



Monroe Community Hospital

LiquaFiber™ Clinical Trial

“Effects of Dietary Fiber – LiquaFiber™ - on Replacing Bowel Medications and Psyllium Fiber use in Long Term Care Residents”

This clinical trial was performed at Monroe Community Hospital in Rochester, New York. Monroe Community Hospital is a 560-bed long-term care facility that has a unique patient mix. The facility has residents of all ages, from children as small as infants to the elderly. The facility boasts one of the finest Alzheimer’s units in the country and has a high speed transitional care unit that offers wonders in a variety of therapies. This study began on March 1st, 2005 and ran until April 20th, 2005.

Problem

Like most long- term care facilities MCH faces the everyday problems associated with constipation and bowel management. One of the contributing factors is the difficulty of patients obtaining the Recommended Daily Allowance of fiber. The products available require large amounts of liquid to be ingested which is very difficult for residence to consume on a consistent basis. The patients are afflicted with taste fatigue and refuse the treatment, hence a variety of bowel medications are ordered to help relieve constipation.

The most common products/drugs that are used today and many in multiple are the following:

- Colace®
- Senna
- Fiber Powders
- Milk of Magnesia
- Sorbitol
- Konsyl®
- MiraLax™
- Fiber Juices
- Lactulose
- Bisacody
- Enemas

These products are expensive in cost, are in many cases difficult for the nursing staff to administer and a hardship on many of the patients. There has not been an easy way to administer natural concentrated liquid fiber that would be safe for the entire patient population. Hence, medical teams have simply prescribed multiple bowel drugs to reach a daily regimen of excretion.

Material and Methods

LiquaFiber™, a liquid fiber product was used in this trial. LiquaFiber™ is an all natural dextrin derived from corn. A single serving of LiquaFiber™ equates to only a ½ ounce of liquid. Each ½ ounce of LiquaFiber™ delivers 5 grams of soluble fiber (*see nutritional info*). The RDA for fiber intake for an adult is 25-30 grams. The average long term care residents has a daily intake of approximately 8 to 11 grams of fiber. The intent of this trial was to judge the effects of additional natural fiber intake on residents while eliminating artificial prescribed bowel medications.

Twenty long-term care residents were chosen who have had a history of chronic constipation and were prescribed to take a variety of oral and suppository bowel medications. A list of ten different bowel products were used on these individuals.

Each resident was given a single serving (1/2 ounce) three times daily for the first week (15 grams/daily of soluble fiber). One resident was given LiquaFiber™ four times daily due to pain medication side effects (20 grams/daily of soluble fiber).

Week 1- LiquaFiber™ - ½ ounce given TID via medicine cup with ½ ounce of patient’s preferred drink additive.

Discontinued from Dr. orders:

Fiber juice product from unit
All powdered Psyllium Fiber products

Monroe Community Hospital, Rochester, NY 14620
Supporting Staff:

Marsha Jackson : Nursing Manager
Miles Lynch : Nursing Manager
Joseph Moore : Director of Nursing
John Vereron : Pharmacy Director
Mary Langworthy : Chief Clinical Dietician



Week 2 - LiquaFiber™- ½ ounce given TID via medicine cup, with ½ ounce of patient's preferred drink additive

Discontinued from Dr. orders:

Colace® – 9 patients

Dulcolax® – 3 patients

Milk of Magnesia – 1 patient

Week 3 - LiquaFiber™- ½ ounce given TID via medicine cup, with ½ ounce of patient's preferred drink additive.

Discontinued from Dr. orders:

Colace® – 2 patients

Milk of Magnesia – 1 patient

LiquaFiber™ - changed to BID – 1 patient

Week 4 - LiquaFiber™ – ½ ounce given TID via medicine cup, with ½ ounce of patients preferred drink additive.

Discontinued from Dr. orders:

Dulcolax® – 1 patient

Senokot® – 1 patient

Week 5 - LiquaFiber™ – ½ ounce given TID via medicine cup, with ½ ounce of patients preferred drink additive.

Discontinued from Dr. orders:

Senokot® – 10 Patients

Fleet – 1 patient

Dulcolax® – 1 patient

Week 6 - LiquaFiber™ – ½ ounce given TID via medicine cup, with ½ ounce of patients preferred drink additive.

Discontinued from Dr. orders:

Sorbitol – 1 patient

MiraLax™ – 1 patient

LiquaFiber™ changed to QID – 1 patient

Week 7 - LiquaFiber™ – ½ ounce given BID via medicine cup, with ½ ounce of patients preferred drink additive.

Discontinued from Dr. orders:

Sorbitol – 2 patients

LiquaFiber™ changed to BID – 12 patients

*** Please refer to table 1 for trial participants detailed information.*

*** Please refer to table 2 which references the specific dates that orders were discontinued.*

Results

After increasing the amount of daily soluble fiber in these twenty residents, we found that LiquaFiber™ was as effective as bowel medications in generating a consistent bowel movement.

