Stool on Day 1 According to Groups

Frequency of Watery Stool on Day 1	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
2	1	1	2
3	7	0	7
4	4	5	9
5	10	12	22
6	8	11	19
7	0	3	3
8	3	1	4
10	2	1	3
30	0	1	1
Median	5	5	5

Mann Whitney U test p value > 0.05 (NS)

Table 3B. Comparison of the Number or Frequency of Watery Stool on Day 2 According to Groups

Frequency of Watery Stool on Day 2	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
1	1	1	2
2	7	0	7
3	12	5	17
4	10	10	20
5	4	12	16
6	1	4	5
10	0	1	1
13	0	1	3
24	0	1	1
Median	3	5	5

Mann-Whitney U test p value 0.000054 (S)

Table 3C. Comparison of the Number or Frequency of Watery Stool on Day 4 According to Groups

Frequency of Watery Stool on Day 4	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
1	12	0	12
2	14	5	19
3	7	13	20
4	2	13	15
5	0	3	3
10	0	1	1
Median	2	3	2-3

Mann-Whitney U test p value 0.0000 (S)

Table 3D. Comparison of the Number or Frequency of Watery Stool on Day 4 According to Groups

Group	≥ 3x	< 3x
With probiotics	9 (25.7%)	26 (74.3%)
Without probiotics	30 (85.7%)	5 (14.3%)

The effect of Ohhira OMX capsules on watery diarrhea was significantly apparent on days 1 to 3 as seen on Table 4. 26 (74.3%) patients already had formed stool on the 1st 3 days of the study period as compared to 4 (11.4%) patients in the non-probiotic group. Nine patients (25.7%) in the non-probiotic group developed formed stool only on the 7th-9th day of treatment. There was a significant difference in the mean days of patients having a formed stool between the 2 group as shown by the p value <0.00001. The mean days was shorter in the probiotic group than in the non-probiotic group (mean (SD) 3.17(1.34) days vs. 5.42 (1.72) days respectively.

Table 4. Comparison of the Mean Number of Days Before A Formed Stool was Achieved According to Groups

Number of Days	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
1 – 3	26	4	30
4 – 6	9	22	31
7 – 9	0	9	9
Mean +/- SD	3.17 +/- 1.34	5.42 +/- 1.72	4.31 +/- 1.90
Median	1 - 6	1 - 9	1 - 9

T-test p value <0.000001 (S)

There were no adverse effects noted.

Secondary Analysis:

Comparisons of baseline weight between the 2 groups were non-significant with p value > 0.05 (Table 5). However, among those given probiotics, 34 patients (97.1%) had weight gain after 10 days of study period compared with 27 patients (77.1%) in the non-probiotic group. The only patient in the probiotic group who didn't gain weight actually had the same weight from the start of the study until day 10. Of the 8 patients in the non-probiotic group who did not gain weight, 4 actually had a decrease in weight from the baseline by 0.1kg (Table 6).

Table 5. Comparison of Weight on Day 1 (Baseline) According to Groups

	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
Mean +/- SD Median	9.18 +/- 2.18 4.9 – 13.5	8.63 +/- 1.70 6 – 12.7	8.91 +/- 1.96 4.9 – 13.5

t-test p value >0.05 (NS)

Table 6. Distribution of Subjects With or Without Weight Gain According to Groups

Weight Gain	Groups		Total
	With Probiotic (n=35)	Without Probiotic (n=35)	
Yes (with) No (same)	34 (97.1%) 1 (2.9%)	27 (77.1%) 8 (22.9%)	61 9

Fisher Exact test p value <0.01 (S)

The actual day weight was gained between the 2 groups proved to be significant with p value <0.05. For the probiotic group, 17 patients (50%) gained weight on the 2nd day of treatment as compared to 7 patients (25.9%) in the non-probiotic group. There was a shorter length of days for weight to be gained in the probiotic group (day 5) compared to non-probiotic group (day 7). However, weight gain may not be solely attributed to the probiotics alone.

Table 7. Comparison of the Actual Day Weight was Gained According to Groups

Actual Day	Groups		Total
	With Probiotic (n=34)	Without Probiotic (n=27)	
Day 2	17	7	24
Day 3	9	9	18
Day 4	5	3	9
Day 5	3	4	7
Day 7	0	4	4
Median	2	3	2-3

Mann Whitney U test p value <0.05 (S)

There was a significant difference between the maximum mean weight gain between the 2 groups (Table 8) with a mean (SD) of 0.35 (0.14) kg vs 0.25 (0.13) between the probiotics and the non-probiotic groups, respectively.

