A NATIONAL STUDY TO COMPARE THE TOLERABILITY AND EFFECTIVENESS OF COLON CLEANSING PREPARATIONS

by

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ABSTRACT

A NATIONAL STUDY TO COMPARE THE TOLERABILITY AND EFFECTIVENESS OF COLON CLEANSING PREPARATIONS

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Colorectal cancer is the third most common form of cancer, and the second leading cause of cancer-related deaths in the United States. Fortunately, 90% of colorectal cancer deaths are preventable if the disease is detected early. Colonoscopy, the gold standard for colorectal cancer screening, allows direct examination of the colon. However, the colon must be cleaned of all stool in order to detect polyps, tumors, inflammation, and other problems. A wide variety of purging agents are available for colon cleansing but all have limitations and poor bowel cleansing is common. The purpose of the study was to (1) describe bowel cleansing preparations being used across the country, (2) compare their cleansing effectiveness and tolerability, and (3) compare their effectiveness in patients with various health characteristics. This prospective, comparative, descriptive design used convenience sampling to collect data from adult patients

scheduled for colonoscopy at four sites (Baltimore, MD; Dallas, TX; Grand Prairie, TX; and Seattle, WA). Three instruments were used to collect data about tolerability of the colonoscopy preparations, colon cleanliness and demographic and other background information. 201 participants were used for data analysis. The findings revealed many preparations are being used in data collection. More intensive preparations are being used. The preparations were good to excellent with 4 liter (L) PEG-ES with the addition of bisacodyl tablets and MoviPrep demonstrating more of the preparations with excellent ratings. Patients did experience a variety of symptoms which included full feeling, fatigue, abdominal pain, and nausea. Patients also reported sleep disturbances and difficulty with the preparation. There was no statistical significance in colon cleanliness among patients with long standing constipation, diabetes, thyroid disease, or depression. Older age patients did have an increase in their cleanliness scores. It is important to continue pooling data from different sites to help in tailoring preparations to specific patient populations. Additional research may assist nurses in developing guidelines for an individualized approach in selecting colon cleansing preparations which are safe and effective.

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INTRODUCTION

Colorectal cancer is the third most common form of cancer and the second leading cause of cancer-related deaths for men and women in the United States (American Cancer Society, 2007). Colonoscopy is the insertion of a fiber-optic tube into the colon that allows the endoscopist to look directly at the walls in order to diagnose inflammation, ulceration, and tumors. Its major use is the early detection of colorectal cancer. Colon cancer symptoms do not appear until the cancer is quite advanced. Fortunately, about 90% of colon cancer arises from slow growing, adenomatous polyps, and their detection and removal during colonoscopy prevents cancer from developing. Experts estimate that 90% of colorectal cancer deaths are preventable if the disease is detected early (Cohen, Faigel, & Rex, 2007). Clearly, screening of asymptomatic individuals reduces mortality from colorectal cancer (Bjorkman, 2007).

The risk of colon cancer rises with increasing age and the American Cancer Society recommends that everyone 50 or older be screened (CDC, 2007). Approximately 93% of cases of CRC occur in people age 50 or older. Unfortunately, only about 30 to 40% of Americans older than 50 have had the recommended screening. This means that about 41.8 million people still need to be screened.

Polyps, tumors, inflammation, and other problems are not visible when covered with stool; thus the colon must always be adequately cleaned before colonoscopy (Balaban, Byrd, Oblinger, et al., 2003; Froehlich, et al., 2005). Clear visibility of the colonic mucosa is imperative for accurate diagnosis and appropriate treatment.

A wide variety of purging agents are available for colon cleansing including: magnesium salts, sodium phosphate, electrolyte lavage solutions, bisacodyl, and enemas. The American

Society of Gastrointestinal Endoscopy (ASGE) recommends three bowel cleansing preparations: (1) a large volume (2 to 4 liter) isotonic, polyethylene glycol based electrolyte lavage solution (PEG-ES); (2) a small volume (90 ml) liquid sodium phosphate solution; or (3) sodium phosphate pills (ASGE, 2001). These three have been studied extensively and are effective in many cases, but all have limitations (Allaire et al., 2004; Barcun et al., 2006; Chia et al., 1995; Frommer, 1997; Hayes et al., 2003; Kastenberg et al., 2001; Reddy, 2002; Regev et al., 1998; Vanner et al., 1990).

Sodium phosphate (NaP) in liquid or pill form is easy to ingest, but is inappropriate when inflammatory bowel disease is suspected. It sometimes produces aphthae ulcers, mucosal changes that are also characteristic of inflammatory bowel disease (Rejchrt et al., 2004; Zwas et al., 1996). Sodium phosphate also leads to fluid and electrolyte imbalance in susceptible people, and is therefore contraindicated for patients with congestive heart failure, ascites, and renal and hepatic insufficiency. Acute kidney disease, orthostatic hypotension, and ischemic colitis have also been reported; therefore, steps to address patient selection and appropriate dosing and hydration are critical with this product (Balaban, 2008; Hookey & Vanner, 2004).

Polyethylene glycol based electrolyte lavage solutions flush stool out of the colon without causing electrolyte imbalance, dehydration, or changes to the colonic mucosa. Unfortunately, many people experience nausea, bloating, or abdominal fullness and are unable to drink the required 3 to 4 liters at a rate of 1 to 2 liters per hour (Balaban et al., 2003).

Background and Significance

Poor bowel cleansing

Despite the many available bowel cleansers, poor bowel preparation is common. Ness et al. (2001) found inadequate colonic cleanliness in 21.7 % of 649 consecutive patients presenting for colonoscopy at a city hospital, most of which was attributed to the patients' inability to ingest the required volume of the preparation. Inadequate preparations were also

identified in 10 to 75% of patients in randomized control trials (Froehlich et al., 2005). The patient characteristics linked with poor bowel cleansing effectiveness include those conditions which contribute to hypomotility and non-adherence to the preparation regimen.

Hypomotility

Hypomotility, slower movement of feces through the colon, can be caused by certain medications, organic disorders (e.g. diabetes), and aging. Many medications contribute to slower colon transit times including opioid narcotics, antidepressants, anticonvulsants, iron supplements, calcium channel blocking drugs, and aluminum containing antacids such as Amphojel. Opioids and antidepressants are the most common culprits. Opioids decrease intestinal motility by suppressing intestinal contractions and inhibiting secretion of fluids into the intestine (Adams, Josephson, & Holland, 2005). Antidepressants decrease motility because of their anticholinergic properties, which block parasympathetic nervous system activity in the gut. It is difficult to empty the colon of diabetic patients who have autonomic neuropathy, a poorly understood condition characterized by decreased motility in the esophagus and intestine, and delayed gastric emptying. Colon cleansing is difficult because oral preparations are hampered by delayed gastric emptying and slow intestinal transit time (Feigenbaum, 2006; Taylor & Schubert, 2001).

Colon cleansing of elderly patients can also be difficult. A decrease in fluid intake, slower peristalsis, and lack of mobility contribute to alteration in gastrointestinal function in the elderly (Amella, 2006). Elderly patients, especially those greater than 80 years old, are more likely to arrive for colonoscopy with inadequate cleansing, irrespective of the preparation used (Lukens et al., 2002). O'Mahony, O'Leary, and Quigley (2002) suggest that this problem may not be the result of aging, but is instead due to prolonged intake of constipating drugs. The ASGE stipulated that additional laxatives or enemas may be necessary for patients with hypo-motility disorders but no specific guidelines are available. Little research has been done in this

area; therefore, health care providers are forced to try a variety of purgatives to see which are most effective for difficult cases.

Non-adherence to bowel cleansing regimens

Many patients avoid colonoscopies because they are unwilling to undergo the necessary cleansing preparation (Harewood et al., 2002; Kather, 2005; Ristvedt et al., 2003). Barriers to compliance include: the large volume of the preparation, unpleasant taste, and high monetary costs (Dengberg et al., 2005; DiPalma & Brady, 1989). Patients with cognitive impairment (dementia, stroke, etc.) and a lack of understanding of the pre-procedure instructions are unlikely to get a clean colon (Kastenberg, 2007). Prior to colonoscopy, patients are usually placed on a clear liquid diet, are told to avoid certain types of liquids, and need to carefully follow the instructions for taking the bowel preparation. Patients sometimes need to get up during the night to empty the bowels, and thus their sleep is interrupted.

The overall negative appraisal of bowel preparation has led to decreased public acceptance (Ristvedt et al., 2003). Drinking four liters (L) of the PEG-ES solution can be daunting. A reduced volume of PEG solution (HalfLytely) was recently approved (Braintree, 2004; DePalma et al, 2003) and may be a reasonable alternative for some patients. The cleansing solutions' unpleasant taste is also a deterrent for some patients. The manufacturers have tried to alleviate this problem by adding flavoring to mask the taste (Gruber et al, 1991; Hayes et al., 2003). Flavoring agents must be used with caution, however, because they can change the osmotic properties of the lavage solution.

Additionally, cost has been described as a deterrent for some patients (Denberg et al., 2005). Most insurance companies will now cover the cost of screening colonoscopy; but sometimes patients pay the costs. The cost of these preparations may range from $5.00 upwards to $50.00 (Wexner, 2006).

There is some evidence that inpatients are less likely to have effective colon cleansing than are outpatients, and are therefore more likely to need to have the colonoscopy repeated

(Reilly, 2004). Inpatients tend to be compromised due to illness and decreased mobility. This limits their ability to consume the required amount of preparation and ultimately results in poorer quality preparations.

Most experts agree that failure to follow preoperative instructions contributes to poor cleansing and subsequently poor examinations. Patient understanding of the preparation instructions is critical to the overall quality of the colon cleansing. Ness et al. (2001) reported that 18% of inadequate preparations are due to failure of patients to follow instructions. Thus, healthcare providers should deliver verbal and written instructions which are clear and easy to follow. He further adds that spending more time with patients reviewing the instructions may increase compliance. A pre-procedure or pre-colonoscopy telephone call to reinforce these instructions and address concerns or misunderstanding may also improve the quality of colon cleansing (Rex, Imperiale, Latinovich, & Bratcher, 2002).

Presently, no perfect bowel cleansing preparations exist. The ideal preparation would: (1) reliably empty the colon of all fecal material, (2) not alter the gross or histologic appearance of the mucosa, (3) require a relatively short period for ingestion and evacuation, (4) cause no patient discomfort, and (5) produce no significant fluids or electrolyte changes (ASGE, 2001).

Since no obvious choice is available, and every preparation has some drawbacks, many healthcare providers still choose bowel cleansing preparations based on their own preference or what they used in school. Gastroenterology nurses usually educate the patients about the proper way to complete the bowel cleansing procedure and answer questions when they arise. In some cases, they are involved in influencing the decision about what preparation should be used. It is therefore important that gastroenterology nurses understand how the preparations work, possible side effects, and the best preparation for different types of patients. Preconceived ideas regarding bowel preparations can be replaced with information collected using the objective viewpoint of research methodology (Allaire et al, 2004). An increased

awareness of the type and effectiveness of these preparations will add to the knowledge base of healthcare providers in practice.

Physiological Framework

Bowel cleansing preparations work in different ways to stimulate defecation and empty the colon. An understanding of the anatomy and physiology of the colon will provide the scientific background and framework for this study. The principal functions of the colon are (1) absorption of water and electrolytes, and secretion, (2) fiber fermentation, and (3) storage and evacuation of stool (Guyton & Hall, 2006). Since these functions are important in understanding how bowel preparations empty the colon, they will be discussed in greater detail.

The colon is approximately 125 cm in length and comprised of layers which include the mucosa, sub mucosa, muscularis, and serosa. The mucosa, the innermost layer, is lined with epithelial cells and goblet cells. The epithelial cells absorb fluid and electrolytes from the lumen of the colon, and the goblet cells produce mucous which not only lubricates fecal material, but holds it together in order to facilitate its transport through the colon. They also protect the mucosa from irritants (Guyton & Hall, 2006). The cecum, ascending colon, transverse colon, descending colon, sigmoid, rectum, and anal canal represent the major segments of the colon (Figure 1). Each segment of the colon is responsible for different functions.

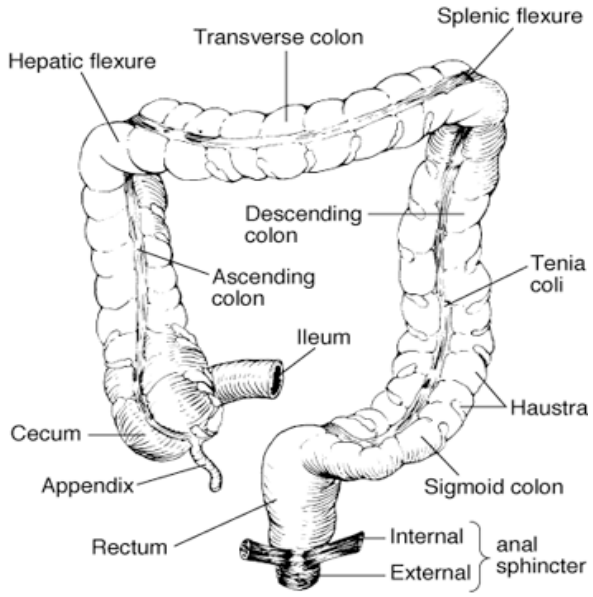

Figure 1. Anatomical figure of the colon. Image obtained from www.fruiteze.com

The submucosa or second layer contains the large blood vessels and lymph vessels. The circular and longitudinal muscles located in the muscularis layer allow propulsion and mixing of the feces. The musculature of the colon is organized in three bands which begin in the most proximal portion (cecum) and extends throughout the entirety of the colon. The final protective or outer layer is the serosa.

Absorption and Secretion

Chyme, a semi-fluid mass from the small intestine, enters the cecum through the ileocecal valve. Under normal physiological conditions, chyme enters the large intestine approximately four hours following digestion. Water and electrolyte absorption and fermentation of undigested fibers and sugars are performed by the cecum and ascending colon. About eight or nine liters of fluid must be absorbed by the digestive tract daily. Under normal conditions, about 1.5 liters of chyme enters the colon daily with only 100-200 ml excreted in the stool. This absorptive capacity prevents an increase in water in the stools that could lead to diarrhea.

Water is absorbed from the colon through osmosis, a process whereby water moves through a semipermeable membrane from an area of high water concentration to low water

concentration (Figure 2). This process occurs in the digestive tract because the intestinal mucosa is able to generate a large osmotic gradient between the intercellular space and the lumen (Guyton & Hall, 2006).

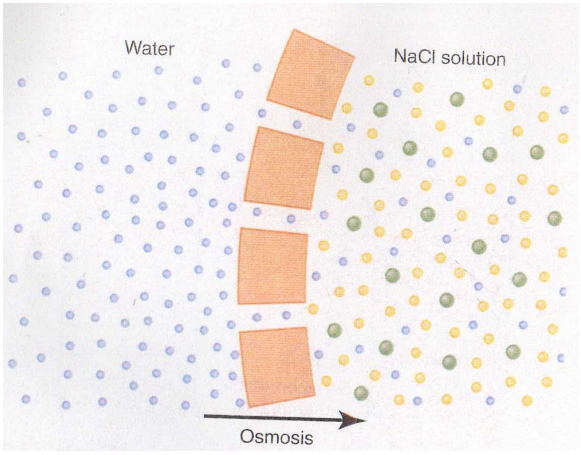

Figure 2. Osmosis Principle, Guyton & Hall, 2006.

The concentration gradient forms when sodium moves from the lumen into extracellular space. Sodium is actively absorbed in both the small and large intestine due to the sodium potassium ATPase pump which regulates the electrolyte transport. Water moves by osmosis toward the area of higher sodium concentration (Figure 3). This same mechanism of action occurs when other substances such as nutrients, ions, and solutes are absorbed into the blood from the intestine.

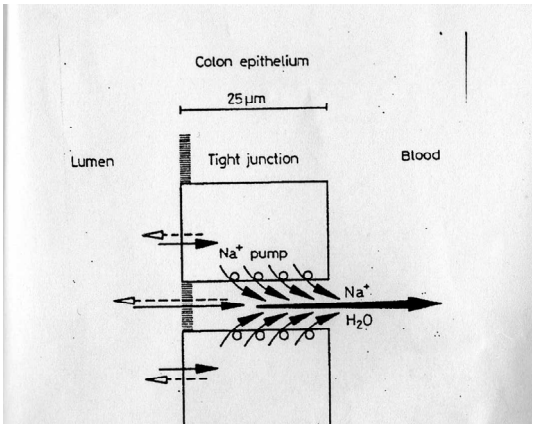

Figure 3. Water transport in intestine. Guyton & Hall, 2006.

Water moves into or out of the intestine until the osmotic pressure is equal to that of plasma. Since the osmolality of extracellular fluid is about 300 mOsm, water will diffuse to this area when the osmolality inside the lumen is greater than 300 mOsm per liter. When intestinal contents are hypertonic or hyperosmotic to the plasma, fluid will move into the lumen. When the contents are hypoosmotic or hypotonic, water will move out of the lumen. Hypertonic solutions stimulate defecation by drawing fluid from the body into the lumen of the colon. Water is transported from plasma to chyme when these hyperosmotic solutions are discharged. Isotonic solutions do not irritate the lumen but rather cause diarrhea because the colon becomes overloaded.

In addition to secretion of mucous discussed previously, secretion of large quantities of water and electrolytes occurs as a response to irritation. This causes dilution of the irritating factors which causes rapid movement of the stool into the anal canal resulting in diarrhea. These processes are critical in influencing transit time (the time it takes for feces to travel through the colon).

Fiber Fermentation

Scientists have long known that fiber is fermented in the colon by bacteria (Floch et al., 2005). When polysaccharides and dietary fiber escape digestion in the upper digestive tract, colonic bacteria breaks them down into gases and short chain fatty acids through fermentation (an anaerobic process). This process normally occurs in the proximal colon and provides nutrients for the colon epithelium. The fermented fiber also contributes to the volume of the feces, and the gases produced by fermentation result in abdominal bloating and an increase in passage of flatus.

Storage and Evacuation

Another major function of the colon is the storage and evacuation of feces. The left colon (descending colon, sigmoid colon, and rectum) are involved in this process which is

facilitated by the musculature of the colon. An interplay of several complex processes results in motility which is responsible for the forward movement of feces.

Motility

The enteric nervous system and the autonomic nervous system innervate the colon. The enteric nervous system has networks in the submucosa and muscle layers of the colon that control motility and secretory functions. Release of certain neurotransmitters activates circuits which cause muscle contractions.

Serotonin (5-hydroxytryptamine: 5-HT) plays a role in secretion, motility, and sensation in the gut (Grundy & Schemann, 2004). In response to an irritant, cells in the intestinal mucosa release serotonin to stimulate peristalsis and secretion to move the irritant out of the body (Parischa, 2006).

The autonomic nervous system is comprised of the parasympathetic system and the sympathetic system. The parasympathetic nerves are excitatory and contribute to the propulsive activity of the distal colon. The sympathetic pathways inhibit motor activity and control excessive water loss (Feldman, Friedman, & Sleisenger, 2002). Similarly, certain laxatives stimulate peristalsis by nerve excitement. Nerves are stimulated by local irritation of the mucosa which increases peristalsis and motility. This causes a decrease in the time for absorption of fluid and water which in turn leads to diarrhea.

Motility in the gastrointestinal tract is described by both propulsive or mixing movements and mass movements (Turnbull, Vanner, & Burnstein, 2007). The propulsive movements (peristalsis) are responsible for the movement of food along the digestive tract and allow the colon content to be exposed to epithelial cells. These propulsive movements occur because the muscles cause portions of the colon to continually bulge into saclike projections known as haustral folds. A mass movement of feces through the colon begins when a constrictive ring occurs at an irritated area of the colon, followed by distention distal to the initial contraction which forces the fecal material down the colon. This contraction is progressive resulting in force

and relaxation which causes movement. This continual pushing of intestinal content in the direction of the anus is termed the “law of the gut” (Guyton & Hall, 2006). This may occur one to three times per day and last approximately ten to thirty minutes.

Normally, motility and absorption are balanced so that by the time feces reach the sigmoid, the appropriate amount of water has been absorbed so stool is firm but still easily passed. When motility slows, the contact time of the feces in the lumen increases which allows more water to be absorbed. This contributes to the production of firm or hard stools which are difficult to expel. Conversely, increasing motility from any cause will decrease the absorption of solutes and water from the feces and leads to diarrhea (LeBlond, DeGowin, & Brown, 2004).

Defecation

Feces is usually stored in the sigmoid colon, until mass movement propels it into the rectum. Due to the sharp angulation between the sigmoid and rectum, the rectum is usually empty of feces. The urge to defecate occurs when the rectum fills from mass movement of feces. Once feces enter the rectum, the rectal wall becomes distended, initiating peristaltic waves in the colon to force the feces into the anal canal (Floch, 2005). Once this wave reaches the anus, the anal sphincters relax and defecation will usually occur. Defecation at this point is augmented by a parasympathetic defecation reflex involving the sacral segments of the spinal cord which results in emptying. The process of defecation can be delayed until convenient or socially acceptable. Defecation can be purposely activated by taking deep breaths and moving the diaphragm downward and then contracting the abdominal muscles to increase the pressure in the abdomen, forcing fecal contents into the rectum. Normal transit time of feces through the colon varies from 10 hours to several days depending on the condition of the colon.