Stool conditions were improved and the added moisture to the stool helps to improve stool movement. It was shown that the following products/bowel drugs were removed from the unit as a result of adding LiquaFiber™ to the resident's diet:

Eight products were removed from the unit and replaced with LiquaFiber™.

- Colace®
- Senna
- MiraLax™
- Dulcolax®
- Fiber Juice
- Sorbital
- Milk of Magnesia
- Psyllium Fiber Powders

Discussion

Comments from the Nursing Department:

1. LiquaFiber™ was easy to dispense.
2. Patient compliance was 100%.
3. Small amount of liquid was easy for resident to consume.
4. Taste fatigue was not an issue- able to mix with numerous beverages that were both hot and cold.
5. Easy to flush through G-tubes.
6. LiquaFiber™ was working in even the most difficult of residents
7. Nursing described more formed stools in patients that were hampered by loose stools.
8. Nursing highlighted a situation where stool softening had occurred in a colostomy patient. The ease of secretion was noted.
9. The number of medications on the floor was reduced greatly, some patients were able to deplete their medications requirements by three products.
10. Patients can naturally feel the bowel movement as it approaches evacuation. Various bowel drugs cause a “flush” approach to excretion and can cause embarrassing situations and the permanent use of incontinent briefs.
11. Nursing time to distribute bowel medication was reduced, with few compliance issues.

Conclusion

Our nursing unit was able to condense the amount of products used to combat constipation drastically. It will not only save on our budget, but it enabled us to give our patients a product that is 100% natural, eliminating many of the synthetic bowel drugs that are given today. Nursing time for bowel management was significantly reduced, due to fewer medications to pass and less negative compliance issues to handle. The use of artificial synthetic bowel drugs is common across our country because there never has been an easy way to consume natural soluble fiber. Now there is LiquaFiber™.

LiquaFiber™ Trial Participants

Patient	Age	Sex	Primary Diagnosis	Reason for Constipation	Current Meds/Products
1	84	F	Colostomy, DM, OBS, Hyperthyroid	Decreased Mobility	Milk of Magnesia
2	85	M	CVA, Dementia Hyperthyroid	Decreased Mobility Low Fiber Intake	Fiber Juice, Senekot®
3	79	F	Parkinsons, Schizophrenia CVA, Chronic Constipation Dysphagia	Psychotropic Meds Low Fiber Intake Decreased Mobility	Senekot® Milk of Magnesia
4	85	F	Dementia, HTN, DM, Anemia	Iron Supplementation	Senekot®, Colace, Dulcolax® Suppository
5	67	F	Diabetes, HTN, GERD, Polio	Decreased Mobility Low Fiber Intake	Fiber Juice, Senekot®
6	88	F	Alcoholic, Dementia, MVA L Hip Fracture, Constipation	Decreased Mobility	Dulcolax® Suppository
7	80	F	IDDM, Schizophrenia, HTN Hypothyroidism, Obesity Constipation	Use of Narcotics Decreased Mobility	Senekot®, Sorbitol
8	72	F	Alzheimers, Dementia, Falls DJD, Hypothyroidism	Use of Narcotics Decreased Mobility	Colace, Dulcolax® Suppository
9	59	M	CVA, Constipation, DJD Depression	Use of Narcotics Decreased Mobility	Senekot®, Colace, Sorbitol
10	79	F	CVA, Dysphagia, Cancer Hypertension, Chronic Constipation	Decreased Mobility	Senekot®

Table 1 : Patients' Related Medical History

LiquaFiber™ Trial Participants

Patient	Age	Sex	Primary Diagnosis	Reason for Constipation	Current Meds/Products
11	87	F	Chronic Constipation, CAD Chronic Depression, CVA HTN,	Decreased Mobility Use of Narcotics Iron Supplementation	Colace
12	57	F	Dementia, Alzheimers, GERD Constipation, Seizure Disorder	Decreased Mobility	Colace, Dulcolax® Suppository
13	80	M	CVA, Dementia Constipation	Decreased Mobility	Colace, Fleet Enema Sorbitol
14	71	M	CVA, Usher Syndrome, DM Dementia, Constipation	Decreased Mobility	Senekot®, Colace
15	88	F	Alzheimers, DJD, Dysphagia Chronic Vertigo, Constipation	Decreased Mobility	Senekot®
16	74	M	Expired 3/14/05	Decreased Mobility	Colace, Dulcolax® Suppository
17	82	M	DMII, HTN, Bladder Obstruction Constipation	Low Fiber Intake Decreased Mobility	Konsyl®
18	60	M	M.S., Anemia, Urinary Retention Sacral Decub, Chronic Constipation	Use of Narcotics Decreased Mobility	Colace
19	87	F	CVA, DM, Dementia, Seizures	Use of Narcotics Decreased Mobility	Senekot® , Colace
20	69	M	CVA, Aphasia, HTN Renal Insuff, Constipation	Iron Supplementation Decreased Mobility	Fiber Juice, Senekot®, Colace Dulcolax® Tab, Miralax™

