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What Patient Related Factors Negatively Impact Patient or
Procedure Outcomes in Screening Colonoscopy?

By

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A thesis submitted to the faculty of
Gardner-Webb University School of Nursing
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Abstract

The success of colonoscopy in early detection and treatment of colonic lesions depends upon adequate bowel preparation. This study addresses factors related to the adequacy of bowel preparation for colonoscopy with a focus on patient factors including variables related to demographics as well as compliance. The hypothesis of the study of factors related to the adequacy of bowel preparation for colonoscopy is that certain patient factors are associated with inadequate colon preparation independent from preparation type or timing of the procedure.

Patient related factors were compared to colonoscopy procedure completion, compliance with colonoscopy preparation instructions and quality of colon preparation. Quality of colon preparation was found to have a significant effect on procedure completion along with compliance of participants with preparation instruction and presence of side effects to the colonoscopy preparation. The only factor studied with a significant impact on compliance with colonoscopy preparation instructions was presence of preparation side effects. The only significant factors related to quality of colon preparation were presence of side effects and compliance with preparation instructions.

The greatest value from this study is that it leads to additional questions for further research. The lack of significance on outcomes of general patient demographics indicates that other factors may influence patient compliance with colon preparation for colonoscopy and procedure completion.

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Chapter 1

Introduction

Colorectal cancer is responsible for over 500,000 deaths annually world-wide (Lieberman, 2004). Death is usually preventable by the detection and removal of colorectal adenomas. Approximately 95% of colorectal cancers arise from these adenomas (Lieberman, 2004). At this time there are several methods to screen for colorectal cancer. These methods include fecal occult blood tests, sigmoidoscopy, barium enema and colonoscopy. In addition to these well established tests, healthcare providers also have available virtual colonoscopy and fecal DNA testing. While all of the tests have sufficient evidence to support the efficacy of their use, each varies in their sensitivity, specificity, cost and safety (Lieberman, 2004). Professional organizations such as the American Society for Gastrointestinal Endoscopy or the American College of Gastroenterology have published recommendation on which screening method to use based on the risk level of the patient. The problem healthcare providers face is to get the patient to the screening. It does not matter how accurate, cost effective or safe a screening procedure is to use if people at risk for colon cancer do not utilize the recommended screening.

Significance of the Study

Colonoscopy is considered the gold standard for evaluation of the colon in terms of its high diagnostic sensitivity and specificity (Selehi, Leung and Wong, 2006). The Joint Advisory Group on Gastrointestinal Endoscopy (2004) recommends complete colonoscopy (the cecum is reached and all colonic and rectal mucosa is examined) should occur in more than 90% of patients. However the success of colonoscopy in early

detection and treatment of colonic lesions depends upon adequate bowel preparation. Ness, Manam, Hoen and Chalasani (2001) noted that inadequate bowel preparation for colonoscopy can result in both missed pathological lesions and cancelled or repeated procedures. In 2008 there were 1,220,883 colonoscopies performed for Medicare patients alone (CMS, 2009). The potential cost in missed lesions, need for repeat procedures due to inadequate preparation and patient satisfaction is substantial (CMS, 2009). Medico-legal risks related to improper performance of colonoscopy in the case of missed colon cancers is another important aspect of adequate bowel preparation (Parente, Marino and Crosta, 2009). Other researchers have previously compared the efficacy of various bowel preparations. However, research investigating reasons for patient non-compliance with bowel preparation instructions and exploring ways to improve patient compliance are lacking. Most patients who refuse colonoscopy screening identify bowel preparation as the most objectionable aspect of the procedure (Parente et al., 2009).

Purpose of the Study

The purpose of this study is to help identify factors leading to inadequate bowel preparation for colonoscopy. This information would be beneficial in determining ways to improve the early detection of colorectal cancer by improving the performance of screening colonoscopy and by increasing participation of patients in a colorectal cancer screening program.