Map/Model: How Colon Cleansing Preparations Work

The goal of colon cleansing is an empty colon. This is accomplished with a clear liquid diet to prevent additional chyme from entering the colon and laxatives and other preparations

designed to remove whatever is already there. The conceptual map/model (Figure 4) illustrates the mechanisms of action of the various cleansing preparations.

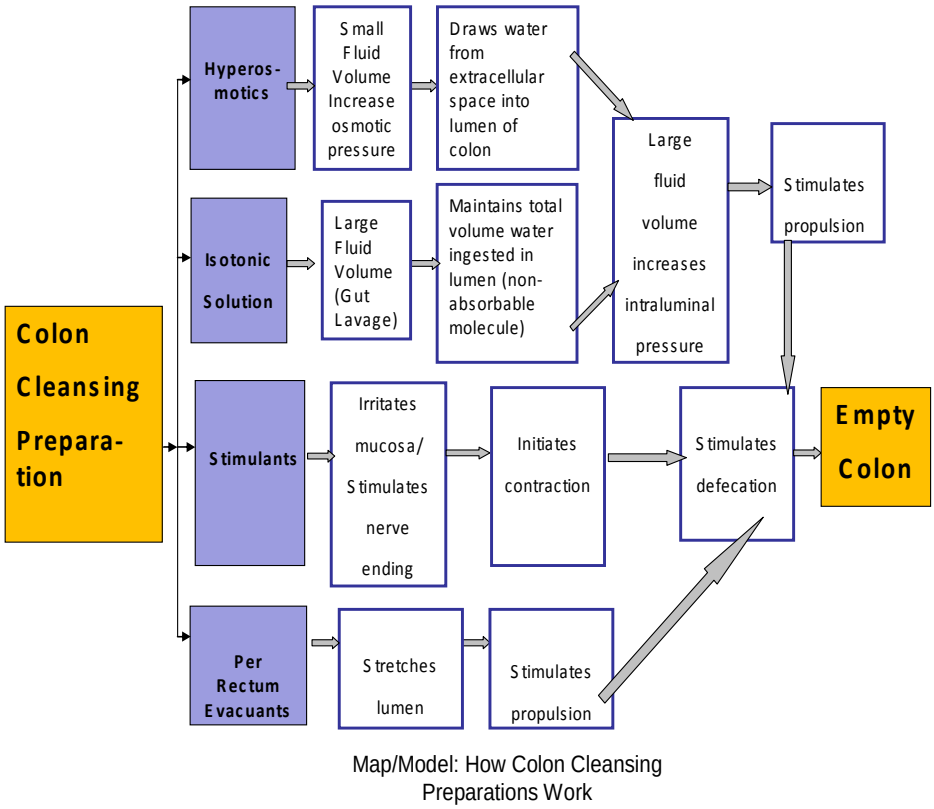

Figure 4. Map/Model: How Colon Cleansing Preparations Work.

The complexity of action of many laxatives remains uncertain and under investigation; however it is generally accepted that most promote defecation by stimulating secretion, attracting water into the stool, and stimulating motility (McEvoy et al., 2006; Sarre, 2005). The usual pharmacological classification of the action of these laxatives include stimulants, osmotic laxatives, and gut lavage (Parischa, 2006). The mechanism of action of these laxatives is summarized below.

Stimulant laxatives

Stimulant laxatives such as bisacodyl and senna are often used to treat constipation, and are used in combination with other preparations for colon cleansing. The mechanism of

action is an increase in intestinal peristalsis caused by nerve irritation of the mucosa and a reduction in the net absorption of fluid and electrolytes (Adams, Josephson, & Holland, 2005). Major side effects of these laxatives are abdominal discomfort, diarrhea, dehydration, and loss of electrolytes caused by the large fluid accumulation resulting in defection (Feldman, Friedman, & Sleisenger, 2002). Additionally, these substances may damage the epithelial cells of the mucosa causing a benign, brownish discoloration attributed to an accumulation of pigment in the lamina propria (Feldman, Friedman, & Sleisenger, 2002).

Bisacodyl

Bisacodyl can be ingested orally as a 5 mg enteric coated tablet or inserted as a 10 mg suppository. When used to clean the colon before colonoscopy, it is usually given one to two hours orally prior to starting a lavage solution. Bisacodyl is activated in the colon where it is rapidly converted by intestinal and bacterial enzymes to the active desacetyl metabolite, an agent that reduces net absorption of electrolytes and water. The resulting fluid accumulation in the colon stimulates defecation (McEvoy et al., 2006). The onset of action occurs within six to twelve hours.

Senna

Senna is an oral laxative that has long been used to treat constipation and has recently been used with bowel cleansing preparations. It is one of a family of anthraquinone laxatives which are plant derived compounds. The usual adult dose of senna is 0.5-2 gram once or twice daily. Following ingestion, it is absorbed minimally in the small intestine; however, in the colon, the enzymes of colonic flora hydrolyze the senna into the active free anthraquinone. The onset of action occurs within six hours following oral administration. Abdominal cramping is the principle side effect which results from the increase in intestinal motility.

Osmotic Laxatives

Osmotic laxatives include hyperosmotic products that draw fluid from the vascular and intercellular spaces into the intestinal lumen to produce diarrhea and soften the feces. Scientists

believe that they work in the following way. The osmotic laxatives are composed of a non diffusible solute such as dissacharride, magnesium, or phosphate that is not easily absorbed. Therefore, osmolality is much higher inside the lumen than in the intercellular and vascular spaces. Water moves from an area of higher water concentration (lower solute concentration) to the area of lower water concentration (higher solute concentration) until osmolality is equalized (Figure 5).

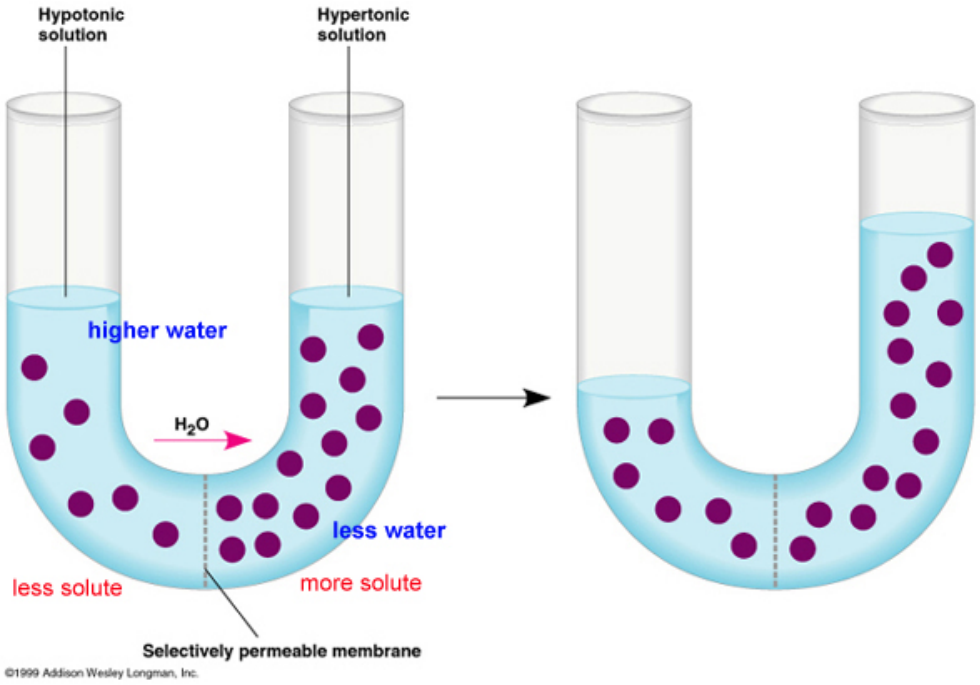

Figure 5. Movement of water through a semipermeable membrane to a higher concentration of solutes. www.biologycorner.com/bio1diffusion.html

The extra fluid in the lumen of the colon increases motility, induces diarrhea, and causes evacuation of feces. This class of laxatives may result in volume depletion due to the rapid loss of fluid; therefore, good hydration and adequate kidney function are essential (Parischa, 2006). Symptoms of volume depletion include thirst, fatigue, and muscle cramps. Electrolyte abnormalities are possible since as much as 20% of the magnesium, sodium, or

phosphate can be absorbed from the lumen into the vascular space. Hypermagnesemia, hypernatremia, hyperphosphatemia, hypocalcemia, or hypokalemia can occur when the person has marginal or poor renal function. Consequently, osmotic laxatives are contraindicated for patients with any condition resulting in poor kidney perfusion (e.g. congestive heart failure, cirrhosis of the liver, and kidney failure) and significant cardiovascular disease. Some patients may experience severe nausea due to the taste (too salty or too sweet).

Dissacharides

Lactulose (e.g. Cephulac and Chronulac) is available as a syrup; each 15 ml contains 10 grams of lactulose. A dose as high as 40 grams is used in bowel cleansing. Lactulose is a dissacharide (two sugars) which passes through the stomach and small intestine undigested or unsplit. When it enters the colon, colonic bacteria are able to break the dissacharide down into substances that are only partially absorbed. The nonabsorbable breakdown products add to the osmotic load, draw fluid into the intestinal lumen, and stimulate motility to produce diarrhea (Pasricha, 2006). A watery evacuation usually occurs one to six hours after lactulose ingestion.

Magnesium Citrate

Magnesium salts are poorly absorbed and therefore act by their osmotic properties in the luminal fluid. The usual dosage is 11-25 g of magnesium in a 240 ml dosage. The high magnesium concentration attracts water which increases the intraluminal pressure and also softens the stool. This influx of water to equalize the osmotic pressure usually produces a semi-liquid or watery evacuation within three hours. Magnesium salts also cause duodenal secretion of cholecystokinine, a hormone that further stimulates fluid secretion and motility (Parischa, 2006).

Sodium Phosphate

Oral sodium phosphate (NaP) has been widely used as a colon cleansing preparation following its introduction in 1990 (Linden & Wayne, 1999; Vanner et al., 1990). One of the features which makes it popular is the smaller volume required. The usual dose of NaP as a

colon cleansing preparation is 90 ml. This dose is usually split so that 45 ml is taken the day before and 45 ml is taken the morning of the procedure. The solution contains 48 g (400 mmol/L) of monobasic sodium phosphate and 18 g (130 mmol/L) of dibasic sodium phosphate per 100 ml (PDR, 2007). The high concentration of sodium phosphate draws fluid into the lumen to stretch its walls and stimulate peristalsis resulting in an evacuation. Since fluid is drawn from within the body, it is critical that patients consume clear liquid liberally in order to prevent dehydration. If an excessive dose is given, as may occur if the patient accidentally takes the 90 ml at one time instead of in divided doses, the sodium and potassium levels in the blood may rise to dangerous and sometimes fatal levels. Toxicity can also occur if the person is unable to evacuate the sodium and phosphate rapidly enough from the colon, such as occurs with a bowel obstruction. As the contact with the lumen of the colon increases, more sodium and phosphate are absorbed.

Gut lavage with polyethylene glycol electrolyte solution (PEG-ES)

PEG-ES is an isotonic, oral gastrointestinal lavage that is sometimes classified with the osmotic laxatives, but its action is somewhat different. It acts as a gut lavage to flush stool out of the colon. The solution consists of a long chain polyethylene glycol solute, a substance with such a high molecular weight that it cannot be absorbed as it passes through the digestive tract. It also contains sodium sulfate, sodium bicarbonate, sodium chloride, and potassium chloride. Since PEG is the major solute and cannot be absorbed, the lavage solution maintains it isotonicity, and no fluid moves into or out of the intestinal lumen. Since there are no fluid shifts, a large volume of solution can be given with virtually no net absorption or excretion of ions or water. Therefore, PEG-ES is safer for people with poor or marginal kidney function, and those susceptible to fluid and electrolyte imbalance (Hawes, Lowry, & Deziel, 2006). Another advantage of PEG is that it does not damage the intestinal mucosa (Schmelzer et al., 2000).

PEG-ES is sold as a white powder that is reconstituted with water to make 4 liters of solution. Following reconstitution, patients drink the 4 liters over three to four hours by

consuming eight ounces every 10 minutes. Ingesting large volumes of isotonic electrolyte solution over a short period of time will effectively cause diarrhea because the absorptive capacity of the colon is overloaded. Patients often have difficulty drinking the large volume required and may experience abdominal fullness, bloating, and nausea (Toldedo & DiPalma, 2001).

Due to the large volume ingested, patients with suspected intestinal obstruction should not be given this preparation. Serious complications have been observed such as esophageal perforation resulting from vomiting, asystole, respiratory difficulties, and aspiration (PDR, 2007). Because of the large volume of fluid ingested, and the risk of vomiting and aspiration, PEG-ES should be used cautiously in patients older than 60.

Per Rectum Evacuants

Evacuants administered via the rectum can be classified as either enema or suppository. A suppository is a small bullet-size solid body which is inserted in the rectum. It contains an irritant which stimulates a bowel movement (Pugh, 2000). While it is effective, it is not usually part of colon cleansing for colonoscopy since it only cleans the distal colon.

On the other hand, an enema can be very effective and can be utilized alone or as adjunct with other bowel preparations. An enema is the placement of fluid or medications in the rectum to induce a bowel movement or empty the bowel. Enemas are effective in bowel preparation because the action is relatively quick, usually occurring within minutes after solutions are instilled. This immediate effect results from initiation of propulsion and secretion. When the enema is administered into the rectum, the colon becomes distended. This stretching of receptors in the rectum initiates impulses that trigger sensations of urgency (Floch et al., 2005). Additionally, when a large amount of stool is present, the solution softens the stool and causes distention of the rectum resulting in defecation (Peura, 2007).

Tap water, mineral oil, and phosphate are common solutions for enema preparation prior to colonoscopy. Some medications such as sodium phosphate will stimulate defecation by

drawing fluid from the body into the lumen and irritating the rectal mucosa, which stimulates propulsion (Schmelzer, 2000). Side effects include abdominal cramping and, on rare occasion, lightheadedness. A disadvantage in use of per rectum evacuants occurs when stool remains proximal to the rectal area. Perforations from enemas are rare but remain a very serious complication. Fleet enemas should be used with caution as hyperphosphatemia or damage to the rectal mucosa can occur.

How do we know the colon is clean?

While many studies address efficacy, there remains little consensus as to what constitutes adequate cleansing of the colon (Kastenberg, 2007). In clinical trials, common ratings of quality of the preparations include: “excellent” – no solid stool with small amount of clear fluid requiring suctioning; “good” – no or minimal solid stool and large amount of clear fluid requiring suctioning; “fair” – collection of semi-solid stool; and “poor” – solid or semi-solid feces present that cannot be cleared (Rex et al., 2006). The endpoint for this proposed study as illustrated in Figure 4 is an empty colon. Measures are based on efficacy of the bowel cleansing preparations. This is an important criterion because it contributes to the ability of the gastroenterologist to complete the colonoscopy in a timely manner, identify lesions, and make a medical diagnosis. An empty colon would allow maximum visibility of the bowel wall with no residual stool.

An individualized approach to colon cleansing preparations may increase adequacy and efficacy of preparations when knowledge of specific guidelines can be developed. As no comprehensive comparison of the various preparations’ effectiveness and side effects existed, this multi-site study was needed.

Purpose

The purpose of this study was to compare the tolerability and effectiveness of colon cleansing preparations used at different sites across the nation.

Research Questions

This study sought to add to the body of knowledge and answer the following questions:

1. What bowel cleansing preparations are being used nationwide for colonoscopy?
2. Are there differences in bowel cleanliness observed during colonoscopy when the different preparations are used?
3. Do patients experience different levels of discomfort with different bowel cleansing preparations?
4. What is the relationship between patient health characteristics and bowel preparations' effectiveness?

Definition of Terms

The following definitions were used for this study:

Colonoscopy: The visual inspection of the colon with a fiber-optic tube, an endoscope, which is inserted into the colon. The endoscope allows the endoscopist to look directly at the mucosa of the bowel in order to diagnose conditions.

Colon cleansing: The stimulated discharge of feces from the colon with the use of laxatives, lavage, and enemas. This process has been used when preparing patients for such procedures as colonoscopy, radiological tests, and urological and surgical procedures. The effectiveness of these preparations is demonstrated by a well cleansed colon which is virtually free of residual stool and excessive amounts of fluid.

Subject experiences: Those discomforts patients experience when undergoing any type of bowel preparation. Many patients experience headache, nausea, vomiting, abdominal cramps or pain, rectal itching, rectal burning, dizziness, a full feeling, and fatigue. In addition, patients may have difficulty with sleep and difficulty with the preparation. Finally, the cost of the preparations varies and may at times cause additional stress for the patient.

Cleanliness: The cleanliness construct is delineated by the amount of residual stool, consistency of stool, and the amount of visible bowel wall.

Assumptions

The following assumptions were identified for this comparative, descriptive study:

1. Subjects will implement the bowel cleansing procedures as prescribed.
2. Patient compliance increases the efficacy of the preparation.
3. Patients will honestly report what they did.
4. Subjects will honestly report discomfort during the preparations.

Summary

Since colorectal cancer is potentially preventable and treatable, it remains one of the Centers for Disease Control and Preventions' (CDC) primary initiatives in encouraging partnerships, education, and research (CDC, 2007). Although different screening techniques exist, colonoscopy is being used more often for Colorectal Cancer (CRC) screening. Patients undergoing colonoscopy must have a clean colon. Inadequate preparation can be costly due to missed lesions, increased risk for complications, increased procedure time, and the need to repeat the procedure. The patient's experience should also be without pain or other problems. Evaluating the many colon cleansing preparations is vital in selecting the appropriate preparations for patients on an individual basis based on clinical history. Ideally, when the preparation is taken properly, the colon will be free of any residual stool and the patient should report minimal discomfort or side-effects. Additionally, healthcare providers should be able to utilize evidence based practice in selection of preparations for patients scheduled for colonoscopy.

Surely, educating health care providers on strategies for easier-to-tolerate bowel preparations should impact the odds of survival for some patients (Cohen, Faigel, & Rex, 2007). If improvements in bowel preparations are to occur, continued research in this area is critical. It is vital to continue efforts toward improving patient compliance and patient acceptance through education and research of preparations (Byrne, 2002). The search for reliable bowel preparations and strategies to improve patient understanding will reduce cost and improve

efficiency. Therefore, it is critical that the search for the perfect preparation which addresses quality, patient satisfaction, and safety continue (Schmelzer, 2005). This study adds to the body of knowledge by providing additional evidence to assist with a more individualized approach to selection of colon cleansing preparations which are safe, effective, and tolerable.

CHAPTER 2

REVIEW OF LITERATURE

During colonoscopy, barium enema, and certain surgical procedures, the lumen of the colon must be essentially free of residual stool and fluid. As discussed in Chapter 1, the lumen can be cleansed with a variety of preparations including stimulant laxatives, osmotic laxatives, polyethylene glycol electrolyte solution (PEG-ES), and per rectum evacuants. While multiple studies have been conducted and multiple preparations are available, there remains little information about selecting the *ideal* preparation for a particular patient. The increasing demand for colonoscopy underscores the necessity for a continual review of the efficacy, tolerability, and safety of bowel cleansing preparations.

An extensive literature review was conducted to find the evidence for the effectiveness and tolerability of different colon cleansing solutions, in order to understand how to choose the best preparation for a particular situation. MedLine, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycInfo were used to find research studies from 1944 to the present. Keywords used included: colon, bowel cleansing, bowel preparations, cathartics, laxatives, tolerability and efficacy. The information from this review was organized into the following categories which will be addressed in this chapter:

1. Historical perspective on use of colon cleansing preparations
2. Effectiveness and tolerability of the various preparations
3. Gaps in the literature

Historical perspective on use of colon cleansing preparations

The very first bowel cleansing preparations were enemas used by Egyptians as early as 1500 B.C. Enemas remained popular through the centuries and were even used by many

primitive societies. The 16th century is known as the age of clysters, another name for enemas, because they were so popular especially among the elite. Oral purgatives came into use later. The earliest were made from plants such as castor oil from the castor bean plant (*Ricinus communis*) and senna, a cathartic made from dried leaves of a plant called *Cassia acutiflora*. Bisacodyl, an irritant laxative, first became available in the 1960's and magnesium preparations have been used in radiology for many decades. The two newest preparations are polyethylene glycol electrolyte solution (Colyte and GoLytely) developed in the early 1980s and oral phosphosoda developed in 1990.

Early cleansing methods were time consuming and exhausting for both the patients and the nurses administering them. For example in 1960, preparation for barium enema included castor oil and a liquid supper the evening before the procedure and enemas until clear the next morning. A 1960 survey of 129 patients scheduled for barium enema found that patients needed anywhere from two to eighteen enemas to get clear returns and the mean number of enemas was five (Raymond, Norgrady, & Vezina, 1960).