Table 1 : Patients' Related Medical History

Bowel Medication Discharge Schedule

	Week 1 2/27/05 - 3/5/05	Week 2 3/6/05 - 3/12/05	Week 3 3/13/05 - 3/19/05	Week 4 3/20/05 - 3/26/05	Week 5 3/27/05 - 4/2/05	Week 6 4/3/05 - 4/9/05	Week 7 4/10/05 -
Patient 1	Milk of Magnesia 9-Mar LiquaFiber™						
Patient 2	Fiber Juice 1-Mar Senokot® LiquaFiber™				30-Mar		
Patient 3	Senokot® Milk of Magnesia 16-Mar LiquaFiber™				30-Mar		20-Apr BID
Patient 4	Senokot® Colace® 10-Mar Dulcolax (suppository) 7-Mar LiquaFiber™				30-Mar		20-Apr BID
Patient 5	Fiber Juice 1-Mar Senokot® LiquaFiber™				30-Mar		20-Apr BID
Patient 6	Dulcolax® (suppository) LiquaFiber™			23-Mar			20-Apr BID
Patient 7	Senokot® Sorbitol LiquaFiber™				30-Mar		20-Apr
Patient 8	Colace® 10-Mar Dulcolax® (suppository) LiquaFiber™				30-Mar		20-Apr BID
Patient 9	Senokot® Colace® 10-Mar Sorbitol LiquaFiber™				30-Mar	9-Apr	
Patient 10	Senokot® LiquaFiber™			23-Mar			20-Apr BID

Table 2 : Bowel Medication Discharge Schedule - Patients 1-10

Bowel Medication Discharge Schedule

	Week 1 2/27/05 - 3/5/05	Week 2 3/6/05 - 3/12/05	Week 3 3/13/05 - 3/19/05	Week 4 3/20/05 - 3/26/05	Week 5 3/27/05 - 4/2/05	Week 6 4/3/05 - 4/9/05	Week 7 4/10/05 -
Patient 11	Colace® LiquaFiber™		14-Mar 15-Mar BID				
Patient 12	Colace® Dulcolax® (suppositories) LiquaFiber™	10-Mar 9-Mar					20-Apr BID
Patient 13	Colace® Fleet Sorbitol LiquaFiber™	10-Mar			30-Mar		20-Apr
Patient 14	Senokot® Colace® LiquaFiber™	10-Mar			30-Mar		20-Apr BID
Patient 15	Senokot® LiquaFiber™				30-Mar		20-Apr BID
Patient 16	Colace® LiquaFiber™	10-Mar					20-Apr BID
Patient 17	Konsyl® LiquaFiber™	27-Feb	patient expired 3/15				
Patient 18	Colace® LiquaFiber™	10-Mar				4-Apr QID	
Patient 19	Senokot® Colace® LiquaFiber™	10-Mar			30-Mar		20-Apr BID
Patient 20	Fiber Juice Senokot® Colace® Dulcolax® (tablets) MiraLax™ LiquaFiber™	1-Mar 9-Mar	18-Mar		30-Mar	9-Apr	20-Apr BID

Table 2 : Bowel Medication Discharge Schedule - Patients 11-20

LiquaFiber™ Nutritional Information

LiquaFiber™ is dextrin that has been widely used as food for many decades and it is found in the Food and Drug Administration (FDA) as Generally Recognized As Safe (GRAS) affirmation regulation (184-1277) It is a highly safe substance and poses no toxicity as food. Other facts concerning dextrin are the effects of improved serum lipid metabolism and the non-effect of mineral absorption and the safety of long-term administration has been confirmed. Indigestible dextrin has stool-improving affects such as increased stool volume, stool condition and routine movements. Dextrin is a safe food effectively used for preventing non-infectious diseases like constipation and diverticulosis.

PRODUCT: LIQUAFIBER™
 PRODUCT NUMBER: GH-12

	Per 100g of Product		Per 15ML/ One Serving	
	Amount	Unit	Amount	Unit
Total Calories	188		28	
Calories From Fat	0	g	0	g
Total Fat	0	g	0	g
Saturated Fat	0	g	0	g
Cholesterol	0	mg	0	mg
Total Carbohydrates	47	g	7	g
Sugar	0	g	0	g
Dietary Fiber	35	g	5	g
Other Carbohydrates	12	g	1.8	g
Protein	<1	g	<1	g
Sodium	10	mg	1.5	mg
Potassium	15	mg	2.25	mg
Phosphorus	35	mg	5.25	mg
Iron	<1	mg	<1	mg
Vitamin A	<5	IU	<1	IU
Vitamin C	0	mg	0	mg

The above data are either calculated from the quantities used in the product formulation and/or calculated laboratory analysis results and believed to be accurate to the best of our knowledge.

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Product as submitted by Global Health Products, Inc.