This study addresses factors related to the adequacy of bowel preparation for colonoscopy with a focus on patient factors including variables related to demographics as well as compliance. My hypothesis is that certain patient factors are associated with

inadequate colon preparation independent from preparation type or timing of the procedure.

Research Question

The research question “*What patient related factors negatively impact patient or procedure outcomes in screening colonoscopy?*” is addressed in the study.

Definition of Terms

The research question contains terms that will be defined for clarity of the study. Terms included in the proposed research question are patient related factors, procedure outcomes, and screening colonoscopy.

The term *patient related factors* refer to physical, behavioral and demographic attributes of the patient. Examples include physical factors such as nausea, vomiting, behavioral factors such as compliance with instructions; and demographic factors such as age, race, sex, educational level, etc.

The term *procedure outcomes* refer to the adequacy of bowel preparation for the procedure indicated as a value on a scale and whether the procedure is completed (the cecum is reached and all colonic and rectal mucosa is examined).

Hypothesis

My hypothesis is that certain patient factors are associated with inadequate colon preparation independent from preparation type or timing of the procedure.

Conceptual Framework

The conceptual framework for this study is Nola Pender’s Health Promotion Model (HPM). The HPM represents a theoretical perspective that “explores the factors and relationships contributing to health-promoting behavior” and by extension to

improving health and quality of life (Srof and Velsor-Friedrich, 2006). Pender's original model emphasized seven cognitive-perceptual factors that directly affect the likelihood of engaging in health-promoting behaviors and five modifying factors that indirectly influence behaviors (Wood, 2008). The HPM classifies health behavior into three specific groupings: "individual characteristics (prior related behavior and personal factors), behavior-specific cognitions (perceived affect, interpersonal influences and situational influences), and behavioral outcomes (commitment to a plan of action, immediate competing demands and preferences and health-promoting behavior)" (McEwen and Wills, 2007).

The individual characteristics are innate factors (gender, age, and genetics) and experience factors that affect future behavior (Srof and Velsor-Friedrich, 2006). These background factors are essentially fixed and cannot be modified. The behavior-specific cognitions and affect category includes "perceived benefits and barriers to behaviors, perceived self-efficacy, and affect cues to behavior" (Srof and Velsor-Friedrich, 2006). This group is the largest and the target of most research utilizing the HPM framework. Social and environmental factors make up the situational and interpersonal influences (Srof and Velsor-Friedrich, 2006).

Individuals participate in health-promoting behaviors when motivated by a desire to increase well-being (Wood, 2008). I will use Pender's HPM as a framework to identify factors which influence either positively or negatively specific health-promoting behaviors (participation in colon cancer screening).

Chapter II

Literature Review

A literature search with criteria for these variables was performed through an EBSCOhost of the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and United States National Library of Medicine (MEDLINE) databases to provide studies for review. The proposed research is aimed at exploring the impact of patient related factors on patient compliance and procedure outcomes in screening colonoscopy. Numerous studies were identified which compare different colonoscopy preparations and various factors affecting colonoscopy outcomes. Nine studies were selected for review which included variables related to patient tolerance or acceptability. All studies selected involved adult patients only. Seven of the studies are similar in that the focus was to evaluate efficacy and adverse effects among various colon cleansing preparations. Three of the studies are more directly related to patient factors affecting successful colonoscopy.

Di Palma, Rodriguez, McGowan and Cleveland (2009) conducted a study to evaluate a new, low-volume bowel preparation for colonoscopy in adults. The study was a single-blind, active control involving two parallel studies of 1,772 outpatients undergoing elective colonoscopy. The survey instruments included a 4-point colon cleansing scale and a patient tolerance questionnaire. The study noted that “split-dosing” of either preparation resulted in increased efficacy and fewer reported adverse events.