At first, endoscopists could only reach the rectum and sigmoid colon; therefore, they were able to use the same cleansing preparations as radiologists and surgeons used to prepare patients for their procedures. When improved technology made colonoscopy possible, the entire colon needed to be clean and PEG-ES and oral sodium phosphate (NaP) were developed to make this possible (DeLuca, 1980; DiPalma & Brady, 1989; DiPalma & Marshall, 1990; Frommer, 1997). Both are effective when given alone and remain the most popular preparations in use today. Unfortunately, both have risk and vary in the tolerability and effectiveness with different patients.

Effectiveness and Tolerability

The majority of studies have compared the effectiveness and tolerability of PEG-ES with sodium phosphate (NaP) in either liquid or tablet form (Balaban et al., 2003; Bujanda et al., 2001; Vanner et al., 1990). Subjects were usually healthy people, and those with ileus or

suspected bowel obstruction, prior alimentary tract surgery, severe gastric outlet obstruction, significant cardiovascular disease and renal disease were excluded. Most researchers found that sodium phosphate was more effective than PEG-ES, probably because subjects found it easier to drink a total of 90 ml (in two divided doses) than 4 L of PEG-ES over a three to four hour time period (Allaire et al., 2004; Cohen et al., 1994; Kossi, 2003; Rostom et al., 2006; Young et al., 2000). Patients who took the PEG-ES were far more likely to report nausea, vomiting, bloating, abdominal cramps, and sleep loss than were patients who took NaP, possibly because the volume ingested was so much greater.

Hsu (1998) conducted a meta-analysis of eight randomized trials (N = 1286) conducted between 1990 and 1996, and found that sodium phosphate produced a superior quality of colon cleanliness when compared to PEG-ES. In addition, compliance with the cleansing procedure was significantly higher and the costs were significantly cheaper when NaP was used. Hsu concluded that subjects receiving NaP were 95% more likely to have an excellent, quality preparation than those who drank the PEG-ES.

Not everyone agrees. Ell et al. (2003) found PEG significantly superior in effective cleansing of the entire colon prior to colonoscopy. Others found no differences in colon cleanliness when comparing sodium phosphate and PEG (Afridi et al., 1995; Reddy, 2002).

Although sodium phosphate is very effective for healthy individuals, it is not appropriate for everyone. Patients with renal failure or insufficiency, congestive heart failure, and liver failure are unable to safely clear the sodium and phosphate, and may develop fatal fluid and electrolyte imbalances (Belooseky et al., 2003; Burbige, Bourke, & Tarder, 1978; Gumurdulu et al., 2004; Hookey & Vanner, 2004; Huynh et al., 1995; Markowitz et al., 2005). Sodium phosphate can also alter the mucosal surface of the intestinal lumen (Sharma et al., 1998). PEG-ES does not produce any of these complications, and is therefore safe for patients with renal, cardiac and liver problems. Only one study was found in the literature examining the effectiveness of colon cleanliness in the diabetic patient. Taylor and Schubert (2001) conducted a prospective,

descriptive study to compare the efficacy of PEG-ES in the diabetic versus non-diabetic patient. Consecutive non-diabetic patients (n = 54) and diabetic patients (n = 45) scheduled for outpatient colonoscopy prescribed 6 L of PEG-ES (GoLytely) participated in the study. During the colonoscopy, the gastroenterologist used a 14 part rating system to evaluate the surface area of mucosa and the consistency of residual stool. The findings revealed only 62% of the diabetic patients had a good or better preparation rating when compared to the non-diabetic patients (97%). PEG-ES, sodium phosphate, and the other colon cleansing preparations will only work if the person is able to ingest them. Taste and volume are the major factors that influence the ability to take the preparations.

Taste

Both PEG-ES and NaP taste so bad that patients have trouble drinking them. Manufacturers of both products have tried various strategies to make them more palatable. For example, PEG-ES is salty, so the manufacturer removed the sulfate to make a less salty product, named sulfate free electrolyte solution (SF-ELS). When 157 subjects were randomly given either PEG-ES or SF-ELS, those receiving SF-ELS reported significantly less fullness and cramping than those who drank PEG-ES ($p< 0.01$) and no differences in colon cleansing effectiveness occurred (DiPalma & Marshall, 1990). The manufacturer of NaP developed a low-salt preparation, called EZ-Prep that subjects also found more tolerable than NaP (Verghese, Ayub, Qureshi, Taupo, & Graham, 2002).

Flavoring packets are sometimes added to PEG-ES lavage solutions in order to improve palatability and increase compliance (Hayes et al., 2003). The addition of different flavorings to the cleansing solutions must be undertaken with caution because they may result in an overall change in the osmolality of the solution. Gruber et al. (1991) found that adding one packet of Crystal Light or two of KoolAid to Colyte improved palatability without altering the osmolality of the solution.

Frommer (1997) reported that patients who received NaP also experienced nausea and vomiting due to the unpleasant taste. The manufacturers developed a tablet preparation to improve palatability. Unfortunately, patients have difficulty taking the large number of pills (40) required. Kastenberg et al. (2001), found sodium phosphate tablets just as effective and safe and more tolerable than PEG solution. In this multi-site study, 886 patients were randomized to sodium phosphate tablets (n = 427) or PEG solution (n = 425). However, the multiple exclusion criteria limited subjects to healthy people.

Balaban et al, (2003) compared the liquid form to the tablet form of NaP. Patients were randomized to receive either liquid NaP (n = 51) or Visicol tablets (n = 50). Patients receiving liquid NaP reported better tolerability based on a 5-point Likert scale. In addition patients ingesting tablet sodium phosphate had poor cleaning in the cecum due to residue remaining as compared to patients taking liquid sodium phosphate. Patients voiced difficulty in taking the large number of tablets and the volume of liquid required to get them down.

Volume

Modification of the PEG-ES solution which resulted in the removal of sulfate was an attempt to improve palatability; however, volume remained a critical factor (Fordtran, 1990). Patients tended to prefer the lower volume of oral sodium phosphate over PEG (Cohen et al., 1994; Rostom et al., 2006; Young et al., 2000). They reported an increase in nausea, vomiting, bloating, abdominal cramps, and sleep loss when ingesting large volumes of preparations. Because of uncomfortable side effects, subjects could not complete the preparation, and therefore had a poorly prepared colon.

There is evidence that a split dose or reduced dose of PEG-ES is sufficient in cleansing the bowel. In a study of 141 patients, Aoun et al. (2005) found that a split dose of PEG was superior to a whole dose of PEG. Patients were randomly assigned in this prospective, blinded, single-center study to receive either a whole dose of PEG or a split-dose PEG (2 L of PEG the day before exam and 2 L of PEG the morning of the exam with minimal diet limitation) on the

evening prior to colonoscopy. The split dose PEG-ES without dietary restriction was better than a whole dose for colon cleansing. Patients felt the split dose was easier to ingest than having to drink 4 L in a single setting. Similar findings were reported by El Sayed et al. (2003) and Verghese et al. (2002).

The addition of stimulant laxatives such as bisacodyl to 2L PEG-ES may improve tolerance and effectiveness. Patients undergoing colonoscopy were randomized to receive the reduced volume of 2 L (n = 93) or 4 L of PEG-ES (n = 93) (DiPalma et al., 2003). Patients receiving the reduced volume were allowed a normal breakfast followed by clear liquids for lunch and dinner and four 5 mg bisacodyl tablets at noon. Each group drank their PEG-ES solution beginning at 6:00 p.m. The clinical symptoms were significantly reduced in the 2 L of PEG-ES group. Patients responded to questionnaires regarding symptoms and tolerance to the preparation based on a five point scale ranging from none to severely distressing. Patients who received the reduced PEG volume experienced significantly less fullness, nausea, vomiting, and overall discomfort. Vomiting occurred in both groups, but was more prevalent in the 4 L of PEG-ES group. These findings were consistent with the findings from earlier studies (Adams et al., 1994; Sharma et al., 1998).

Researchers are now examining a reduced volume of NaP in order to decrease complications in patients undergoing colonoscopy. One strategy examined by Hookey et al. (2004) was to use a much smaller dose to maintain the advantages of oral NaP while minimizing the risk of adverse events. In this prospective, randomized, endoscopist-blinded trial, patients scheduled for outpatient colonoscopy were assigned to drink 4 L of PEG lavage solution over a two hour period the evening prior to colonoscopy or ingest 45 ml of NaP at 7:00 p.m. the evening prior to colonoscopy. The NaP was diluted in 240 ml glass of liquid followed by four 5 mg bisacodyl tablets at 9:00 p.m. On the morning of the colonoscopy, patients were instructed to self-administer a small volume, 10 mg bisacodyl enema. While this study experienced a high drop out rate, the researchers found the patients taking the NaP tolerated

their preparation better. The findings suggest that a smaller volume of NaP in combination with stimulant laxatives is much better tolerated than PEG. While the researchers did not report increased efficacy, the lower doses of NaP confer a higher safety profile.

Frommer (1997) reported superior cleaning of the right side of the colon when the dose was taken as a split dose on the day prior to the procedure and on the morning of the procedure. Patients requiring colonoscopy were randomly assigned to one of three preparations in a single-blind prospective study. Group A (n = 160) drank 3 L of PEG at 2:00 pm the day before the procedure. Group B (n = 161) drank 45 ml of NaP solution at 7 am and 7 pm the day before examinations, and the final Group C (n=166) drank 45 ml NaP solution at 6 pm the day before and 6 am on the morning of the procedure. Bowel cleansing was significantly better with the Group C regimen than Groups A or B. The researchers concluded that the timing of NaP in regimen C was responsible for the superior cleansing compared with PEG. They also found cleansing of the right side of the colon was superior in the two day dose as well. Overall, there was a high incidence of nausea and vomiting in patients ingesting NaP by either regimen compared with PEG. The researchers suggested either diluting the NaP in water before drinking or drinking water before the dose to prevent nausea or vomiting.

Barclay (2004) assessed the safety, efficacy and patient tolerance of a 3-dose regimen of sodium phosphate. Although the conventional 2-dose 90 ml regimen of NaP provides good colonic cleansing in the majority of patients, colonoscopic visualization remains suboptimal in others. In this prospective study, patients were randomized to either a 3-dose regimen (n = 131) of NaP taken in 45 ml doses at 5:00 pm the day before procedure, 45 ml 5 hours later at 10 pm and a third dose 45ml, 3 hours before the time of the procedure. In the 2-dose group (n=125), patients ingested 45 ml of NaP at 10 pm the night before the procedure and a second dose ingested 5 hours prior to scheduled time of the procedure. The quality of colonoscopic visualization was significantly better in the 3-dose group. Subject discomfort was experienced

by patients in both groups but overall patient acceptance was lower in the 3-dose regimen. A higher serum phosphate level was observed in the 3-dose group.

The FDA (2006) reported that patients taking more than 45 ml of oral sodium phosphate may be vulnerable to electrolyte shifts and this product must be used with caution. The emphasis is now on reducing the dose of sodium phosphate to improve patient tolerability (Khasab & Rex, 2005; Rex, Chasen & Pochapin, 2002). As described previously, two new products have been developed which contain a lower dose of liquid sodium phosphate (EZ-Prep) and lower number of sodium phosphate tablets (OsmoPrep). If the cleansing efficacy is not impaired, this trend may continue. Patients must be instructed in the importance of dilution of the dose, adequate hydration, and adherence to the prescribed dose in order to prevent serious adverse events.

Additional Regimens

The use of other preparations either alone or as adjunct is being studied in order to increase compliance, reduce the required amount of a preparation, and improve the overall quality of the colon preparations. These products include lactulose, senna, metoclopramide, magnesium citrate, and diet preparations. No studies were found addressing the effectiveness of lactulose as an adjunct preparation. Senna and metoclopramide are additional adjunctive agents which may improve patient acceptance of colon cleansing preparations (Brouwers et al., 1980; Kositchaiwat et al., 2006; Radaelli et al., 2005; Toledo & DiPalma, 2001). Magnesium citrate, one of the older bowel preparations, has been studied recently as a preparation alone and in conjunction with another preparation (Delegge & Kaplan, 2005; Regev, 1998).

Two studies examining the use of magnesium citrate as an adjunct appear promising. Sharma et al. (1997) reported the effect of magnesium citrate used with bowel cleansing preparations. Patients were randomized to 4 L of PEG or 2 L of PEG preceded by magnesium citrate. The patients ingesting the magnesium citrate stated the preparation was more tolerable.

The quality of the cleansing effectiveness and the procedure time was significantly better in the reduced PEG group.

A more recent study by Sharma et al. (2001) also examined magnesium citrate with PEG preparation. Patients undergoing colonoscopy were randomized to receive either 4 L of PEG-ELS (n = 21), 2 L of PEG-ELS with 20 mg bisacodyl (n = 24), or 2 L of PEG-ELS preceded by 296 ml of magnesium citrate (n = 23). Magnesium citrate is a hyperosmotic laxative and also has risks similar to NaP. The potential for hypermagnesemia exists in those patients with congestive heart failure and impaired renal function. Electrolytes were monitored for these patients and no significant changes were reported. It was reported the decreased volume with magnesium citrate did increase tolerability and the quality of the preparation as well. A thorough history is required prior to prescribing magnesium citrate (Kontani, Hara, Ohta, & Ikeda, 2005).

Berkelhammer et al., (2002) found magnesium citrate superior to NaP when the preparation is taken the day prior to the colonoscopy. Magnesium citrate was found to induce less recto-sigmoid apthous ulcers than NaP. Patients preferred taking the preparation the day prior to the colonoscopy because of the concern for travel to the health care facility and possible needing to continue to expel stool.

Dietary Restrictions

Dietary restrictions are necessary to prevent additional residue in the cleansed colon. Patient dissatisfaction with dietary restrictions has led to development of alternative regimens. Rapier and Houston (2006) suggest using lower volume preparations in combination with a low-residue diet in order to improve patient satisfaction and compliance. A total of 114 patients were randomized to one of three bowel cleansing preparations: (1) clear liquid diet day prior to colonoscopy and laxative kit consisting of magnesium citrate, oral bisacodyl tablets, and a bisacodyl suppository; (2) laxative kit consisting of magnesium citrate, oral bisacodyl tablets, a bisacodyl suppository, and the low-residue diet kit; (3) PEG in combination with the low-residue diet kit. The overall quality of the colon cleanliness for each regimen was acceptable. The study

suggest that less restrictive diets may play a role in the search for the ideal colon cleansing method and improve patient compliance.

Scott et al. (2005) compared the efficacy, patient acceptability, and compliance of two dietary regimens before bowel cleansing with oral NaP. This prospective, single-blind, two-site trial divided the required two 45 ml doses of NaP into three 15 ml portions which were mixed into eight ounces of ginger ale. The patients drank the first dose at 7:00 pm the evening before the exam and the second dose the next morning 3 to 4 hours before leaving for the clinic. Patients in the first group (n = 100) ate a light breakfast followed by clear liquids until after the colonoscopy. Patients in the alternate group (n = 100) were instructed to eat a normal breakfast followed by a low-residue diet lunch, and clear liquids after 2:00 pm. The low residue diet consisted of items such as skinless chicken, turkey, fish, eggs, chicken noodle soup, and applesauce. The addition of a low residue diet did not affect the overall clinical efficacy significantly. This method ensured patients would drink at least three eight fluid ounce glasses of clear liquids with each dose. Patients in both groups experienced adverse events such as nausea, vomiting, bloating, and cramping. The researchers reported patients ingesting the low-residue diet reported increased energy levels and decreased feelings of hunger.

Gaps in the Literature

While multiple studies have been conducted and multiple preparations are available, there remains little information about selecting the ideal preparation for a particular patient. The increasing demand for colonoscopy underscores the necessity for a continual review of the efficacy, tolerability, and safety of bowel cleansing preparations. In controlled trials, NaP preparations consistently exhibit better cleanliness of the bowel for colonoscopy. However, due to the potential for large fluid shifts and electrolyte disturbances, it is recommended only for use in healthy individuals. PEG-ES is much safer in healthy and unhealthy patients but its large volume causes nausea, bloating, and other symptoms which limit the amount ingested. The use of adjunctive therapies, reduced dosing, and split dosing may provide alternative approaches to

enhance the quality of colon cleanliness. Patient acceptance remains critical in adherence to any regimen. In order to increase patient compliance and achieve optimum examinations of the colon, health care providers need guidelines which address the following:

1. Which preparations are best for specific types of patients?
2. How can compliance be improved?

Which preparations work best with specific patient health characteristics?

The number of inadequate preparations has forced healthcare providers to add additional medications such as lactulose, metoclopramide or magnesium citrate to preparations (Huppertz-Hauss et al., 2005). Whether this is working in all patients is unknown. While studies report PEG superior and the gold standard when comparing efficacy (Ell, 2003), other researchers suggest NaP superior in regards to bowel cleansing and the time required to visualize the mucosa. NaP has been reported as superior to PEG in regards to bowel cleansing and the time required to visualize the mucosa (Kossi et al., 2003). This leaves clinician with confusing and unanswered questions about the guidelines relating to which preparations to use with specific patient characteristics such as those with hypomotility. We do not know which preparations are being used in a natural setting as opposed to clinical trials which are looking at a specific preparation to use and patient characteristics.

How can compliance be improved?

Individualizing patient instructions

Earlier studies searching for effective, more tolerable bowel regimens reveal more complicated regimens decrease the likelihood of completion by patients (Dodds et al., 1977). Historically, patient preparations involved one to two days of a clear liquid or low residue diet in conjunction with laxatives and/or enemas. Since bowel preparations in the past were inconvenient and time consuming, development of quick acting and smaller volumes that are effective was critical. Patient compliance is improved with simplicity and tolerability (Toledo & DiPalma, 2001).

However, in spite of advancements and changes to colon cleansing preparations, patients continue to be noncompliant which increases the chances of sub-optimal preparations and missed diagnosis. This may be due to unclear directions or misunderstanding by the patient.

Patients might be more accepting of the colon cleansing preparations and use them more appropriately if they know how they work. Strategies to improve patient understanding of the pre-procedure instructions may contribute to the effectiveness of the preparation (Rex, Imperiale, Latinovich, & Bratcher, 2002). Huber (2005) recommended the following to improve patient compliance: (1) keep instructions simple; (2) use written material in addition to the verbal instructions and list items included in a clear liquid diet or prescribed diet; and (3) communicate frequently with the patient. At times, it may be necessary to individualize the instructions and the preparations based on the patient's prior history in order to improve compliance (Greenwald, 2003). Experts agree that additional studies examining patient instructions may help to improve quality and compliance (Darby, 2007).

Matching the colon cleansing preparation to the right patient

The role of patient characteristics in the tolerability and effectiveness of colon cleansing preparations must be explored as it remains unclear. Since the choice of colon cleansing preparations remains one of the modifiable factors that may improve patient satisfaction, research in this area is vital (Balaban et al., 2003). Patient's unique anatomical factors may affect their ability to tolerate certain preparations. A better understanding of these individualized effects may aid in prescribing appropriate preparations (Hsu, 1998).

Presently, no single preparation exists that is effective and tolerated in every patient. Therefore, further research is needed with various patient populations to address the influence of characteristics such as age, sex, ethnicity, medications, and medical history on each preparations effectiveness. The search for the optimal bowel cleansing method remains a major initiative of many digestive disease organizations (Burke & Church, 2007). Additional knowledge

about specific patient characteristics should provide valuable information regarding strategies to improve tolerability, safety, and efficacy of colon cleansing preparations. There are no studies that address specific guidelines for preparations that work best with hypomotility, chronic constipations, or a history of inadequate bowel cleansing during prior colonoscopy (Cohen & Tennyson, 2007).

Summary

This review began with an historical perspective of bowel cleansing preparations. The critical issue of safety of the two most popular preparations (PEG-ES and NaP) was reviewed. Strategies to optimize tolerability and effectiveness of bowel cleansing preparations were also discussed. The poor tolerance of bowel preparations remains one of the major contributors to the low adherence rates for colorectal cancer screening and suboptimal preparations remain a serious problem for the endoscopist (Rex et al., 2006). Patients with inadequate preparations have lower detection rates of polyps and other diseases of the colon. When the preparation is inadequate, patients may have to repeat the colonoscopy at an interval shorter than the preferred schedule.

The strategies identified to improve adherence include: improving the preparation's taste, reducing the volume or giving it in split-doses, allowing low residue diets, and using more than one preparation at a time. Additional steps are needed by healthcare providers to offer several bowel preparations rather than one so that patients can be matched with the preparation that is more likely to be safe, effective, and well tolerated. This review revealed areas which have not been fully explored and the research questions for this study will begin to fill this gap in the literature. The gaps identified from this review revealed the following:

1. Insufficient knowledge about how individual characteristics (e.g.medical diagnosis, age, intestinal motility, and gender) influence the effectiveness of different bowel cleansing preparations.

2. Inadequate information about the effectiveness of the preparations on people with various ethnic/racial backgrounds.

3. Few guidelines for choosing the appropriate preparation for a given population. (For example, diabetics may require a stronger stimulus for defecation.)

4. Inadequate information about which preparations are being used in practice.

The identification of which adjunctive agents are being used in practice and their efficacy for patients with specific patient characteristics should provide valuable information in the decision making process for health care providers. This study will add information about which is the *best* preparation for different patient characteristics in regard to tolerability, efficacy, and safety.