Table 8. Comparison of Mean Gain in Weight (Maximum) According to Groups

Mean Gain in Weight (in kg)	Groups		Total
	With Probiotic (n=34)	Without Probiotic (n=27)	
0.1	3	6	9
0.2	5	8	13
0.3	10	9	19
0.4	7	2	9
0.5	6	1	7
0.6	2	1	3
0.7	1	0	1
Mean +/- SD	0.35 +/- 0.14	0.25 +/- 0.13	0.308 +/- 0.146

t-test p value <0.01 (S)

It was shown in Table 9 that weight loss occurred in the 1st 3 days in 11 patients given probiotics without any losses in the succeeding days as compared to the non-probiotic group whose losses extended until the 10th day. This is statistically significant with p value of 0.001.

Table 9. Comparison of the Mean Number of Days Weight Loss Occur According to Groups

Number of Days	Groups		Total
	With Probiotic (n=11)	Without Probiotic (n=20)	
1 – 3	11	10	21
4 – 6	0	6	6
7 – 9	0	1	1
10	0	1	1
>10	0	2	2
Median Number of Days	2	4	3

Mann Whitney U test p value 0.001

Maximum weight loss between the 2 groups was not significant (Table 10). There was no difference between the mean weight loss of the probiotics and the non-probiotic groups.

Table 10. Comparison of Mean Loss in Weight (Maximum) According to Groups

Mean Loss in Weight (in kg)	Groups		Total
	With Probiotic (n=11)	Without Probiotic (n=20)	
0.1	5	10	15
0.2	6	9	15
0.4	0	1	1
Mean +/- SD	0.15 +/- 0.05	0.16 +/- 0.08	0.158 +/- 0.067

t-test p value >0.05 (NS)

DISCUSSION

The normal human gastrointestinal tract contains hundreds of different species of harmless bacteria, referred to as intestinal flora. When the normal balance of these bacteria is disturbed by illness, the most common effect is diarrhea. Diarrhea flushes intestinal microorganisms out of the gastrointestinal tract (GIT) leaving the body vulnerable to opportunistic infections. In a study done by Fuller and Gibson, rotavirus was still the most common causal agent of gastroenteritis in infants 5-24 months of age.[1]

The most important beneficial colonizing bacteria to maintain the integrity of the GIT are the Lactobacillus acidophilus, found mainly in the small intestine and Bifidobacteria bifidum, common in the large intestine. These friendly bacteria not only produce and liberate numerous beneficial substances, including vitamins, amino acids, antibiotics, and other antimicrobial substances, but they are necessary for maximizing the absorption and utilization of nutrients.[2] OMX probiotics contain strains of Lactobacilli and Bifidobacteria.

A number of studies have been carried out on the effect of several probiotic species on the treatment and prevention of diarrhea. The most commonly used microorganisms were lactic-acid-producing bacteria (LAB) such as lactobacilli and bifidobacteria. Clinically significant benefits of probiotics have been demonstrated in the treatment of rotavirus-induced diarrhea.[3]

This randomized clinical trial is the first to study locally the effects of OMX probiotics in infants having acute non-bloody diarrhea. Most studies done abroad used probiotics in the treatment of chronic diarrhea, antibiotic-associated diarrhea, traveler's diarrhea and Clostridium difficile-associated diarrhea (RCDAD). Some studies dealt on rotavirus-associated diarrhea. In a clinical trial done in Finland in 1997, wherein 60 children between 6

and 36 months of age admitted for rotavirus-associated diarrhea were given different dosages (1 group was given 10^{10} colony-forming units (cfu) while the other group received 10^{7} cfu) of probiotics once a day for 5 days , they've concluded that the main effect of probiotics was on the duration of watery diarrhea and there was a correlation between the dosage of probiotics and the clinical effect. The mean (SD) duration of watery diarrhea was 2.5 (1.5) days in the placebo group, 1.9(0.9) days in those given the small dosage and 1.5 (1.1) days in the large dose .[4] In a study done by Rosenfeldt et al in 2002, they've shown that in children from day care centers with mild diarrhea, those that were given probiotics had shorter mean duration of diarrhea (3.29 days) than those in the placebo group (5.79days).[5] Another meta-analysis done by Huang in the US in children < 5 years old with acute onset diarrhea, they concluded that co-administration of probiotics with standard rehydration therapy reduces the duration of acute diarrhea by approximately 1 day.[6] (random-effects pooled estimate = 0.8 days (-1.1) P < 0.001).

Our study supports their findings. We have shown that oral rehydration solution supplemented with OMX probiotics substantially reduced the duration of illness in infants having acute non-bloody diarrhea (mean (SD) 3.17 (1.34) vs 5.42 (1.72) days in the non-probiotic group) (P value <0.000001). In our study there was a 41.5% reduction in the duration of diarrhea in infants given probiotics or a reduction in the duration of diarrhea by 2.25 days (p < 0.00001). This study further showed that on day 4 of treatment, 85.7% or 86% in the non –probiotic group still had diarrhea as compared to 25.7% or 26% in the probiotic group with a relative risk reduction (RRR) of 70%. An RRR of 70% means that the use of probiotics reduced the risk of diarrhea by 70% relative to that occurring among the non-probiotic group. It is known for a fact that the impact of a treatment is related not only to its relative risk reduction, but also to the risk of the adverse outcome it is designed to prevent. The NNT or the number of patients who must receive an intervention of therapy during a specific period of time to prevent one adverse outcome in this study was 1.67. Given the relative risk of 30%,, a 70% RRR of diarrhea generates an ARR of 60% (0.60).This means

that we would have to treat only 1.67 or approximately 2 patients to prevent an episode of diarrhea. Considering the cost of probiotic, this would help a clinician in the decision to start therapy wherein he has to consider the patient's risk of the adverse event and its cost if left untreated.