An earlier study by Di Palma, Wolff, Meagher and Cleveland (2003) compared reduced volume versus four liters volume lavage solutions for colonoscopy colon cleansing in 200 outpatients. This study was randomized and single-blinded. The survey

instruments were a 4-point colon cleansing scale and patient treatment questionnaire previously mentioned. The study found no difference in colon cleansing but found that the reduced volume preparation resulted in fewer side effects. Of note, the questionnaires were completed by the patient and no data was reported related to patient compliance with the colonoscopy preparation instructions.

Ell et al., (2003) conducted a study comparing three different types of bowel cleansing solutions for colonoscopy. The study was a prospective, randomized, single-blind study involving 185 outpatients undergoing elective colonoscopy. The survey instruments included a 5-point cleansing scale and a patient symptom questionnaire. For this study the preparation types and patient instructions were clearly outlined in the report. In addition, the timing of the procedures was also controlled to reduce the impact of external variables on results. The researchers found that the preparation with the fewest adverse effects was not the preparation with the greatest efficacy in colon cleansing. There was no data reported related to patient compliance with preparation instructions.

A second study by Ell, et al., (2008) compared the use of a low-volume versus standard polyethylene glycol (PEG)-based solution for bowel cleansing. This study involved 359 hospital inpatients and was randomized and single-blinded. A 5-point cleansing scale mentioned previously was utilized to determine efficacy of bowel cleansing and a patient adherence and acceptability questionnaire was employed. Nursing staff assisted in data collection related to patient adherence and acceptability. Increased interater reliability in assessing colon cleansing was obtained by using an independent expert panel that reviewed videotapes of procedures. Successful bowel cleansing was

obtained with both solutions but patient adherence and acceptability was higher with the low-volume preparation.

Law, Choi, Chu, Ho, and Wong (2004) completed a comparison study of three different colonoscopy preparation regimens. The study was a randomized, single blind trial. A total of 299 outpatients for elective colonoscopy were included in the study. This study focused on quality of bowel preparation, side effects and patient acceptance. The survey instrument included a 4-point rating scale for cleansing and patient interviews by nursing staff. The researchers reported that increased patient tolerance of the low-volume, two dose regimen along with good bowel preps indicated that this should be the standard regimen for bowel preps (Law et al., 2004). Specific data related to patient compliance with either regimen was not reported. An unexpected finding indicated that patients who underwent colonoscopy in the afternoon had better bowel preparation. This was attributed to the split dosing regimen with the final dose of solution early in the morning prior to the procedure.

A study by Ness, Manam, Hoen, and Chalasani (2001) focused on potential associations between specific patient characteristics and inadequate colonic preparation. A convenience sample was obtained from 649 of 714 consecutive patients who presented for colonoscopy. Data was collected by nursing personnel during routine pre-procedure evaluations and staff endoscopist reports on bowel preparation adequacy (Ness et al., 2001). Data collected during nursing evaluations included: age, sex, race, height, weight, hospital setting, patient status, preparation type, compliance instructions, and medical history data. Staff endoscopists utilized a 4-point scale to report bowel preparation quality after the procedure. An inadequate colonic preparation was reported in 21.7% of

observed colonoscopies with only 18% reporting a failure to follow preparation instructions (Ness et al., 2001). Two patient characteristics were significantly associated with colonic preparation quality independent of preparation type; 1) compliance with instructions, and 2) procedure starting time. However, the majority of inadequate colon preparation events could not be explained by reported patient failure to adequately follow preparation instructions (Ness et al., 2001). The study was limited by dependence on data gathered by nursing and endoscopy staff at the time of procedure. Patient recall and availability of medical records may have biased certain data. The study concluded that certain patient-specific variables may help to identify patients at an increased risk for inadequate colonic preparation (Ness et al., 2001).

Paulo et al., (2008) completed a study comparing colon cleansing preparations. The study consisted of a randomized, single blind comparison involving 60 ambulatory patients focusing on cleansing quality, side effects, tolerance and cost. A 5-point rating scale was used for evaluating colon cleansing and patient questionnaires related to tolerability were the survey instruments. The colon cleansing scale had been used in two previous studies. The findings noted that all patients were able to tolerate and complete the preparations. Two of the solutions were noted to have higher quality bowel preparations with no decline in patient safety.