CHAPTER 3

METHODS AND PROCEDURES

The purpose of this descriptive, comparative study was to: (a) compare differences in bowel cleanliness achieved by the different bowel cleansing preparations (effectiveness), (b) compare differences in discomfort with the various bowel preparations (tolerability), and (c) identify factors that influence the patient's ability to take the bowel cleansing preparations before colonoscopy. The instruments used in this multi-center approach identified types of colon cleansing preparations prescribed for people with diabetes, chronic constipation, and other illnesses that influenced motility. The researchers did not manipulate the situation; instead, they examined the characteristics of the sample and prescribing regimens as they were used in the natural setting. This chapter describes the setting, population and sample, informed consent protocol, data collection procedures, measurement methods, and data analysis utilized in this study.

Setting

Data was collected from four endoscopy facilities in the following cities: Baltimore, Maryland; Dallas, Texas; Grand Prairie, Texas; and Seattle, Washington. The researcher was associated with one of the sites. Endoscopy nurses from the other endoscopy sites responded to a call for volunteers at the Society of Gastroenterology Nurses and Associates (SGNA) Annual Course, attended an orientation meeting, and volunteered to be the research team leaders. Four additional facilities were originally scheduled to participate but were not able to begin data collection due to limited staffing, other research projects, or delays with Institutional Review Board (IRB) applications.

One endoscopy facility is a freestanding clinic in a suburban area. The other facilities are located in hospitals and medical teaching facilities in large metropolitan areas. The study was approved by the IRB at the University of Texas at Arlington and also approved by each hospital's IRB. Since the freestanding clinic did not have a separate IRB, the UTA IRB served as the approval institution.

At one facility, personnel met with patients at least a day before the colonoscopy to give them instructions for taking the bowel cleansing preparations. In the other three, patients received their written instructions by healthcare personnel, through the mail or from the physician who referred them. Various bowel cleansing preparations were used at the chosen sites, including: PEG-ES solutions (2 liters and 4 liters), oral sodium phosphate, lactulose, magnesium citrate, bisacodyl, Fleets phosphate enemas, and tap water enemas.

Sample

The target population for this study was adults scheduled for colonoscopy in the United States. The accessible population included those patients scheduled for colonoscopy at the sites included in this study. Non-random, convenience sampling was used to recruit 201 subjects from the four sites. Everyone, who was at least 21 years of age and signed a consent form for colonoscopy, was asked to be in the study. Subjects had to be mentally alert in order to describe any discomfort experienced during the cleansing procedure; therefore, anyone who was mentally impaired and unable to sign the consent (Appendix A) was excluded from the study. Additional exclusion criteria included those patients with colon resection, colostomy, or ileostomy. Data collection occurred over a nine month period.

Participants included multiple ethnicities but were limited to those who spoke and understood English. The power analysis for ANOVA was conducted and determined that a sample of 159 with alpha 0.05 would achieve a power of .80 and detect a medium effect.

Measurement Methods/Instruments

Three instruments were used in the data collection process. These instruments were used in previous pilot studies about bowel preparation for outpatients receiving colonoscopy (Odeyemi, 2005) and inpatients receiving colonoscopy (Schmelzer et al, 2006). All data collection instruments in this study were in a Teleform ® format to facilitate data entry and analysis. The three instruments included: (a) the descriptive (demographic) data form, (b) the subject experiences with the bowel cleansing preparation form, and (c) the colon cleanliness scale.

Descriptive (Demographic) Data Form

The *Descriptive (Demographic) Data Form* (Appendix B) incorporates items from the SGNA Minimum Data Set, which is a standard form designed to allow comparisons of gastroenterology nursing data across clinical populations. Validation of the data set was obtained from gastroenterology nurses through online forums and focus groups (Bean, 2005). The researchers added a question about bowel movement frequency and modified certain items to get more detailed information. Two certified gastroenterology nurses reviewed the final form to establish face validity. The form worked well in the outpatient pilot study, except for a couple of questions that were unclear to the data collectors (Odeyemi, 2005). These questions were clarified for this study as follows: 1) the area for recording the height was changed to include feet and inches, and 2) diet was expanded to include not only clear liquid but other dietary regimens.

The form consisted of 24 total items presented in three parts. Part I includes questions about demographics (gender, ethnicity, etc.), chronic illness, and indications for colonoscopy. Part II lists questions about how the bowel preparations were provided, how the bowel preparation was chosen, and the procedure for giving the instructions. Part III contains questions about the type and amount of bowel preparation used, whether the patient followed the clear liquid or other diet prescribed, and a description of the last stool before colonoscopy.

Subject Experiences with the Bowel Cleansing Preparation

Tolerability was measured in this study using *The Subject Experiences with the Bowel Cleansing Preparations* (Appendix C). The *Subject Experiences with the Bowel Cleansing Preparation* form is a modified visual analogue scale designed to measure the presence and intensity of nine types of discomfort including: headache, nausea, vomiting, abdominal cramps or pain, rectal itching, rectal burning, dizziness, full feeling, and fatigue. Two additional questions address the ease of the preparation and sleep disturbances. All 11 items have been described in reports about bowel cleansing preparations (Allaire et al; 2004, Balaban et al., 2003; Kastenberg et al., 2007). Participants were instructed to fill in a circle to rate severity of the discomfort so that data could be scanned electronically for easier data entry. Test retest reliability of this form was conducted during the pilot study (Odeyemi, 2005) with a Pearson's correlation of 0.906 ($p < 0.00$).

Colon Cleanliness Scale

The Colon Cleanliness Scale (Appendix D) is a modification of a scale used by Balaban and colleagues (2003). Validation of the constructs for cleanliness for this scale has been reported using similar criteria (Aronchick et al., 1999; Rostom et al., 2004). The addition of specific, objective descriptions was added to the assessment criteria. The form which consists of two sections containing 29 items was found to measure the dimensions of cleanliness required during a pilot study (Mlinar, Schmelzer & Daniels, 2007).

The first portion of the form describes the amount of residual stool, the consistency of stool, and the percentage of visible bowel wall in each of six segments of the colon (rectum, sigmoid colon, left descending colon includes splenic flexure, transverse colon, right ascending colon includes hepatic flexure, and cecum). The amount of residual stool is rated using a four-point Likert scale: "0" = no residual, "1" = small residual stool, "2" = moderate residual stool, and "3" = large amount of residual stool. The ratings for the amount of residual stool also have descriptors which add objective criteria for the rating. "Small residual amount" is described as

requires suctioning with only a syringe of water to clear; “moderate” requires much flushing with water to clear, and “large” requires a repeat preparation prior to completing the colonoscopy. “Consistency” of stool is rated using a six-point Likert scale: “0” = no residual stool, “1” = clear liquid, “2”= colored liquid stool, “3” = particulate stool, “4” = semi-solid stool, and “5” = solid stool. Additional objective description for particulate stool includes mixture of liquid and stool particles. Finally, a five point Likert scale describes the percent of visible bowel wall: “0” = all, “1” = about ¾, “2” = about ½, “3” = about ¼, and “4” = none. The scores are added together to obtain a total score which ranges from best possible rating of zero to poorest quality rating of 72.

The second section of the *Colon Cleanliness Scale* has questions about the times the endoscopist inserts the endoscope and reaches the cecum. If the gastroenterologist is unable to reach the cecum, the time and location of the most proximal point reached is recorded. The time may be an important factor because reaching the cecum occurs more efficiently and rapidly when there is no stool present.

Practicality of this scale was tested during a pilot study (Schmelzer & Daniels, 2007). Pictures of segments of the colon were arranged into four sets with each picture containing the six sections of the colon as listed on the colon cleanliness scale. Doctoral nursing students were given instructions on completing the form. The nursing students reported the instrument would not create interference with usual clinical activities and was easy to complete.

Reliability and validity of this scale was tested using pictures of segments of the colon during colonoscopies (Mlinar, Schmelzer, & Daniels, 2007). These pictures were arranged into nine sets with each picture containing six sections of the colon with various levels of colon cleanliness. All nine sets were assembled into books that had the pictures on one page and the colon cleanliness scale on the opposite page.

The researchers mailed a book of pictures to four experienced health professionals (one nurse practitioner and three physicians) who regularly perform colonoscopies and asked

them to rate the cleanliness of the colons using the *Colon Cleanliness Scale*. All the experts had the same sets of pictures, but they were arranged in random order. Pearson correlations were performed for each pair of raters (1 with 2, 1 with 3, 1 with 4, 2 with 3, etc.) for each section of the colon. Raters 3 and 4 had excellent levels of agreement ($r > 0.82$ in every section, $p < 0.05$). The grand total of the combined scores for the six sections revealed a high correlation ($r > 0.82$, $p < 0.05$) for every pair of experts (Mlinar, Schmelzer, & Daniels, 2007).

Procedure

Following University of Texas at Arlington (UTA) IRB approval, formal approval was obtained from each participating site. The research team site coordinator and research team members completed protection of human subjects training as specified by the UTA Office of Research Integrity and Compliance as well as their institution's requirement. All sites had their own IRB except one site, which was a freestanding ambulatory facility. One teaching hospital required the research site coordinator be a member of the faculty of that institution. Fortunately, a faculty member agreed to participate in this role after reviewing the protocol.

The principal investigator at UTA coordinated the entire study. Study documents were printed, collated, placed in subject folders, and shipped to the individual sites. Prior to shipping study packets, research team site coordinators received orientation to the research during an introductory meeting at an educational conference and a site visit by the principal investigator. All of the site coordinators attended the orientation meeting except one. The study protocol was reviewed with this site coordinator via telephone and during the site visit. In order to establish precision in data collection, a training module was developed and utilized (Appendix E). Research site coordinators and site team members reviewed the subject consent form and used the form as a script when recruiting patients. The training module listed the steps to follow in completing the patient demographic form and the colon cleanliness scale. In addition, the research team members were able to use standard guidelines to explain the subject experience form to participants and instruct them in completing the form. The research team site

coordinator was responsible for maintaining the master record, securing the subject consent forms, and securing the subject folders. The principal investigator maintained communication regularly with the site by telephone and e-mail. Additionally, one site visit was made to ensure that data collection was proceeding as planned. Research team site members at each site followed standardized data collection steps to ensure consistency (Appendix F).

At each site, potential subjects were contacted on their initial visit to the facility or when reporting for their colonoscopy. Clinical personnel identified those patients meeting the inclusion criteria and referred them to the research site coordinator or team member. The study was explained, and written, informed consent was obtained from those patients who met the inclusion criteria and agreed to participate in the study. When patients were recruited prior to the day of the colonoscopy, the consent form and Part I and II of the descriptive (demographic) data form were completed. Part III of this form, subject experience form, and the colon cleanliness scale were then completed on the day the participants reported for the colonoscopy. When the patients were recruited on the actual day of the colonoscopy, all data was collected on one day. Data was collected in the following manner:

1. After the patient provided consent for the colonoscopy, the research site team member explained the study and obtained informed consent. Two copies of the informed consent were signed and one copy returned to the patient. One site required an additional copy of the consent form in the medical record.
2. A patient subject folder with a unique identifier on all required forms was obtained for each participant. A checklist attached to each folder (Appendix G) ensured consistency and completeness. The research nurse then asked participants the questions on Part I of the *Descriptive (Demographic) Data form*.
3. The research site team member completed Part II of the *Descriptive (Demographic) Data* form.

4. When the patient returned to the facility for the colonoscopy, the research nurse obtained the patient subject folder and asked the participant to complete the *Subject Experiences with the Bowel Cleansing Preparation* form while in the pre-procedure area. If the patient was enrolled on the day of the colonoscopy, all instruments were completed as previously described.
5. The research site team member completed Part III of the *Descriptive (Demographic) Data* form which assessed compliance with the preoperative instructions and whether the diet and the regimen was followed as prescribed.
6. The research site team member reminded the gastroenterologist that the *Colon Cleanliness Scale* must be completed during the colonoscopy. The gastroenterologist verbally described the cleanliness of each part of the colon as the procedure was performed, while the nurse recorded the information on the cleanliness scale.
7. The final section of the *Colon Cleanliness Scale* was completed by the procedure nurse.
8. Patient folders were reviewed for completeness prior to transferring patients to the recovery room area.
9. Research site team coordinators secured the consent forms and data separately in a locked area until data collection was completed at each site. All completed instruments including the master list (Appendix H) were mailed to the principal investigator at UTA for data analysis and final storage when data collection ended. Consent forms for two of the sites are secured at UTA. The IRB at the other two sites required storage of the consents at their facility.

Ethical Considerations

Participation in the study was completely voluntary and informed consent (Appendix A) was obtained from each participant and maintained in the researcher's files according to IRB guidelines. As previously discussed, patients were recruited for this study following

colonoscopy scheduling. Patients were notified of any risks or benefits and the purpose of the study. There were no direct benefits and no risks related to participation in the study, since the study was purely descriptive (no intervention). All subjects received the same medical and nursing care whether or not they chose to participate in the study. The research team members informed subjects that participation was completely voluntary and once they enrolled, withdrawal could occur at any time.

Privacy and confidentiality of all participants was protected by assigning a unique tracking number to each subject for use with all study forms and known only by the investigators. If pathology was detected during colonoscopy, it was not recorded on any study forms. The signed informed consents were secured separately under double lock and key. Information was reported in the aggregate, not by individual responses or individual descriptions of the colon's cleanliness. Protection of subjects was reviewed by the UTA IRB and/or site specific IRB.

Data Analysis

Data were analysed using SPSS (Statistical Package for Social Sciences) for windows version 16.0 for all research questions. All instruments were examined for missing data to prepare for data analysis. Stray marks were cleaned and where bubbling was not clear, these marks were emphasized. No missing data was replaced. After all data sets were prepared, the Teleform ® instruments were scanned and placed into data sets.

The descriptive (demographic) data form provided information which assisted in identifying specific patient characteristics. Descriptive statistics were used to summarize patient characteristics including gender, age, ethnicity, chronic illnesses, and reasons for colonoscopy. Frequencies were computed to obtain a profile of demographic characteristics of the sample.

Frequencies and means were computed to obtain a profile of the sample on the subject experiences with the bowel cleansing preparations. Additional subject experiences were also

reviewed and summarized. This frequency provided insight into how often experiences occur and their intensity with the different colon cleansing preparations.

The different colon cleansing preparations identified were placed in groups. Analysis of variance (ANOVA) was used to determine if there were significant differences in colon cleanliness between the different preparations. Cross tabulations of the different colon cleansing preparations were analyzed to identify any trends or patterns with the overall quality of the preparation with specific patient characteristics such as chronic health problems and medications.

Limitations

Since the study was descriptive, the researchers had no control of intervening variables. There was no random sampling or random assignment to groups. The researchers decreased selection bias by asking each successive patient scheduled for colonoscopy who meets the selection criteria to be in the study until the specified number of subjects was reached.

Each individual site varied in the way instructions were given to the patients for colonoscopy. Furthermore, the bowel cleansing preparations were limited to those commonly used by the selected sites and the researchers had no influence over the preparations selected. Research team members were trained in the use of the instruments and protocol. Site coordinators received training and in turn trained the data collectors at their facilities to make data collection as consistent as possible.

Data was collected in the same manner for each patient at each site. Research team members used checklists attached to each subject folder which assured completeness prior to discharge of the participants. Patients self reported the amount of bowel cleansing preparation ingested. All the colonoscopies were performed by gastroenterologists. Two of the sites had previously participated in pilot studies and gastroenterologists and staffs were familiar with the colon cleanliness scale. To increase comfort with use of the colon cleanliness scale at the other

two sites, the gastroenterologist and research team members were given a book with images of segments of the colon with various levels of cleanliness with the scale. Any questions about how to complete the instrument were reviewed by the site coordinator prior to its use with subjects. The sample size and precise data collection allowed the identification of patterns despite the lack of randomization to groups. In addition, the researchers had previously tested all the forms and the data collection procedures which contributed to their accuracy and efficiency.

Summary

This chapter described the setting, population and sample, informed consent protocol, data collection procedures, and methodology. The data analysis process was also described. Finally, protection of human subjects and limitations of the study were also discussed.

CHAPTER 4

FINDINGS AND DISCUSSION

This chapter presents the findings of the study. It describes the demographic information of the sample, analysis of the data, and the findings related to the four research questions. It also presents specific patient characteristics such as reasons for colonoscopy, medical conditions, and medications identified that may have affected colon cleansing. A discussion of the limitations, implications for nursing, and recommendations for future research are summarized.

Sample Characteristics

The total number of participants was 201 with representation from each of the sites as follows:

1. Freestanding ambulatory surgical center (n = 102)
2. Hospital 1 (n = 58)
3. Hospital 2 (n = 24)
4. University medical center (n = 17)

Figure 6 presents the age distribution of the sample. A total of 116 (57.7%) women and 85 men (42.3%) participated in the study. A majority of the participants were Caucasian (79.1%, n = 159) followed by African American (11.9%, n = 24), Hispanic (4.5%, n = 9), Asian (2%, n = 4), and American Indian (0.5%, n = 1). Another three percent of the sample was represented by Nigerian (n = 2), Puerto Rican (n = 1), and Asian Indian (n = 1) participants (Figure 7).

The ages ranged from 22 years to 81 years ($\overline{X}$ = 55, Mode = 51). Five of the participants recruited for the study did not keep the scheduled colonoscopy appointment due to family emergencies or rescheduling purposes. Eighty-seven of the participants (43.5%) were in the age range of 50 to 59. Twenty seven of the participants (13.5%) were 70 years of age or older. The age range with smallest group of participants was 18-29 (5.5%) with eleven participants.

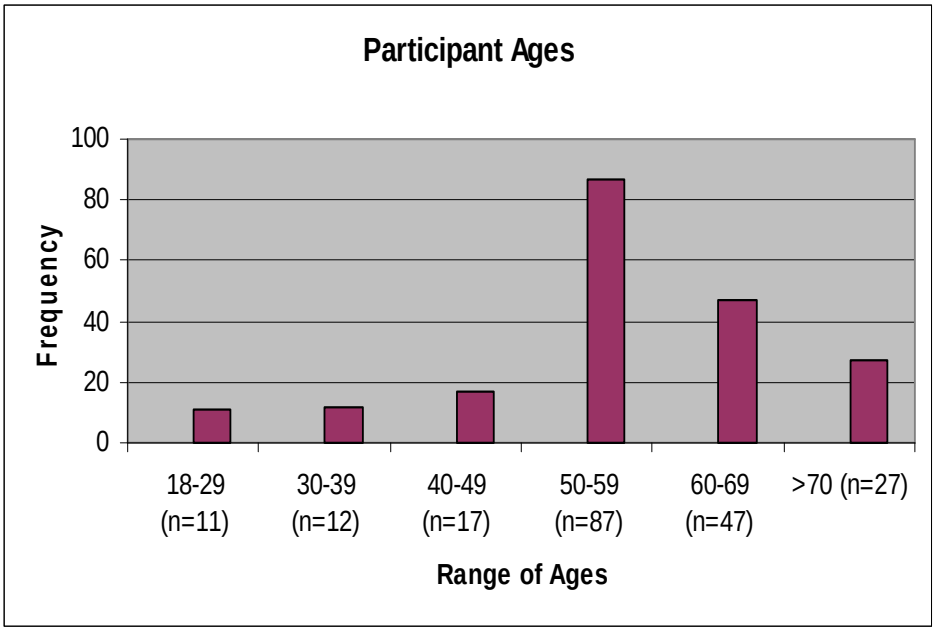

Figure 6. Participant Ages (N = 201).

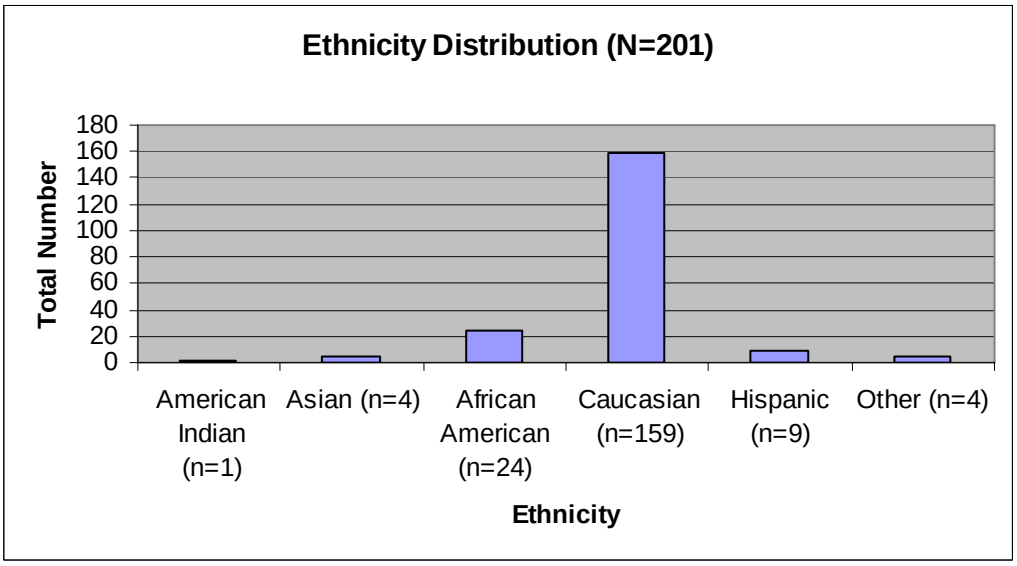

Figure 7. Ethnicity Distribution of Sample.