Probiotics are believed to exert biological effects through a phenomenon known as colonization resistance, whereby the indigenous anerobic flora limits the concentration of potentially harmful (mostly aerobic) bacteria in the GIT. Probiotics are thought to occupy binding sites on the gut mucosa, preventing pathogenic bacteria from adhering to the mucosa.[7] Lactobacillus casei has been demonstrated to increase levels of circulating IgA in infants infected with rotavirus. This has been found to be correlated with shortened duration of rotavirus-induced diarrhea. Lactobacillus GG has also been shown to potentiate intestinal immune response to rotavirus infection in children. Lactibacillus acidophilus and Bifidobacterium bifidum appear to enhance the nonspecific immune phagocytic activity of circulating blood granulocytes. This effect may account, in part, for the stimulation of IgA responses in infants infected with rotavirus.[8-9]

The clinical profile of the subjects in our study was comparable between the 2 groups. The mean age of the patients was 12.50 months of age. With more males (57.1%) affected than females (42.9%). Majority of the subjects (44%) were purely breastfed , some were mixed fed (23%) while the rest was briefly breastfed then were eventually shifted to formula milk or mixed feeding. This may mean that although breastmilk has good protective agents against gastrointestinal infection, they may not be enough to prevent diarrhea in infants.

The weight loss noted among the patients can be attributed to diarrhea. Diarrhea does not let food stay in the gut long enough for the body to absorb the nutrients it needs. Plus, if the gut is damaged by the virus, it cannot absorb very well important vitamins, minerals proteins and calories from food. Supplementing with probiotics offer a more

proactive defense by assisting in the manufacture of essential vitamins such as the B vitamins, niacin, folic acid, pyridoxine, and biotin. It is worthy to note that those who were not given probiotics had longer number of days with weights loss (median 4)(P=0.001) and lesser mean gain in weight (0.25 kg vs 0.35 kg in the probiotics group) (p value <0.01).

According to Fuller, just as not all strains of bacteria are the same not all probiotics are the same. The effectiveness of a probiotic depends not only on its content but also on how it is prepared and processed, and how it is packaged. Although the super strains of Bifidobacteria do good things to everyone, an age-specific species is recommended. The probiotic to be used must also be suitable for the age of the individual. For adults, the B. bifidum Malyoth strain is best while infants and young children require the gentler B. infantis which is what OMX capsules contain. According to studies done in 1992, probiotics products that have been processed using centrifugation or ultrafiltration are of inferior quality because the processing removed the invaluable supernatant which contains anti-microbial compounds, vitamins, enzymes, cellular building blocks, antioxidant and immunostimulants. The full- culture production method wherein the entire bacterial mass are freeze-dried and packaged is the most desirable process which results in a true quality product.[10] However, latest researches claim that probiotics processed by natural fermentation all throughout the preparation produce higher quality and viable live bacteria because it does not damage the bacteria's fragile cell walls which reduce the effectiveness of the bacteria. OMX probiotics were prepared this way. They are available not in the usual powder, liquid nor capsule form but in paste form within a hard gelatin capsule. These capsules take 5-7 hours to break apart and are affected by the varying pH balances in the GIT as they travel. They begin breaking up and releasing bacteria in the stomach and continue the process in the small and large intestines until all of the beneficial bacteria has been released into the body. Supplementing with 100 million to a billion probiotics per day may provide protection for infants.[11] In our study, we use 60 million viable bacteria contained in OMX probiotics and it proved to be

effective in shortening the course of diarrhea. Dosaging and the right bacteria count are issues that need to be addressed in a clinical trial.

CONCLUSION

Long duration of illness such as diarrhea has obvious public health and economic consequences, such as direct medical cost as well as the indirect costs of parents having to take time off work to look after their sick children. In our study, the mean age of those affected by diarrhea was 12.5 months old, mostly males with normal nutritional status and majority were purely breastfed. Our study showed that the use of probiotics significantly affect the duration of diarrhea. The mean days were shorter (3.17 days) in the probiotics group than in the non-probiotics group (5.42 days) (ARR=0. 60 RR= 0.30 NNT = 1.67). Its use also produced no adverse effects.

RECOMMENDATION:

This study is not a placebo-controlled clinical trial thus, well-designed placebo controlled studies are recommended.

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