Rapier and Houston (2006) compared the efficacy of three bowel preparation regimens incorporating a diet kit with the usual preparation solutions. The study was a prospective, randomized, and single blind trial that focused on efficacy and patient tolerance. The survey instruments were a 5-point rating scale for cleansing and a patient tolerability questionnaire. The colon cleansing scale utilized in this study was well

defined and previously utilized in another study. The study findings noted that the use of a better tasting, lower volume preparation in combination with a low-residue diet kit is safe and effective (Rapier and Huston, 2006). A noted vulnerability in this study is that patients' compliance with preparation implementation was not included in the data.

Selehi, Leung and Wong (2007) conducted a study to evaluate factors that influence successful outcomes in colonoscopy. The study consisted of a convenience sample including all procedures completed in a three month period (n = 229). A 3-point rating scale was used to evaluate bowel preparation and the procedure was rated as complete or incomplete. Factors influencing successful colonoscopy were identified as bowel preparation, sedation type and endoscopist experience levels. The study was retrospective and limited to a single unit. These researchers suggested that additional studies evaluating sedation protocols, patient education regarding importance of bowel cleansing and a more tolerable bowel preparation regimen would be warranted (Selehi et al., 2007).

Summary

Several of these studies focused mainly on the efficacy and safety of the various colonoscopy bowel preparations. While all included variables related to patient tolerance, side effects and adverse effects or acceptance, preferences such as taste, or ease of use, few of the studies examined patient compliance with bowel preparation instructions and reasons for non-compliance.

Inadequate bowel preparation prior to colonoscopy is a significant problem. The potential costs both economic and in terms of patient discomfort are substantial (Ness et al., 2001). Further study to determine what factors are associated with poor colon

preparation and incomplete procedures may lead to interventions which can improve the diagnostic sensitivity of and patient compliance with screening colonoscopy. Progress in this area can help to reduce the incidence of and the mortality related to colorectal cancers.

Chapter III

Methodology

Research Design

The research is a secondary analysis. It has a descriptive correlational design because there is no treatment or intervention. Data was obtained from a single group and correlational statistical analyses will be used to examine relationships between variables (Burns and Grove, 2009). The descriptive correlational design focuses specifically on relationships among study variables which may lead to hypotheses for later studies (Burns and Grove, 2009).

Sample and Selection Procedures

The inclusion criterion for the sample is clients undergoing elective screening colonoscopy. Quota sampling was planned to ensure adequate representation from the study population based on demographic factors such as age, race, sex, educational level (Burns and Grove, 2009), but due to study constraints was not employed. Clients that had previously diagnosed gastrointestinal disease process or previous screening colonoscopy were excluded from the study. There were no exclusions related to colon preparation type. Study participants are clients selected from both hospital-based and free-standing outpatient endoscopy centers.

Ethical Considerations

Before beginning any research study, the researcher must review any ethical considerations relevant to the type of study proposed. This particular quantitative study presents no apparent risk of harm to the study participants. Of primary concern in this study are the participants' right to privacy. The Health Information Portability and

Accountability Act (HIPAA) Privacy rule, enacted in 1996 and implemented in 2003, was designed to protect against disclosure of individually identifiable health information (IIHI). Researchers must either de-identify the IIHI, obtain informed consent to use the IIHI or receive a waiver from an Institutional Review Board (IRB) (Burns and Grove, 2009). For this study all information was de-identified following data entry by obliteration of the medical record number on the original data gathering tool. A waiver of written consent was granted from the Wake Forest University and the Gardner Webb University Institutional Review Boards.