In order for bowel cleansing preparations to be effective, patients must follow the prescribed diet. Eating solid food the day prior to the exam or morning of the exam may interfere

with maximum emptying of the colon. Most participants (n = 183, 91%) followed a clear liquid diet but thirteen (6.5%) of the participants ate solid food the day before or morning of the colonoscopy. The number of hours since participants ate solid food ranged from 14 to 72 hours, and 36 hours was the most frequently reported amount of time (n = 77, 36.3%).

Compliance with the colon cleansing preparation is also vital to the overall cleanliness of the colon. Compliance increases when the patient understands the instructions. Participants received pre-procedure instructions in a variety of ways (see Figure 8). Most instructions were in writing (n = 184, 91.5%), some were given by the RN (n = 74, 36.8%) and some written instructions were sent in the mail (n = 37, 18.4%). A follow-up telephone call was made to 107 (n = 53.2%) of the participants following the preliminary instructions received.

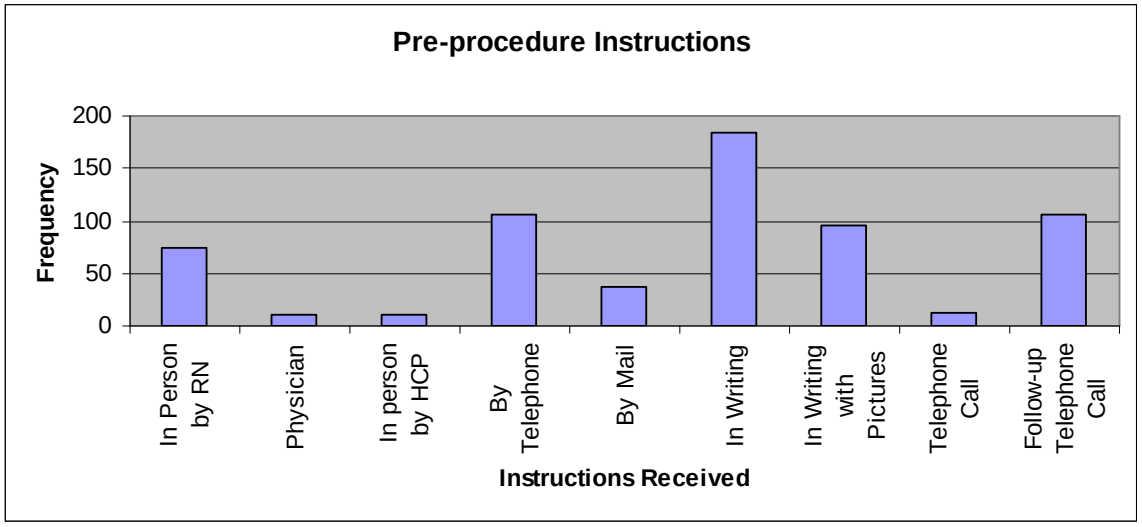

Figure 8. Frequency of Pre-procedure Instructions for Sample.

This was the first colonoscopy for 107 (53.2%) of the participants while the other 94 participants (46.7%) having one in the past. Eighty patients (39.8%) listed colorectal cancer screening as the indication for the procedure followed by forty-six patients (22.9%) with a prior history of colon polyps. The other most frequently reported reason (Figure 9) was bleeding (n = 29, 14.4%). Other reasons not listed on the questionnaire included diarrhea, screening for other scheduled surgery such as prostate cancer or hemorrhoidectomy, abnormal computed

tomography (CT) Scan, and abnormal radiology procedure. Some people listed more than one reason for the procedure.

Of those participants who had a prior colonoscopy, oral sodium phosphate and PEG-ES were listed more often as the preparation used but many could not recall what they took.

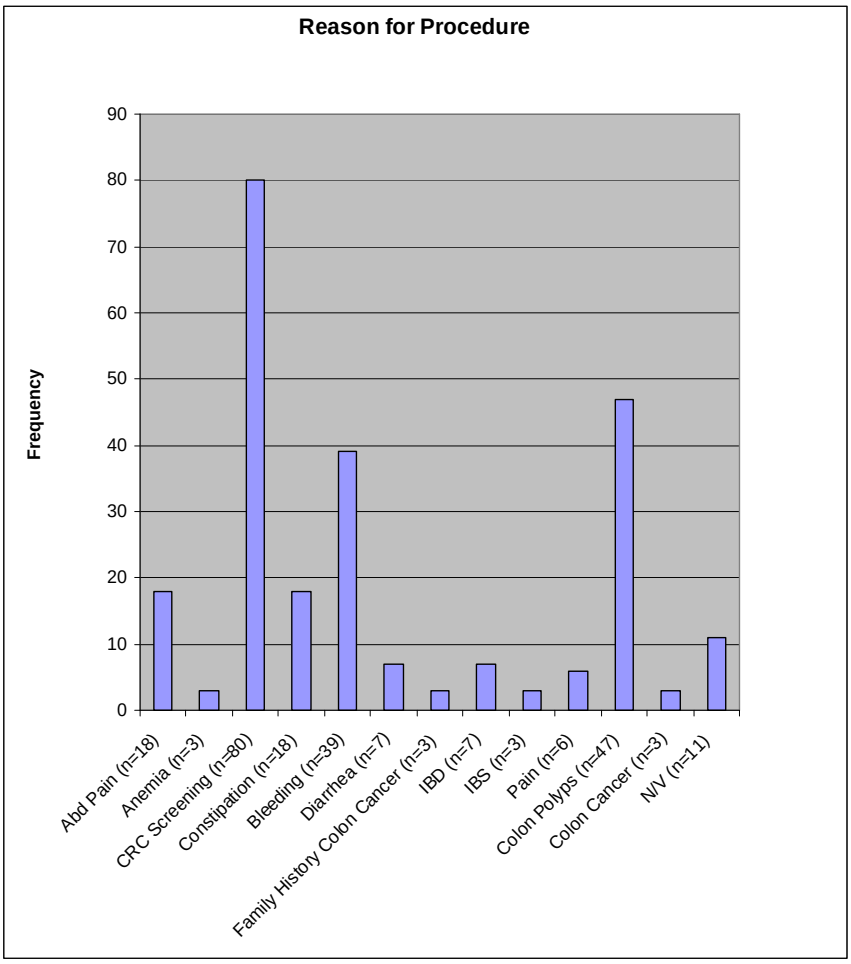

Figure 9. Reasons for Procedure.

While the age of the participants is an important criteria when prescribing colon cleansing preparations, medical co-morbidities and the concurrent use of medications must also be considered due to their potential effect on the safety and efficacy of the preparation. Table 1 lists the frequency of reported chronic health conditions of the participants. The most frequent reported chronic health problem was depression (n = 22, 10.9%) followed by diabetes (n = 18,

9.0%). Patients were given the opportunity to report other conditions that were not listed on the demographic form. A number of conditions were reported and the most frequent occurrence was hypertension.

The most frequent medication was hypertensive medication (n = 71, 35.3%). Other most frequently occurring medications were non-prescription over the counter pain relief medication (n = 32, 15.9%) and anti-depressants (n = 22, 9.0%) (Table 2). This is an important consideration as medications may increase or decrease the motility in the gastrointestinal tract or may have a synergistic effect with the preparation prescribed.

Table 1. Reported Chronic Health Conditions.

Health Condition	Frequency	Percent
Celiac disease	0	0
Congestive heart failure	0	0
Depression	22	10.9
Diabetes	18	9.0
History of previous myocardial infarction	4	2.0
Inflammatory bowel disease	5	2.5
Irritable bowel syndrome	3	1.5
Liver disease	6	3.0
Neurological problems	20	10.0
Renal insufficiency or failure	2	1.0
Other (Osteoarthritis, migraines, herniated discs, kidney disease, hypertension, sleep apnea, asthma, kidney stones, coronary artery disease, hyperlipidemia)	69	34

Table 2. Routine/Current Medications.

Medication	Frequency	Percent
Antidepressants	18	9.0
Blood thinners	15	7.5
Constipation relief agents	12	6.0
Insulin	3	1.5
Hypoglycemic (oral)	14	7.0
Heart	11	5.5
Anti-hypertensives	71	35.3
Prescription pain medication (narcotic)	12	6.0
Non-prescription pain medication (over the counter)	32	15.9
Thyroid	15	7.5
Other	131	65.2

While 8.9% of participants (n = 18) reported constipation as the reason for the procedure, only twelve participants (6%) reported taking constipation relief medications. A large majority of the participants reported having at least one bowel movement per day (n = 89, 44.3%). The least frequent bowel movement reported was less than one every three days (n = 8, 4%). Figure 10 summarizes the frequency of bowel movements reported by the participants.

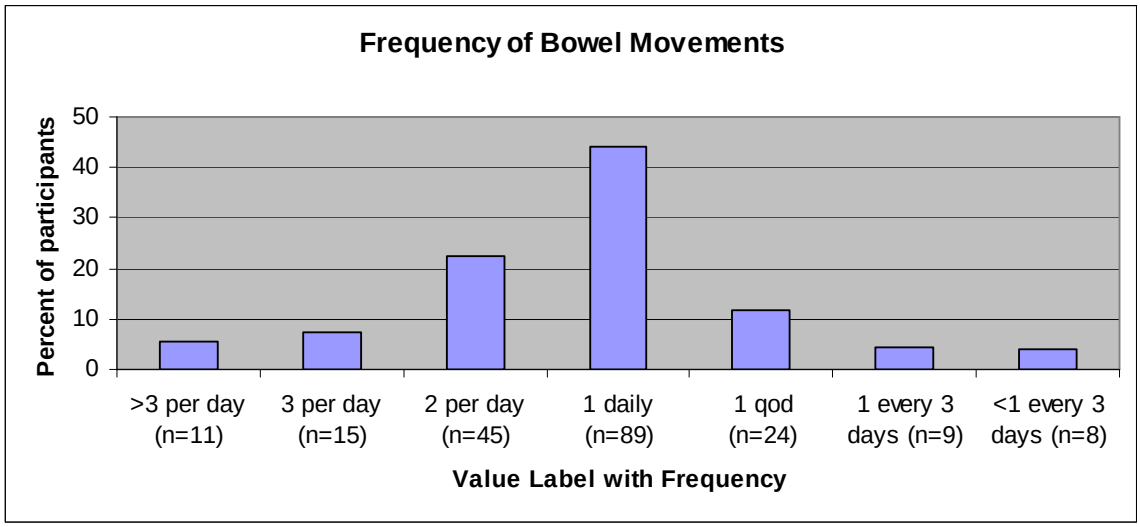

Figure 10. Frequency of Bowel Movements.

Research Question 1

What bowel cleansing preparations are being used nationwide for colonoscopy?

A variety of bowel cleansing preparations were identified from this sample. Frequencies and percentages for the bowel cleansing preparations are reported in Table 3. One half of the subjects came from a facility that provided bowel cleansing preparations, and the other half purchased their own. Of the three preparations recommended by the ASGE, 3% (n = 7) received sodium phosphate liquid and only three (1%) received sodium phosphate tablets (Visicol). When PEG-ES (4 L) was used in this sample (54%), bisacodyl was also prescribed (n = 110). Only five of the participants were prescribed PEG solution without receiving additional medications such as bisacodyl or magnesium citrate. The other most frequently used preparations were MoviPrep (n = 40, 27%) and HalfLytely (n = 26, 13%). Two subjects took magnesium citrate. Participants prescribed Miralax (n = 16, 8%) were also prescribed bisacodyl. The facility or physician plays a major role in the selection of the bowel preparation. At times, patient preference can be honored, but at other times the physician must give priority to the patient's health status. Patients selected their preparation 37.8% of the time (n = 77) and physician's selected the preparation 61.7% of the time (n = 124).

Table 3. Frequency Bowel Cleansing Preparations.

Bowel Cleansing Preparation	Frequency	Percent
4 L PEG-ES (NuLytely) + 5 Bisacodyl tablets (n = 74)	74	37
2 L PEG-ES plus ascorbic acid (Moviprep) (n = 40)	40	20
2 L PEG-ES (Halflytely) + 2 Bisacodyl tablets (n = 26)	26	13
Miralax + 4 Bisacodyl tablets (n = 16)	16	8
4 L PEG-ES (NuLytely) + 5 Bisacody tablets + Lactulose 120 ml + 4 Saline enemas (n 16)	16	8
Lactulose 120 ml + 5 Bisacodyl tablets + 4 Saline enemas (n = 10)	10	4
Sodium Phosphate (30 ml, 45 ml, 90 ml) (n = 7)	7	3
4 L PEG-ES (Golytely/Nulytely) (n = 5)	5	2
Visicol tablets (n = 3)	3	1
4 L PEG-ES (Colyte, Golytely) + 2 Bisacodyl tablets (n = 2)	2	0.1
Magnesium Citrate (n = 3)	2	0.1

In this study, physicians tended to prescribe a combination of bowel cleansing preparations. For example, when PEG-ES (Nulytely) was prescribed, five bisacodyl were also ordered. Lactulose and saline enemas were also utilized as adjunct preparations in some cases.

Research Question 2

Are there differences in bowel cleanliness observed during colonoscopy when the different preparations are used?

The cleanliness scores were analyzed in two ways. (1) The total cleanliness score was a total of the residual stool score, consistency score, visibility score, and ranged from 0 to 48 (Figure 11). As can be seen in the frequency distribution in Figure 11, the cleanliness scores were skewed to the left, toward the lowest scores, which indicate greatest cleanliness. (2) A mean score was also obtained for each preparation using only the residual stool score and the consistency score. This was performed in order to run ANOVA. The mean scores for each

preparation are listed in Table 4. The lowest mean cleanliness score revealed was for the preparation with 4 L of PEG, 120 ml lactulose, five bisacodyl tablets, and four saline enemas. The mean score for total cleanliness was 12.30 and the mean score for total residual plus total consistency was 10.92. The preparation with the next lowest mean score was the lactulose 120 ml plus five bisacodyl tablets, and four saline enemas; however, there were only ten participants prescribed this preparation. PEG-ES (4 L NuLytely) with five bisacodyl tablets exhibited a mean cleanliness score of 15.49

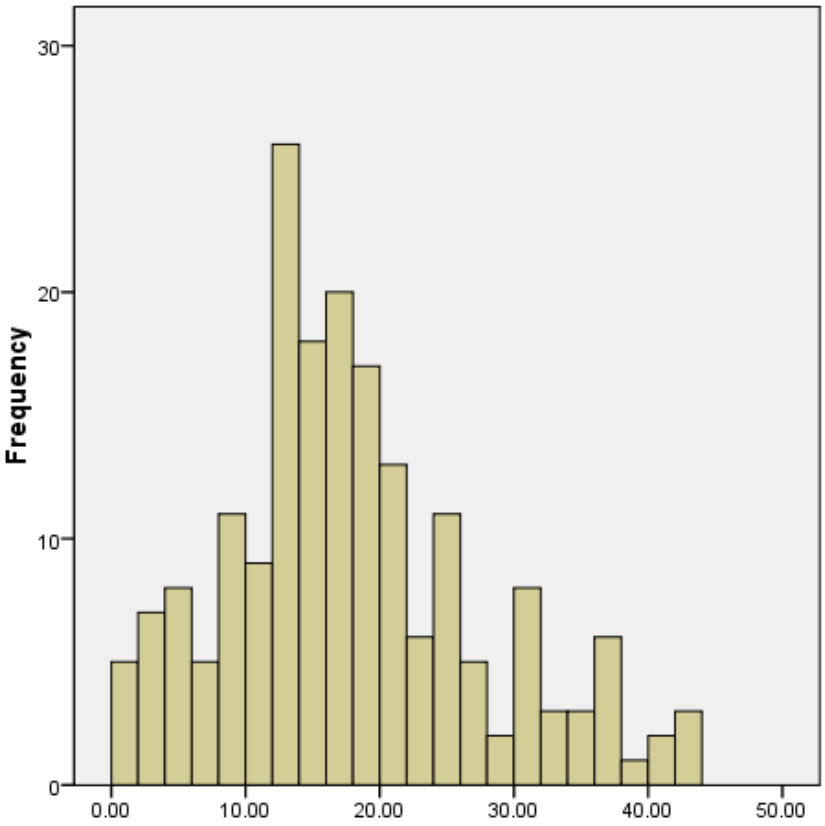

Figure 11. Frequency Total Cleanliness Scores; Range 0-48; Mean 17.17; SD 9.548

Table 4. Bowel Cleansing Preparation Mean Cleanliness Scores.

Bowel Cleansing Preparation	SD	Mean Total Cleanliness Score (residual + consistency +bowel wall visible)	Mean Total (residual + consistency)
PEG-ES (Nulytely) + Bisacodyl tablets (5) (n=67)	8.88	15.49	13.91
PEG plus ascorbic acid (Moviprep) (n=40)	11.45	17.18	14.24
Halflytely + Bisacodyl tablets (2) (n=26)	10.32	17.80	14.23
PEG-ES (Nulytely + Bisacodyl tablets (5) + Lactulose 120 ml + Saline Enemas (4) (n=26)	8.59	12.30	10.92
Miralax + Bisacodyl tablets (4) (n=16)	9.54	17.17	14.24
Lactulose 120 ml + Bisacodyl tablets (5) + Saline enemas (4) (n=9)		13.0	11.11
Sodium Phosphate (30 ml, 45 ml, 90 ml) (n=7)	5.17	15.0	12.33
Magnesium Citrate (n=2)	3.53	5.5	4.0
Visicol tablets (n=3)		8.0	3.66

Participants prescribed the HalfLytely, MoviPrep, and Miralax revealed means which were similar in both categories and slightly higher than the means for the other preparations most frequently used in this sample.

The time it takes to reach the cecum can sometimes be affected by the overall cleanliness of the colon. The gastroenterologist reached the cecum in 94.8% of the time with a mean time of 12 minutes. Two of the procedures were terminated due to the poor quality of the colon cleansing preparations. Both of these participants were female. Three additional cases where the gastroenterologist did not reach the cecum were due to severe bowel adhesions and a tumor/mass. Figure 12 reflects the means of the time to cecum for the different bowel cleansing preparations.

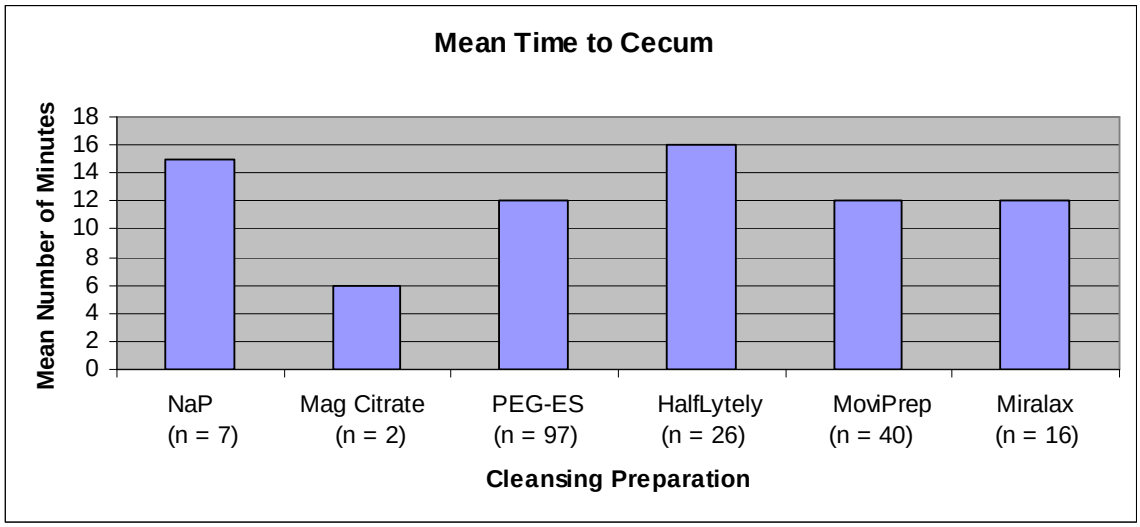

Figure 12. Mean Time to Cecum in Minutes by Cleansing Preparations.

The mean time to the cecum was very close for all preparations except for sodium phosphate and magnesium citrate. Sodium phosphate had the highest mean time and magnesium citrate had the lowest mean time, but these findings are not significant because so few of the subjects received these preparations.

A majority of subjects (n = 194, 96.5%) reported liquid stools after completing the bowel preparation. Only 3.5% of the participants (n = 7) reported semi-solid to solid stools. The color of the last stool was yellow (n = 102, 50.7%) the majority of the time followed by clear (n = 62, 30.8%) and brown (n = 28, 13.9%). The amount of liquid stool is critical because of the amount of time used to flush and clear the mucosa for visibility. While the preparations consistently revealed some amount of liquid stool present, the preparations which had the smallest amount of residual stool reported was PEG-ES plus bisacodyl tablets.

Two preparations with the largest amount of residual stool were: (a) lactulose plus bisacodyl tablets plus saline enemas (n = 10) and (b) Miralax (n = 16). The various preparations did not produce significantly different colon cleanliness (ANOVA *df6*, p .524). In order to use cross tabulations to analyze the different preparations, the total cleanliness score described previously was placed in a category labeled “excellent”, “good”, “fair”, or “poor”. In an earlier pilot study, physicians provided both a global cleanliness score and a rating on each section of the

colon. A detailed analysis revealed the total scores, which ranged from 0-18, yielded an "excellent" rating; a "good" preparation score ranged from 19 to 36**;** a "fair" preparation ranged from 37-53; and finally a "poor" preparation score ranged from 54-72.

The cross tabulations allowed an easy format to see how many of the different preparations yielded a "good" to "excellent" preparation. The majority of all participants (78%) had scores which were either "good" to "excellent" with 12% of the participants with "fair" to "poor" preparation reported.

The use of cross tabulations based on the total cleanliness score ranges revealed PEG-ES (NuLytely), five bisacodyl tablets, lactulose 120 ml, and the four saline enemas had 76% of the preparations in the "excellent" category. The next preparation with the highest percentage of "excellent" rating was PEG-ES 4L (NuLytely), with the five bisacodyl tablets (73%). MoviPrep had 65% (n=26) with an excellent rating. The ratings for the preparations are listed in Table 5).

Table 5. Percent Excellent Rating of Preparations Based on Total Cleanliness Score.

Cleansing Preparation	Excellent	Good	Fair	% Excellent
4 L PEG-ES (NuLytely) + 5 Bisacodyl tablets (n = 74)	55	16	3	73%
2 L PEG-ES (Moviprep) (n = 40)	26	11	3	65%
2 L PEG-ES (HalfLytely) + 2 Bisacodyl tablets (n = 26)	14	10	2	54%
4 L PEG-ES (NuLytely) + 5 Bisacodyl tablets + Lactulose 120 ml + 4 Saline Enemas (n = 26)	12	4	0	76%
Miralax (n = 16)	2	14	0	12%

Research Question 3

Do patients experience different levels of discomfort with different bowel cleansing preparations?

Only eleven of the participants reported no discomforts. Of these eleven, six received the 4 L PEG-ES, three received HalfLytely, one received MoviPrep, and one received the Sodium Phosphate liquid. The statistical analysis provided a report on not only the presence of different subject experiences (Figure 13), but the intensity as well (Figure 14). The most commonly reported discomfort from the bowel cleansing preparations was full feeling (n = 126, 63%) followed by nausea (n = 94, 47%), fatigue (n = 90, 45%), and abdominal cramps/pain (n = 81, 41%).

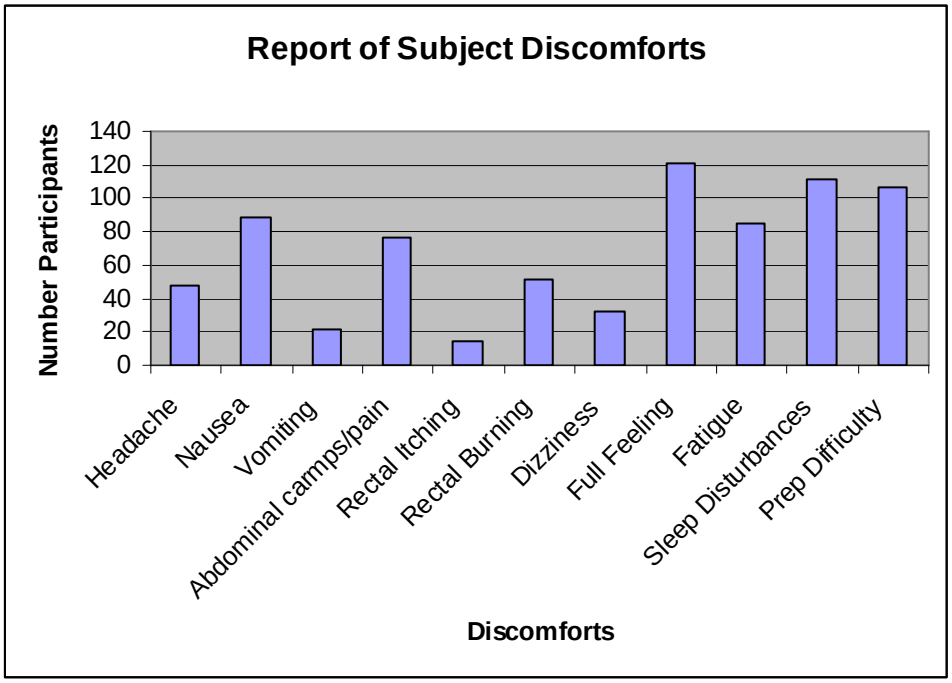

Figure 13. Number of Participants Reporting Subject Discomfort

Rectal burning and headache were the next most frequent reported at 28% (n = 57) and 26% (n = 53). Dizziness and vomiting were similar and reported only 18% (n = 37) and 13% (n = 27) of the time respectively. The least common reported was rectal itching (n = 19, 9%). Subjects also reported increase frequency and intensity of sleep disturbances (59%, n = 116) and difficulty with the preparation (57%, n = 112). The mean intensity scores for subject discomforts

experienced with the preparations are illustrated in Figure 14. The discomfort scale ranged from zero to ten.

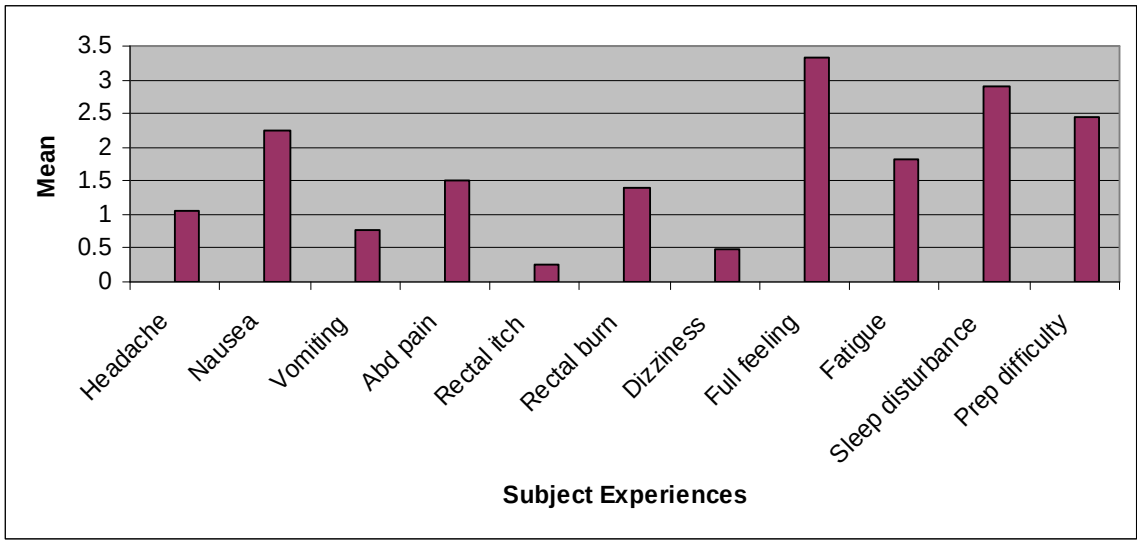

Figure 14. Mean Intensity Subject Experiences for all preparations

The highest mean intensity recorded was full feeling followed by nausea, fatigue, and abdominal pain. The preparation which had similar mean intensity as the overall subject experiences for colon cleansing preparations was Miralax (Table 6). The occurrence of full feeling, sleep disturbances, preparation difficulty, and nausea were similar. Patients with Miralax experienced more fatigue rather than abdominal cramps/pain identified in the overall preparations.

The combination of 4 L PEG-ES, five bisacodyl tablets, 120 ml lactulose, and four saline enemas was the bowel cleansing preparation with the highest level of discomfort identified by the means. The intensity of abdominal pain, full feeling, and preparation difficulty was above a mean intensity of three in these categories (Table 6). The mean intensity of nausea ranged between less than one and four for the different preparations. The preparation with 120 ml lactulose, five bisacodyl tablets, and the four saline enemas also had elevated mean intensity scores for nausea, abdominal pain, full feeling, fatigue, sleep disturbance, and preparation difficulty.

Although PEG-ES was combined with other laxatives in the sample, the only one of the combinations that is recommended in the literature is the reduced volume of PEG-ES (HalfLytely) with bisacodyl. It was prescribed for only 26 (13%) of the participants, and had the lowest mean discomfort score and the lowest reports of sleep disturbance of all the PEG-ES combinations. MoviPrep, a reduced volume which was also administered as a split dose also revealed a decrease in overall mean intensity scores for discomforts. Thirty-five of the participants on MoviPrep ingested it as a split does ingesting one liter the evening before the colonoscopy and the second liter during the early am. Subjects reported beginning the second liter at times varying from 0230 to 0845. These subjects did not have an increase in the mean intensity scores for sleep disturbances. Subjects who received Magnesium citrate reported little discomfort overall, but did report rectal burning and rectal itching. The mean intensity scores for each bowel cleansing preparation are reported in Table 6.

Additional descriptors cited by participants were “migraines”, “awful taste,” “cold chills,” “scared feeling”, “sore rectum”, and “surface bleeding.” One participant also added “if I have to repeat a colonoscopy in five years, I will not go through this same preparation, I wish there was another way.” Overall, 59% of participants reported some degree of sleep disturbance. A majority of the participants (57%) also reported difficulty with the preparation.

Table 6. Mean Intensity Score by Colon Cleansing Preparations. Range 0-10.

Colon Cleansing Preparation	H/A	Nausea	Vomiting	Abd Pain	Rectal Itch	Rectal Burn	Dizzi-Ness	Full Feeling	Fatigue	Sleep Dis-turbance	Prep Diffi-culty
4 L PEG-ES (NuLytely) +5 Bisacodyl tablets (n = 74)	.79	2.61	1.27	2.83	.16	1.27	.46	3.91	1.73	2.89	2.46
MoviPrep (2 L PEG) (n = 40)	1.18	1.82	.13	1.44	.56	1.74	.67	3.23	1.67	2.79	2.77
2 L HalfLytely + 2 Bisacodyl tablets n = 26)	.67	2.40	.60	3.27	.53	.87	.00	3.0	2.0	.93	1.80
4 L PEG-ES (NuLytely + 5 Bisacodyl tablets + Lactulose 120 ml + 4 Saline Enemas (n = 26)	1.80	3.08	1.28	2.56	1.20	1.32	.80	2.96	2.68	2.72	2.80
Miralax + 4 Bisacodyl tablets (n = 16)	.38	.69	.13	1.25	.13	.88	.12	3.62	1.5	3.25	.44
Lactulose 120 ml + Bisacodyl tablets (5) + Saline enemas (4) (n =10)	2.20	4.40	2.13	3.01	.33	1.47	1.20	4.20	3.20	4.13	4.40
Sodium Phosphate (30 ml, 45 ml, 90 ml) (n = 7)	.86	1.14	.00	1.0	.14	2.14	1.0	1.14	2.14	2.57	3.57
Magnesium Citrate (n = 2)	.5	.5	.00	.00	1.0	3.5	.50	.00	.50	.50	2.00
Visicol tablets (n = 3)	.33	3.67	.33	1.67	.00	1.0	.33	2.33	1.0	2.67	2.67

The preparations which included lactulose and bisacodyl had the highest mean intensity score of full feeling. The preparations with the lowest mean intensity score for full feeling were the sodium phosphate preparations. Subjects prescribed four bisacodyl tablets and Miralax also revealed a higher mean intensity score for full feeling. Those subjects with the elevated mean intensity for full feeling also experienced nausea with minimal occurrences of vomiting. The mean intensity of subject experiences was reduced with the 2 L PEG solution volumes when compared to the 4L PEG-EG. This is similar to those findings described by DiPalma et al., (2004). The participants who ingested MoviPrep did have an overall decrease in mean intensity scores in all categories except for sleep disturbances.

Research Question 4

What is the relationship between patient health characteristics and bowel preparations' effectiveness?

It has been reported that the quality of bowel cleansing preparations may be lower in a certain subset of patients. Subsets include elderly patients, inpatients, and patients with hypo-motility disorders, constipation, thyroid insufficiency, and diabetes. No inpatients were included in this sample. Cross tabulations statistical analysis was used to examine this small subset of patients (Table 7) in relation to the cleanliness of the colon.

Table 7. Frequency of Subset of Patients

Variable	Frequency
Inpatients	0
Age >70	27
Hypomotility Disorders	
Constipation	12
Diabetes	18
Depression	22
Thyroid Disease	15

In addition, cross tabulations were used to identify if any trends or patterns exist with certain medications which may also slow the motility of the colon and interfere with the quality of bowel cleansing. These include prescription pain medications, non prescription pain medications, and antidepressants.

Participants age 70 years or older (n = 27) had overall cleanliness scores which were on average higher due to the increased amount of residual stool. A correlations scatter plot did reveal a small positive correlation between age and mean cleanliness score. A Pearson correlation coefficient was calculated for the relationship between participants' age and total cleanliness score. A weak correlation was significant ($r(189) = .164$, $p < .01$). As the age increased, the mean cleanliness score also increased. The sample was too small to detect any statistical significance in cleanliness for patients with constipation, diabetes, depression, and thyroid disease. This subset was also spread out over several different preparations. Patients with diabetes and depression had total consistency scores greater than 12.

The overall cleanliness of the colon can be affected by certain medications. There were many different medications listed under "other" but the most frequent occurring medications for this sample are summarized in Table 8 with the overall cleanliness rating.

Table 8. Medication and Cleanliness of Colon Rating

Medication	Excellent Preparation	Good Preparation	Fair Preparation	Poor Preparation	Total
Antidepressants	10	6	1	0	17
Constipation Relief	5	6	1	0	12

Table 8. Continued

Diabetes Medications	9	6	1	0	16
Heart Medications	4	6	1	0	11
Antihypertensives	36	26	3	0	65
Prescription Pain Medication	6	5	0	0	11
Non-prescription pain medication	16	13	2	0	31
Thyroid	8	4	2	0	14

Subjects reporting use of constipation relief medications and heart medications revealed a majority of the preparations in the “good” rating category rather than “excellent” in the overall cleanliness of the colon. The subjects who reported use of antidepressants, hypertensive medications, prescription pain medications, and non-prescription pain medications had a “good” to “excellent” colon cleanliness rating the majority of the time.

Additional Findings

The participants did have a chance to write comments on the subject experience form. Most of them complained about the bad taste. Fifty-seven percent of the subjects reported some difficulty with the preparation prescribed. Subjects reported the liquid diet was one of the biggest problems and contributed to a disruption in daily activities. Finally, one subject reported using a wine glass to drink the preparation because it made it more appealing. A large

percentage of participants reported difficulty with the preparation and experiencing sleep disturbances (59%).

Discussion

The following section is a discussion of the study results which were reported in the aggregate for the four study sites. Methodological issues, implications for nursing, limitations, and recommendations for future research are also addressed.

Demographic Data

A total of 116 women (57.7%) and 85 (42.3%) men participated in the study. This is different from reported findings that females have a lower adherence to completion of scheduled colonoscopy (Denberg et al., 2005). It is felt that women may have more apprehensions about having a colonoscopy than men. The increase in the number of women in this sample may be that women are becoming more informed about the advantages of colorectal cancer screening. The average age reported for this sample was 55 as revealed in Figure 6 which is consistent with other studies examining colon cleansing preparations (Adams et al., 1994; Anderson & Baker, 2007; DiPalma et al., 2003).

Whereas many previous studies did not look specifically at ethnicity, this is an important criterion to examine. According to United States cancer statistics (CDC, 2009), colon and rectal cancer is the fourth most common cancer among African Americans and the third most common among Hispanics. There were only 11.9% African American (n = 24) and 4.5% Hispanic (n = 9) in this sample. According to United States statistics, African Americans and Hispanics comprise 13.4% and 14.8% of the population respectively. Therefore, this study was not representative of these minorities. Possible explanations are that minorities are not being screened in proportion to their numbers or that sites used in this study do not see many minorities. Other researchers have found that minorities are not undergoing the recommended screening; therefore, their cancers are not being detected until advanced stages (Colon Cancer Alliance, 2009). Certainly, strategies for increasing colorectal cancer screening of minorities should be encouraged.

This study did not address family history of colon cancer. This is an important criterion due to the genetic component of colon cancer for first and second degree relatives and recommendations that patients with genetic history of colon cancer be screened in the fourth decade rather than the fifth. This criteria will be added to the demographic data form for use with future studies.

The average time to reach the cecum by the gastroenterologist was 12 minutes. This average is within the range of a study reported by Zuber-Jerger et al. (2008) in which the average time to reach the cecum was 10.5 +/- 10.2 minutes. Increased times to reach the cecum may be related to cleanliness of the colon but may also be influenced by other factors (Hsieh et al., 2008). In this study, there was no relationship between cecal intubation time and colon cleanliness.

Colorectal cancer screening was the most frequently reason reported reason for the colonoscopy for this sample (n = 80, 40%). In the United States, colorectal screening lags far behind screening tests for breast cancer and prostate cancer. Liebermann (2005) reported screening for colorectal cancer accounted for only 30% of all colonoscopies. The average for this sample is higher than the reported national average which may indicate the trend toward CRC screening is increasing.

People with thyroid disease, constipation, diabetes, and depression are prone to poor bowel motility but this was not evident in this study. The demographic data form listed those health problems which would impact bowel preparations, but one of the frequent conditions recorded which was not on the form was hypertension. These patients are at an increased risk for stroke and kidney failure which are conditions that could affect bowel cleanliness. According to national averages, heart disease, diabetes, and depression are among the most frequent health problem reported in America. Therefore, this condition will be added to the form for use with future studies. Stroke is another condition which could impact bowel cleansing and will also be added.

Bowel Cleansing Preparations Used

We do not know how many physicians are prescribing the preparations recommended by the ASGE across the country. Eighty-one percent (n = 163) were prescribed PEG-ES in some form or other in this sample. PEG-ES without any additional medication was only prescribed to five participants (2%). The other two recommended preparations (sodium phosphate liquid and tablets) were prescribed five percent of the time. The recent changes in the boxed warning label from The Federal Drug Administration on the sodium phosphate medications may contribute to reluctance to use these preparations (FDA, 2008). The products can still be purchased with prescription from a physician. Currently, the prescribing dose of this medication across the country is unknown and continued evaluation is required.

Only nine patients in this sample received the sodium phosphate preparations as recommended by the ASGE. Patients with known hypertension or renal disease, or who are on specific diuretics would have been precluded from receiving sodium phosphate because it is contraindicated (Cohen & Tennyson, 2007). Six of these participants were prescribed a lower than recommended dose. Possibly healthcare providers are concerned about sodium phosphate's safety and are avoiding its use with all patients, even those for whom it is not contraindicated.

Are there differences in bowel cleanliness?

While researchers have reported use of metoclopramide, senna, and magnesium citrate as adjunct medications to increase the quality of colon cleansing preparations, only magnesium citrate was used in this sample (Delegge & Kaplan, 2005); however, magnesium citrate can result in volume depletion and is contraindicated in those patients with poor kidney perfusion and significant cardiovascular disease.

Since 50% of the participants came from one site, and that site routinely prescribes adjunct medications for patients who take pain medications or have constipation, this could have skewed the overall cleanliness scores. Experts agree that additional adjunct medications

may provide more effective cleanliness than one preparation alone. Physicians may also be prescribing multiple cleansers because of fears regarding flat adenomas which are easily missed when stool is present in the colon. Future studies utilizing this scale will attempt to have the same number of subjects from individual sites.

Scott et al. (2005) reported improvement in bowel preparation efficacy could be achieved through patient compliance. One of the strategies used for improved patient compliance in this study was the pre-procedure instruction. The results of this current study revealed a large majority of participants received education prior to the procedure by a licensed healthcare worker (registered nurse).

As reported by Allaire et al. (2004), compliance of preparations is enhanced when simple and in writing. A large percentage (91.5%, n = 184) of the participants received pre-procedure instructions in writing. Another 16.9 percent (n = 34) of the participants also received instructions in writing with pictures. A smaller percentage of the sample received pre-procedure instructions in the mail (18.4%). It is not known if this group of participants (n = 37) understood the instructions or had questions which needed to be addressed. This was not a question on the demographic data form. Sixty-one percent (n = 124) of the preparations were selected by physician or by institution protocol. 91% (n = 183) of the participants reported compliance with the dietary restrictions which was overwhelmingly clear liquid diet (94%, n = 189). Studies are indicating a trend toward liberalization in diet restrictions by adding a low fiber diet, which may increase compliance but only seven participants (n = 3.5%) were prescribed a low-fiber diet.

Discomforts with different bowel cleansing preparations

Only eleven participants revealed no discomforts. The remaining subjects experienced discomfort with every combination of preparations. While split dosing has been reported for prevention of certain side effects such as hypovolemia, bloating, cramping, and nausea, there were 35 participants prescribed the split dosing (Aoun et al., 2005, DiPalma et al., 2003). The lower volume doses of 2L PEG-ES were used in this sample but those participants prescribed

the HalfLytely and Moviprep experienced similar discomforts of full feeling, abdominal pain, and nausea. Those participants on the lower volume dose did have lower mean intensity scores for subject discomfort when compared to the other preparations. This is similar to previous reports by Toledo and DiPalma (2001).

The mean intensity scores for sleep disturbances and difficulty with preparations were elevated for this sample (Table 6). Surprisingly, the participants who ingested the Moviprep as a split dose with the second dose given in the early morning (0230 to 0845) reported had similar mean intensity scores for sleep disturbances as the other PEG-ES preparations. The times for beginning the second liter varied from 0230 to 0845.

Overall, the participants in the study did have an increase in the mean intensity for sleep disturbance. The pre-procedure instructions may be a factor regarding when patients were instructed to begin the preparation and when they actually did so. The times for ingestion of the other preparations were recorded as either hours to complete the preparation or time the preparation began or the time which ingestion was completed. The specific minutes between the ingestion of individual doses of the preparation were not recorded. This may be a variable which could be added to future studies.

Participants who received sodium phosphate had low mean intensity scores for full feeling, abdominal pain, and nausea but high scores for fatigue, rectal burning, sleep disturbance, and preparation difficulty. This is similar to prior studies which report a decrease in reports of nausea, vomiting, bloating, and abdominal cramps with lower volume preparations like sodium phosphate (Allaire et al.; 2004; Cohen et al.; 1994; Kossi, 2003; Rostom et al. 2006; Young et al, 2000).

Health characteristics influence on bowel preparations' effectiveness

Participants older than 70 represented 13 percent of the sample (n = 27). The colon cleanliness was negatively correlated with age (r = 1.0, p .024). Others have also reported that

elderly people are more likely to have inadequate cleansings (Amella, 2006; Lukens et al., 2002).

The sample was too small to identify statistical significance between colon cleanliness for participants reporting specific health characteristics such as diabetes, constipation, or thyroid disease. Diabetes is present in 8% of the adults in the United States and its prevalence is increasing. As reported by Taylor and Schubert (2001), diabetic patients who ingested PEG were found to have poorer preparation than non diabetic patients. In this sample, 18 patients were diabetic. While the patients with diabetes had an increased mean in the total consistency scores, a majority of this subset (56%) had preparations which were rated “excellent” based on the total cleanliness score. These results are different from those reported by Taylor and Schubert (2001); however, the use of adjunct medications in the majority of this sample may contribute to an increase in the overall cleanliness of the colon for these patients.

Similarly, 8 of the 14 subjects with thyroid disease had an excellent cleanliness rating. While constipation affects nearly 18% of the United States population, only 6% of the sample reported constipation or use of constipation relief medications. The patients with a history of constipation (n = 12) had a lower percentage of excellent preparations (41%). This is consistent with reports that inadequate cleansing is related to intake of constipating relief medications (O’Mahony, O’Leary, & Quigley, 2002).

Antidepressants also slow motility of the gut and can influence the overall cleanliness of the colon during bowel cleansing. Twenty-two participants reported a history of depression and revealed 40 percent (n = 9) with an overall excellent rating for cleanliness of the colon. The lower rating for excellent preparation is expected in this group of patients due to the slower transit times (Feigenbaum, 2006).

A small percentage of the sample reported taking medications such as opioids which contribute to slower colon transit times and delay gastric emptying (Feigenbaum, 2006; Taylor & Schubert, 2001). Only 10 patients listed prescription pain medication and another 31 took non-

prescription pain medications. Nine percent (n = 4) of this group revealed a fair prep but the remainder 91% (n = 37) had a good to excellent preparation. Again this could be due to the increase in the number of adjunct medications prescribed in this sample which supports the suggestion by Reilly and Walker (2004), that patients taking narcotics and laxatives may require additional preparation to properly cleanse the colon.

Hypertension occurs in 51.9% of seniors in the United States and is increasing in younger adults. Based of the frequency of hypertension, the history of the patient is critical since medications prescribed may cause problems with kidney function. Some calcium channel blockers are known to slow transit time of the gastrointestinal system (Adams, Josephson, & Holland, 2005).

Hypertension was reported by 71 of the participants (35%) as a health problem. This is an important condition that was precluded from the demographic form as a chronic health problem but will be added in the future.

Conclusions

Bowel cleansing quality may be enhanced with the addition of adjunct medications or a more intensive preparation. There were many different preparations used in this small sample. Overall, the preparations were effective with “good” to “excellent” ratings. Sodium phosphate was prescribed infrequently in this sample and may be attributed to the recent boxed warnings on the label or just not prescribed by the sites in this study. The sample was too small to identify any specific preparation which worked best. Also, differences did not appear since the preparations were effective with the addition of adjunct medications and almost all the colons were clean.

Thirty-five of the participants were prescribed the split dose of Moviprep which has the added benefit of reduced volume, improved taste, and no requirement for bisacodyl which can cause abdominal discomforts. A large percentage of the participants prescribed the Moviprep

also had excellent ratings on the preparations. Patients do continue to experience subject discomforts but had lower mean intensity scores.

Limitations

This study describes the experiences of four centers performing colonoscopy. Since the study was purely descriptive:

1. Subjects were not randomized.
2. Subjects self reported the amount of preparation ingested.
3. Preparations were limited to only those prescribed by each individual site.
4. The researcher had no control over intervening variables at each site such as how pre-procedure instructions were given.

An additional limitation is that 50% of participants were from one site; therefore, results cannot be generalized to all groups of patients undergoing colonoscopy. The following steps were taken to decrease variability:

1. All participants who met the inclusion criteria were asked to participate.
2. Gastroenterologists performed all the colonoscopies.
3. All forms were carefully designed for validity and reliability and the questions on the forms were specific and not open to interpretation.

Nursing Implications and Future Studies

Colonoscopy remains the gold standard in diagnosing colorectal cancer; therefore, the choice of the colon cleansing preparation is critical. As collaborators in the care and treatment of patients, nurses must remain knowledgeable about the different colon cleansing in order to provide quality care. PEG-ES and sodium phosphate have been well studied in randomized clinical trials. This study examined what preparations are being prescribed in a variety of settings. Utilization of best practices in selection of colon cleansing preparations can be enhanced by clinical studies. The data from this study can be used in providing information for future studies in the following areas:

1. Revisions to data collection forms
2. Patient instructions
3. Older age populations
4. Pooling data

Revisions to data collection forms

The forms allowed for the collection of precise information. The demographic form should gather information regarding the family history of colon cancer and will be added to the form for use with future studies. In addition, the form listed conditions which are known to affect gastrointestinal motility but this study revealed that hypertension is a significant chronic health problem. This will be added to the demographic form. One site suggested that an additional scoring on the colon cleanliness scale should occur following any suctioning, washing, or flushing. This may be a consideration for future studies.

Patient instructions

With the increase in the use of adjunct medications, the identification of specific guidelines will be critical. Some of the participants received their pre-procedure instructions via mail. Patients must be made aware of the importance of hydration before, during, and after the procedure. Written instructions should include information on hydration guidelines which not only contributes to the safety of the patient but the effectiveness of the preparation (Dykes and Cash, 2007). Ingesting the preparations properly may reduce the subject discomforts. It is not known if patients understood the directions since this was not addressed. The use of adjunct medications may have also contributed to the presence and intensity of subject discomforts in this sample and additional studies may help determine which combination of preparations lend themselves to a clean colon with a decrease in subject discomforts.

Older age populations

As the United States population ages, it is important to identify the preparations used safely with this age group without causing any adverse events. It is known that as the population ages, the potential for chronic health conditions such as heart disease, hypertension, diabetes, and constipation also increase. The addition of sites with patients older than sixty will add to the database in examining which preparations are being used and their effectiveness.

Pooling of data

The continual pooling of data with multiple sites in different geographical areas should provide objective criteria in the selection of colon cleansing preparations for specific patient characteristics. The addition of more sites may also increase the cultural diversity of the sample will also provide information that may help in formulating specific guidelines.

Summary

This study was a descriptive study to determine what colon cleansing preparations were being used in a natural setting, how effective these preparations are in cleansing the colon, and what discomforts patients experience with the different preparations. Findings showed a trend toward more intensive colon cleansing preparations by the addition of more medications; therefore, most of the preparations in this sample were “good” to “excellent”.

No difference was noted between the patients with slower intestinal motility due to the small number in this sample and the use of more intensive preparations. Additional data are needed to find the evidence for final recommendations for guidelines on use of certain preparations with specific patient populations. A continued pooling of data from sites in the future will provide the evidence to make sound judgments regarding the selection of colon cleansing preparations. The colon cleansing preparation should be tailored to the patient. The search for the ideal colon cleansing preparation which is tolerable should not only increase the chance of safe and effective colonoscopy, but decrease the preparation as one of the barriers to colonoscopy.

APPENDIX A

STUDY CONSENT AND APPROVAL LETTERS

INFORMED CONSENT

PRINCIPAL INVESTIGATORS: Glenda Daniels, MS, BSN, CGRN, PhD Candidate;
Marilee Schmelzer, PhD, RN

TITLE OF PROJECT: A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations

This Informed Consent will explain about being a research subject in an experiment. It is important that you read this material carefully and then decide if you wish to be a volunteer.

PURPOSE

The purposes of this research study are as follows:

- Describe bowel cleansing preparations used at various institutions across the USA.
- Compare the bowel preparations' cleansing effectiveness.
- Compare patient discomfort with different bowel cleansing preparations.
- Determine whether the patient's health is related to bowel cleansing.

You have been asked to be in the study because you are going to have a colonoscopy. The colon must be empty for a colonoscopy. When people are going to have a colonoscopy, they need to take something the evening before that will clean the colon. Sometimes, they also take something the next morning to clean the colon.

The researchers want to know how well the colon cleansing procedure works. They want to know:

- If you have any problems during the colon cleaning procedure,
- Whether you have any discomfort during the colon cleansing procedure,
- How clean your colon is during the colonoscopy

DURATION

You will only be in the study on the day you take your colon cleansing preparation and the day of your colonoscopy.

PROCEDURES

The procedures, which will involve you as a research subject, include:

1. The researcher will collect the following information from you:

   - Your age, height, weight, and race
   - Your health problems,
   - The reason you are having the colonoscopy,
   - Whether you have had a colonoscopy before,
   - Medications you take daily.

JAN 1 8 2008
APPROVED BY THE UTA - IRB
The IRB approval for this consent
Document will expire on
JAN 1 7 2009

_____Subject Initials

PRINCIPAL INVESTIGATORS: Glenda Daniels, MS, BSN, CGRN, PhD Candidate; Marilee Schmelzer, PhD, RN

TITLE OF PROJECT: A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations

2. The researcher will ask how you when you had your last bowel movement. She will ask how often you usually have a bowel movement.

3. The researchers want you to keep track of how much of the colon cleansing preparation you drink.

4. A nurse will fill in some information about the type of bowel cleansing preparation you received and who gave it to you.

5. A nurse will ask you if you drank only clear liquids and how much bowel cleansing preparation you took. The nurse will ask you what your last stools looked like.

6. Prior to your colonoscopy, you will fill out a short (one page) survey. The survey lists 9 discomforts that can occur. The researchers want to know if you had any of them. They also want to know how easy it was to do the bowel cleaning procedure and if your sleep was interrupted. It will take about 5 minutes to fill out the survey.

7. While the doctor is doing your colonoscopy, he or she will see if there is any stool in your colon. He will describe any stool to the nurse who will write the description on a form. The form only has questions about how clean your colon is and how quickly the colonoscopy was done.

POSSIBLE RISKS/DISCOMFORTS

The possible risks and/or discomforts of your involvement include loss of confidentiality. There are no other risks since the study is only describing how well the bowel procedure works.

POSSIBLE BENEFITS

The possible benefits of your participation are: none.

The researchers will use the information to determine what colon cleansing methods works best for specific patients. Patients will probably be more willing to have a colonoscopy when we have easy procedures for cleansing the colon. Clean colons make it easier to detect tumors in their early stages when they are easier to cure.

ALTERNATIVE PROCEDURES / TREATMENTS

The alternative procedures / treatments available to you if you elect not to participate in this study are: none.

_____Subject Initials

PRINCIPAL INVESTIGATORS: Glenda Daniels, MS, BSN, CGRN, PhD Candidate; Marilee Schmelzer, PhD, RN

TITLE OF PROJECT: A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations.

You will receive the same care before, during, and after your colonoscopy whether or not you are in the study. The researchers are only observing what happens and asking you questions.

CONFIDENTIALITY

Confidentiality will be maintained by assigning a unique tracking number to each subject known only by the investigators. Any pathology detected during colonoscopy will not be recorded on any study forms. The signed informed consent form will be secured separately from data forms in a locked area. Information will be reported in the aggregate, not by individual responses or individual descriptions of the colon's cleanliness. Every attempt will be made to see that your study results are kept confidential. A copy of the records from this study will be stored in the Center for Nursing Research at the University of Texas at Arlington School of Nursing for at least three (3) years after the end of this research. A copy of the consent form will be given to you and a second will be stored at the University of Texas at Arlington School of Nursing. The results of this study may be published and/or presented at meetings without naming you as a subject. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the UTA IRB, the FDA (if applicable), and personnel particular to this research (individual or department) have access to the study records. Your medical records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as noted above.

COMPENSATION FOR MEDICAL TREATMENT: None

FINANCIAL COSTS

The possible financial costs to you as a participant in this research study are: None

Your hospitalization, the colon preparation, and the colonoscopy are not part of the study. You will have the same charges for the hospitalization, colon preparation and colonoscopy whether or not you are in the study.

CONTACT FOR QUESTIONS

If you have any questions, problems or research-related medical problems at any time, you may call Glenda Daniels at or Marilee Schmelzer at 817-272-2776. If you have any questions about your rights as a research patient, you may contact the Chairman of the Institutional Review Board (UTA) at 817-272-1235.

JAN 1 8 2008
APPROVED BY THE UTA - IRB
The IRB approval for this consent
Document will expire on

JAN 1 7 2009

_____Subject Initials

PRINCIPAL INVESTIGATORS: Glenda Daniels, MS, BSN, CGRN, PhD Candidate;
Marilee Schmelzer, PhD, RN

TITLE OF PROJECT: A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations

VOLUNTARY PARTICIPATION

Participation in this research experiment is voluntary. You may refuse to participate or quit at any time. If you quit or refuse to participate, the benefits (or treatment) to which you are otherwise entitled will not be affected. You may quit by calling Glenda Daniels whose telephone number 817-637-7568. You will be told immediately if any of the results of the study should reasonably be expected to make you change your mind about staying in the study.

By signing below, you confirm that you have read or had this document read to you. You will be given a signed copy of this informed consent document. You have been and will continue to be given the chance to ask questions and to discuss your participation with the investigator.

You freely and voluntarily choose to be in this research project.

PRINCIPAL INVESTIGATOR: _____ DATE

_____ DATE
SIGNATURE OF VOLUNTEER

_____ DATE
SIGNATURE OF PATIENT/LEGAL GUARDIAN (if applicable)

_____
SIGNATURE OF WITNESS (if applicable)

JAN 1 8 2008

APPROVED BY THE UTA - IRB
The IRB approval for this consent
Document will expire on

JAN 1 7 2009

_____Subject Initials

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of
Research Administration

Box 19188
202 E. Border St., Suite 201
Arlington, Texas
76019-0188
T 817.272.3723
F 817.272.1111
http://www.uta.edu/research
Expertise at UT Arlington
www.uta.edu/expertise

January 18, 2008

Glenda Daniels, MS, BSN, CGRN
Marilee Schmelzer, PhD, RN
Nursing
Box 19407

RE: Expedited Approval of Protocol

TITLE: *A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations*

IRB No.: 08.004s

The University of Texas at Arlington Institutional Review Board (UTA IRB) has determined that this research is eligible for expedited review in accordance with Title 45 CFR 46.110(a)-(b)(1), 63 FR 60364 and 63 FR 60353, categories (5)(7).

The IRB Chairman (or designee) approved the protocol pending agreement to participant letters from the other sites. The approval is effective January 18, 2008. IRB approval for the research shall continue until January 17, 2009. In order for the research to continue beyond the first year, Continuation Review must be completed within the month preceding the date of expiration indicated above. A reminder notice will be forwarded to the attention of the Principal Investigator (PI) at that time.

The approved subject sample size is 800.

Important Note: The IRB approved and stamped informed consent document (ICD), showing the approval and expiration date of the article must be used when prospectively enrolling volunteer participants into the study. The use of a copy of any consent form on which the IRB-stamped approval and expiration dates are not visible, or are replaced by typescript or handwriting is prohibited. The signed consent forms must be securely maintained on the UTA campus for the duration of the study plus three years. The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UTA IRB, Regulatory Services staff, OHRP and by study sponsors (if the study is funded).

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to this office within 24 hours. In addition, pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

All investigators and key personnel identified in the protocol must have documented *Human Subjects Training* or *CITI* Training on file with this office.

If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

The UTA Office of Research Administration Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Jan Parker by calling (817) 272-0867.

Sincerely,

Patricia Turpin, PhD, RN CNAA, BC

Patricia Turpin, PhD, RN, CNAA, BC
Associate Clinical Professor
UTA IRB Chair

Encl (if applicable):
- Consent Form(s)
- Questionnaire(s) or Survey(s)
- Recruitment Advertisement
- Project Summary

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

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http://www.uta.edu/research
Expertise at UT Arlington
http://www.uta.edu/expertise

BeAMaverick.

January 15, 2009

Glenda Daniels, MS, BSN, CGRN
Marilee Schmelzer, Ph.D., RN
Nursing
Box 19407

RE: Continuing Review Approval Letter

TITLE: ***A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations***

Submission No.: 2009.01178

IRB No.: 08.004s

The University of Texas at Arlington IRB Chair (or designee) reviewed and approved the status of '*continuing / No Changes*' for a period not to exceed one year, effective **January 18, 2009.** IRB approval for the research shall continue for a period not to exceed twelve months [45 CFR 46.109(e)]. In order for the research to continue, Continuing Review must be completed within the month preceding the date of approval indicated above. A reminder notice will be forwarded to the attention of the Principal Investigator (PI) at a time sufficient enough to allow for the continuation review to occur.

The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations. http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm

Important Note: The research records, including the signed consent forms must be securely maintained on the UT Arlington campus for at least three years after the completion of the research unless a longer retention period is specified by a sponsor, funding source, or regulation. The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP and by study sponsors (if the study is funded).

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to this office within 24 hours. In addition, pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

All investigators and key personnel identified in the protocol must have documented *CITI Training* or *Responsibility in Human Subject Research – IRB 101*on file with this office.

If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required. To determine whether the collaborating facility is engaged in research, go to: www.hhs.gov/ohrp/assurances

The UT Arlington Office of Research Administration Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Philip Oilepo by calling (817) 272-0828.

Sincerely,

Patricia Turpin

Digitally signed by Patricia Turpin
DN: o=The University of Texas System, ou=The University of Texas at Arlington CA, ou=www.verisign.com/repository/CPS Incorp. by Ref.,LIAB.LTD(c)99, cn=Patricia Turpin, email=pturpin@uta.edu
Date: 2009.01.15 22:02:36 -06'00'

Patricia G. Turpin, PhD, RN, NEA-BC
Associate Clinical Professor
UT Arlington IRB Chair

APPENDIX B

DESCRIPTIVE (DEMOGRAPHIC) DATA FORM

Subject # 4 0 0 0

Age: ___

Descriptive (Demographic) Data

Part I

Form # ____

Height: ___ feet ___ inches

Weight: ___ . ___ pounds

Date ___ / ___ / ___

Gender: O Male O Female

Ethnicity: O American Indian
O Asian
O Black
O Caucasian
O Hispanic
O Other (Please specify) _____

Usual frequency of bowel movement:

O > 3 per day O 3 per day O 2 per day O 1 daily

O 1 every other day O 1 every 3 days O < 1 every 3 days

Reason for Procedure: O Abdominal pain
O Colorectal Cancer Screening
O Constipation
O Bleeding
O Inflammatory Bowel Disease
O Irritable Bowel Syndrome
O Pain
O Colonic Marking for Surgery (tattooing)
O Prior History of Colon Polyps
O Prior History of Colon Cancer
O Other _____

Chronic health problems: O Celiac Disease
O Congestive Heart Failure
O Depression
O Diabetes
O History of previous Myocardial Infarction
O Inflammatory Bowel Disease
O Irritable Bowel Syndrome
O Liver disease (specify) _____
O Neurological problem (specify) _____
O Renal Insufficiency or Failure
O Other _____

9537268033

Subject # 4000

Form #

Routine Medications: O Antidepressants

O Blood Thinners

O Constipation Relief

O Diabetes-insulin

O Diabetes-oral

O Heart

O Hypertensive

O Perscription Pain Medications (narcotic)

O Non-perscription Pain Medications (Over the counter)

O Thyroid

O Other _____

Colonoscopy: O Regularly scheduled O Repeated (because of poor prep)

Colonoscopy: O Outpatient O Inpatient

Has patient had a colonoscopy before? O Yes O No

If yes, what type of bowel cleanser was used? _____

Part II

Preparation for colonoscopy

Bowel prep supplies: O Provided by Institution O Bought by patient at a store

Bowel prep diet: O Provided by institution O Bought by patient

Choice of bowel prep dependent on: O Algorithm or protocol

O Patient preference

O Physician preference

O Other (specify) _____

Instructions for bowel prep provided (choose all that are applicable):

O In person by RN

O In person by physician

O In person by other healthcare personnel

O By Telephone

O By Mail

O In Writing

O With pictures of bowel prep container

O Follow-up telephone call

4315268032

Subject # 4 0 0 0

Form # ____

Part III

Type of bowel prep	Amount ordered	Amount ingested	Approximate Time ingested
Bisacodyl tablets	___ tablets	___ tablets	
Bisacodyl suppositories	___ suppositories	___ suppositories	
Fleet enema	___ enemas	___ enemas	
Fleet phospo-soda	____ ml	____ ml	
Citrate of magnesia	____ ml	____ ml	
Lactulose	____ ml	____ ml	
PEG-ELS (NuLytely, Colyte, Golytely)	____ ml	____ ml	
HalfLytely	____ ml	____ ml	
Saline enema	___ enemas	___ enemas	
Movi prep	___ . ___ ml	___ . ___ ml	
Tap water enema	___ enemas	___ enemas	
Visicol tablets	___ tablets	___ tablets	
Other (specify)			

Diet Restrictions for Procedure:

O Maintained prescribed diet

O Did not maintain prescribed diet

Type of Diet for Procedure:

O Clear Liquid O Low Fiber O Other (specify):_____

Hours since last ate solid food ___

Description of last stool before colonoscopy:

Consistency of last stool: O Liquid O Semi-solid O Solid

Color of last stool: O Clear O Yellow O Brown O Other (specify):_____

1148268033

APPENDIX C

SUBJECT EXPERIENCES WITH THE BOWEL CLEANSING PREPARATION

Subject Experiences with the Bowel Cleansing Preparation

Subject # 4 0 0 0 **Form #**

You were asked to follow a procedure to empty your colon. We would like to know if you experienced any discomfort.

Please fill in the circle that best shows how much discomfort you experienced. The further the circle is to the left the lower the amount of discomfort. The further the circle is to the right, the higher the amount of discomfort.

For example, if you did not have the discomfort at all, fill in the circle closest to the left like so:

No discomfort ● O O O O O O O O O O **Severe discomfort**

Otherwise, fill in the circle that best indicates the amount of discomfort you experienced.

No headache	O	O	O	O	O	O	O	O	O	O	O	Severe headache
No nausea	O	O	O	O	O	O	O	O	O	O	O	Severe nausea
No vomiting	O	O	O	O	O	O	O	O	O	O	O	Severe vomiting
No abdominal cramps/pain	O	O	O	O	O	O	O	O	O	O	O	Severe abdominal cramps/pain
No rectal itching	O	O	O	O	O	O	O	O	O	O	O	Severe rectal itching
No rectal burning	O	O	O	O	O	O	O	O	O	O	O	Severe rectal burning
No dizziness	O	O	O	O	O	O	O	O	O	O	O	Severe dizziness
No full feeling	O	O	O	O	O	O	O	O	O	O	O	Severe full feeling
No fatigue	O	O	O	O	O	O	O	O	O	O	O	Severe fatigue
My sleep was not interrupted	O	O	O	O	O	O	O	O	O	O	O	My sleep was severely interrupted
The bowel prep was very easy	O	O	O	O	O	O	O	O	O	O	O	The bowel prep was very difficult

Did you experience any additional discomforts? If so, please describe them on the back side of this sheet.

2995485372

APPENDIX D

COLON CLEANLINESS SCALE

Subject # 4 0 0 0

Colon Cleanliness Scale

Form # ☐☐☐☐

Section of colon	Amount of residual stool 0 = None 1 = small (requires suctioning with only a syringe of water to clear) 2 = moderate (requires much flushing with water to clear) 3 = large (bowel prep must be repeated)	Consistency of stool 0 = No stool 1 = clear liquid 2 = liquid stool 3 = particulate stool (mixture of liquid & stool particles) 4 = semi solid stool 5 = solid stool	Amount of bowel wall visible 0 = All 1 = about 3/4 2 = about 1/2 3 = about 1/4 4 = None
Rectum	☐	☐	☐
Sigmoid colon	☐	☐	☐
Left descending colon (includes splenic flexure)	☐	☐	☐
Transverse colon	☐	☐	☐
Right ascending colon (includes hepatic flexure)	☐	☐	☐
Cecum	☐	☐	☐

Time scope inserted in patient: ☐☐:☐☐ Time endoscopist reached cecum: ☐☐:☐☐

If unable to reach cecum, time endoscopist reached most proximal point ☐☐:☐☐

If unable to reach cecum, most proximal section reached:

O Rectum O Sigmoid colon O Left descending colon O Transverse colon O Right ascending colon

Unable to reach cecum due to: O Inadequate Cleanliness O Other (specify): _____

1554352678

APPENDIX E

TRAINING MODULE

A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations

University of Texas at Arlington (UTA) IRB Number: **08.004s**

HANDBOOK OF GUIDELINES AND STEPS FOR DATA COLLECTION FOR SITE COORDINATOR AND RESEARCH TEAM MEMBERS

Contact Information:

Glenda Daniels, MS, BSN, CGRN
PhD Candidate
University of Texas at Arlington
glendabd@usa.net

Marilee Schmelzer, PhD, R.N.
The University of Texas at Arlington
School of Nursing
411 S Nedderman Drive
UTA Box 19407
Arlington, Texas 76019-0407
Telephone: 817-272-2776
schmelze@uta.edu

TABLE OF CONTENTS

- Cover Sheet with Emergency Contact Information
- Table of Contents
- Emergency Contact Information
- Guidelines/Purpose of Study
- Procedure for Study
- Data Collection Steps following patient agreement to participate
- Examples of forms for use during data collection

    - Subject Checklist
    - Consent form
    - *Descriptive (Demographic) Data Form*
    - *Subject Experiences with the Bowel Cleansing Preparation Form*
    - *Colon Cleanliness Scale*

- Master Record (example of form which must be completed and returned to UTA at completion of the study by the site coordinator)

Note: All subject folders with *Descriptive (Demographic) Data Form, Subject Experiences with Colon Cleansing Preparations,* and *Colon Cleanliness Scale* will be shipped to sites via FedEX by UTA. Once completed, all subject folders will be returned to UTA via FedEX for analysis. UTA will cover cost of all shipping. Individual sites may be required to maintain the consent forms locally based on IRB's. If so, the consent must be maintained for the minimum of three years. The forms returned to UTA will be secured for three years following conclusion of the study.

Emergency Contact Information

Glenda Daniels, MS, BSN, CGRN
PhD Candidate
University of Texas at Arlington
glendabd@usa.net

Marilee Schmelzer, PhD, R.N.
The University of Texas at Arlington
School of Nursing
411 S Nedderman Drive
UTA Box 19407
Arlington, Texas 76019-0407
Telephone: 817-272-2776
schmelze@uta.edu

GUIDELINES

Thank you for your participation in this national, multi-site study comparing various colon cleansing preparations' effectiveness and side effects. Permission has been obtained from the University of Texas at Arlington Institutional Review Board (IRB) and permission from your site.

The purpose of the study is to:

- Describe bowel cleansing preparations used at various institutions
- Compare the bowel preparations' cleansing effectiveness
- Compare patient discomfort during bowel preparation

Research team members at your site have completed human subjects training in accordance with IRB guidelines and will be responsible for collection of data. It is important that all staff is aware of the study in order to assist in identifying potential subjects and referring to the research team. A site coordinator has been identified at your site and is responsible for the following:

1. Receive the shipped study materials and verify contents
2. Review study procedure with institution and research team members
3. Teach research team members to use the forms appropriately
4. Store completed subject folders in secure location
5. Store the signed consent forms in separate envelope in secure location
6. Complete the master record included in this instruction manual
7. All consent forms, subject folders, and master record will be returned to UTA in appropriate shipping boxes and envelopes supplied by UTA

The site coordinator should notify the institution of the study. When patients are scheduled by the institution for colonoscopy or arrive at the facility for colonoscopy, the patient should be referred to the research team member after they have signed consent for the colonoscopy or scheduled for colonoscopy. The research team member will discuss the study with the patient and if the patient agrees to participate, determine eligibility and sign consent forms. Two copies of the consent form must be initialed and signed by each individual participant. If the second copy of the consent must be maintained at your institution, this will satisfy the guidelines for UTA IRB and forwarding a copy of the consent to UTA will not be necessary as long as the consent form is secured a minimum of three years following the completion of data collection and according to site IRB guidelines.

Note: If the patient does not keep the appointment, the site coordinator should record this information on the Master Record. The subject folder should be secured until returned to UTA. If a patient must be rescheduled and consents again to the study, a new subject folder and number will be assigned.

PROCEDURE

When the patient is referred for the National Colon Cleansing Study, a research team member will meet with the patient to determine eligibility. The inclusion criteria are as follows:

1. 21 years of age
2. Scheduled for colonoscopy
3. Mentally alert in order to complete subject experience form
4. Understands and read English/Spanish

(Please note: patients with colon resection and/or colostomy/ileostomy will be excluded from this study.)

If the patient agrees to participate in the study, a research team member should obtain a subject folder which will include the following:

- Checklist
- Consent forms x 2
- Descriptive (Demographic) Data Forms which consist of Part I, Part II, and Part III)
- Subject Experiences Form which is one page
- Colon Cleanliness Scale which is one page

Research team member should address the following information and the following can be used as a script to address key parts of the study:

Hello, I am _____, one of the research team members. Our facility is participating in a study to compare the effectiveness and side effects, if any, of different colon cleansing preparations and would appreciate your participation since you are scheduled for a colonoscopy and have been given a colon cleansing preparation *OR (prescription for colon preparation) OR (have completed a colon cleansing preparation).* The study will be coordinated by team members at this site. Since the colon must be empty, you will be an excellent participant because your colon will be cleaned OR (has been cleaned) for your scheduled colonoscopy. If you agree to participate, you must sign a consent form. If you prefer not to participate, there will be no changes in your previously scheduled procedure. The study involves completion of three survey or questionnaire forms which will be completely confidential.

Since you are agreeing to participate, I will be asking you a few questions such as your age, height, weight, ethnicity, how often you have a bowel movement, why you are having the colonoscopy, and if you have any other medical problems. These questions will take about five minutes.

In addition, I will ask about the colon preparation order you received and what instructions you received.

When you return for your colonoscopy or just prior to your colonoscopy, you will need to complete a subject experience form which will let us know if you experienced any of the ten side effects listed. You may add information if it is not included on the form. Also, one of the research team members will ask you additional information about the preparation and how much of the preparation you ingested and how long it took. We also want to know when your last bowel movement occurred. This should take about 5-10 minutes to complete. All information will be confidential.

Finally, during your colonoscopy, the physician will see if there is any stool in your colon and describe the stool to the research nurse who will record his description on a form.

There is no risk from participation in this study since the study is only describing how well the bowel procedure works. Your confidentiality will be protected because no names will be on the forms but instead a unique identification number. If any of the study results or findings is published, no names will be used.

There is no benefit for participation in the study and the alternative is to not participate. You will receive the same care before, during, and after your colonoscopy whether or not you are in the study. You do not have to be in the study and you can change your mind at any time. You will not be paid for your participation in this study and you will not pay any additional money to be in the study. The colonoscopy is not part of the study. You will have the same charges for your colonoscopy whether or not you are in the study. All persons who participate in this study require informed consent.

A copy of the consent form will be given to you which details what we have discussed and identifies contact numbers if you have additional questions about the study or your rights as a participant.

If the patient agrees to participate, follow the data collection steps.

DATA COLLECTION STEPS FOR INCLUSION IN STUDY

1. If the patient agrees to participate in the study, remove the consent form(s) from the Subject Folder. Patient should read thoroughly then sign both copies.
2. Return one copy to the patient
3. Replace one copy in the left pocket of the subject folder
4. Remove the *Descriptive (Demographic) Data Form*
    a. Complete Part I (Part I includes questions about demographics such as gender, ethnicity, height, weight, age, illnesses, indication for procedure.
    b. Complete Part II (Part II contains questions about the bowel preparations were provided, how the bowel preparation was chosen, and the procedure for giving the instructions.
    c. Address any questions patient may have and confirm understanding
5. If patient is discharged, remind patient he/she will complete the *Subject Experience Form* when returning for colonoscopy
6. The research team member will obtain the subject folder when the patient arrives for colonoscopy OR if the patient signs consent and is enrolled in the study morning or day of colonoscopy, steps 1-6 will be followed then:
    a. Complete Part III of the demographic form (Part III will answer questions about the type and amount of bowel preparation used, whether the diet prescribed was followed, and a description about the last bowel movement).
    b. Have patient complete the *Subject Experience Form* (The patient will need to fill in the circle which is designed to measure the presence and intensity of types of discomfort: headache, nausea, vomiting, abdominal cramps or pain, rectal itching, rectal burning, dizziness, full feeling, fatigue; and ease of the preparation and sleep disturbances).
7. During colonoscopy, the research team member/data collector will record the following on the *Colon Cleanliness Scale*:
    a. Time endoscope inserted in the rectum
    b. Record ratings for each segment of the colon for the amount of residual stool (0, 1, 2, or 3), the consistency of stool (0, 1, 2, 3, 4, or 5), and the percentage of visible bowel wall (0, 1, 2, 3, or 4) in the rectum, sigmoid colon, left descending colon, transverse colon, right ascending colon, and cecum.
    c. Time cecum reached
    d. If the cecum is not reached, record most proximal section reached
8. The research team member will review the forms for completeness
9. The site coordinator will remove the consent form and place in a designated envelope and maintain in secure location
10. The subject folder will be maintained in secure location
11. The site coordinator or research team member will complete information on The Master Record

FORMS

- SUBJECT CONSENT FORM
- INDIVIDUAL SUBJECT CHECKLIST
- *DESCRIPTIVE (DEMOGRAPHIC) DATA FORM*
- *SUBJECT EXPERIENCES WITH BOWEL CLEANSING PREPARATIONS*
- *COLON CLEANLINESS SCALE*

INDIVIDUAL SUBJECT CHECKLIST/DATA COLLECTION STEPS

During Office Visit prior to the day of the Colonoscopy OR alternate enrollment during day of colonoscopy). Study explained and patient agrees to participate.

_____ Obtain Subject folder with assigned Unique Number

_____ Informed Consent Form Signed (two copies)

_____ Give one copy to patient

_____ Ask subject questions in Part I of *Descriptive (Demographic) Data Form*

_____ Complete Part II of *Descriptive (Demographic) Data Form*

_____ Place forms in Subject Folder and secure until day of colonoscopy or continue if day of colonoscopy

Prior to Colonoscopy

_____ Ask patient information to complete Part III of *Descriptive (Demographic)Data Form*

_____ Ask patient to complete *Subject Experiences with the Bowel Cleansing Preparations Form*

During Colonoscopy

_____ Gastroenterologist rates colon based on colon cleanliness scale

_____ Data Collector/Research Nurse completes *Colon Cleanliness Scale* during the Colonoscopy and records responses based on gastroenterologist verbal description

_____ Research nurse checks forms for completeness prior to patient discharge

_____ Consent form removed from folder and secured **(Consent form may be retained at site based on local IRB guidelines)**

_____ Place all completed forms in the folder and secure subject folder until transport to Principal Investigator

_____ Record unique number and subject name in Master Record (Copy will be mailed to UTA)

A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations
UTA IRB Number: **08.004s**

MASTER RECORD

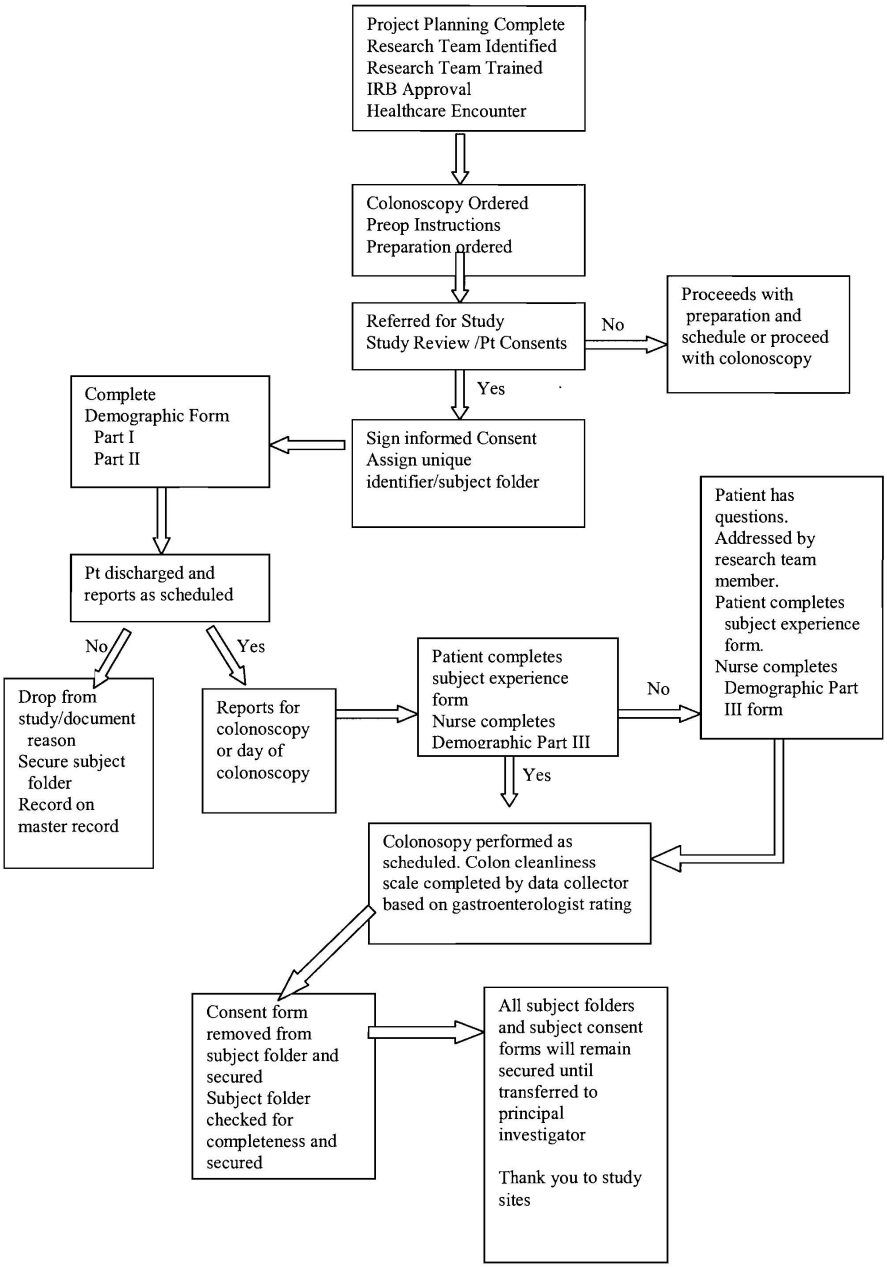
Note: the form number is the number to be recorded for subjects.
Example:

Form #(Subject Number)	Subject Name	Comments

APPENDIX F

DATA COLLECTION FLOW CHART

DATA COLLECTION FLOW SHEET



APPENDIX G

SUBJECT CHECKLIST

INDIVIDUAL SUBJECT CHECKLIST/DATA COLLECTION STEPS

During Office Visit prior to the day of the Colonoscopy OR alternate enrollment during day of colonoscopy). Study explained and patient agrees to participate.

_____ Obtain Subject folder with assigned Unique Number

_____ Informed Consent Form Signed (two copies)

_____ Give one copy to patient

_____ Ask subject questions in Part I of *Descriptive (Demographic) Data Form*

_____ Complete Part II of *Descriptive (Demographic) Data Form*

_____ Place forms in Subject Folder and secure until day of colonoscopy or continue if day of colonoscopy

Prior to Colonoscopy

_____ Ask patient information to complete Part III of *Descriptive (Demographic)Data Form*

_____ Ask patient to complete *Subject Experiences with the Bowel Cleansing Preparations Form*

During Colonoscopy

_____ Gastroenterologist rates colon based on colon cleanliness scale

_____ Data Collector/Research Nurse completes *Colon Cleanliness Scale* during the Colonoscopy and records responses based on gastroenterologist verbal description

_____ Research nurse checks forms for completeness prior to patient discharge

_____ Consent form removed from folder and secured **(Consent form may be retained at site based on local IRB guidelines)**

_____ Place all completed forms in the folder and secure subject folder until transport to Principal Investigator

_____ Record unique number and subject name in Master Record (Copy will be mailed to UTA)

APPENDIX H

MASTER LIST

A National Study to Compare the Tolerability and Effectiveness of Colon Cleansing Preparations
UTA IRB Number: **08.004s**

MASTER RECORD

Note: the form number is the number to be recorded for subjects.
Example:

Form #(Subject Number)	Subject Name	Comments

REFERENCES

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BIOGRAPHICAL INFORMATION

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