The right to autonomy and confidentiality has its basis in the right to privacy. Essentially each study participant has the right to assume that any data collected will be kept confidential. Using de-identified subject data provides confidentiality but does not allow the researcher to contact the subject or access the subject's medical data if additional information is needed. Breaches of confidentiality can occur when unauthorized persons gain access to raw study data. These breaches can be by accident or direct action. Researchers have the responsibility to protect anonymity and to maintain confidentiality (Burns and Grove, 2009). Anonymity was maintained by obliterating the identifying information on the raw data.

Finally when considering ethics in conducting research, we must include the potential for research misconduct. The goal of research is to further knowledge and this is only accomplished when research is conducted with honesty in performing studies, reporting data and publishing results (Burns and Grove, 2009).

Measurement Methods

Data was obtained via concurrent review of medical records by this researcher including endoscopist report of bowel preparation quality and completeness of procedure. A data gathering tool was utilized for data gathering and information was entered into a database following de-identification. The endoscopist rated colon preparation on a four-point cleansing scale previously validated in other studies to evaluate bowel preparation (Rapier and Houston, 2006). Procedure success will be indicated by rating as complete, partially complete, or procedure cancelled. Operational definitions of study variables and rating scales are outlined on the data gathering tool found in Appendix A.

Data Collection and Analysis Plan

Research staff retrieved basic demographic data (medical record number, patient age, educational level and procedure date) and colonoscopy prep information on the data collection tool as well as the endoscopist reported ratings for colon cleansing and procedure completion as well as any additional information from the medical record and enters it onto the data collection tool for database entry. See Appendix A for the data gathering tool.

The collected data was analyzed in a SPSS program which identified trends and relationships among the variables. Relationships identified will be interpreted and reported in the results portion of the study documentation.

Limitations

The proposed study limitations are related to its dependence on data which is recorded by nursing and endoscopy staff at the time of the procedure. In addition,

availability and completeness of medical records may lead to biases. The generalizability of the study may be limited by the clinical setting.

Chapter IV

Results

Data was obtained on 150 patients undergoing screening colonoscopy. There were 106 participants from two sites included in the study with the remaining forty-four excluded due to incomplete data. Of the 106 participants, 70.8% received care at a free-standing endoscopy center (n = 75) and the remainder (n = 31) received care from a hospital-based outpatient endoscopy center. The majority of the participant's (74.5%) were white, non Hispanic (n = 79), with 20.8% (n = 22) being African-American. There were slightly more female participants (55.7%, n = 59) than males (44.3%, n = 47). Participant ranged in age from 27 to 72 years with a mean age of 51.97 years. The language spoken was predominately English (97.2%, n = 103) with only 0.9% (n = 1) speaking Spanish and 1.9% (n = 2) whose primary language was classified as other. The participant's educational level was primarily high school graduate (37.7%, n = 41), and college graduate (40.6%, n = 43) with some participants having some college (17%, n = 18). A summary of the data on the patient related factors can be found in Table 1.

Table 1
Summary of Data: Patient Related Factors

Factor	n	%
Location of Care		
Freestanding Center	75	70.8
Hospital Based	31	29.2
Race		
African American	22	20.8
Asian	3	2.8
Hispanic	1	0.9
Other	1	0.9
White	79	74.5
Gender		
Female	59	55.7
Male	47	44.3
Age		
18 - 35	8	7.5
36 – 50	36	34.0
51 – 65	54	50.9
66+	8	7.5
Language		
English	103	97.2
Other	2	1.9
Spanish	1	0.9
Educational Level		
Grade School Only	1	0.9
Some High School	3	2.8
High School Graduate	41	38.7
Some College	18	17
College Graduate	43	40.6

Data was gathered related to certain factors associated with the colonoscopy procedure. The colon preparation types were noted with the majority of participants utilizing Golytely/Colytely with Ducolax (84.9%, n = 90). Golytely/Colytely Split Dosing was utilized by 12.3% (n = 13) and Gatorade/Miralax was utilized by 2.8% (n = 3). Side effects from the colon preparation was noted by 20.8% (n = 22) of participants. The major side effect reported was nausea (9.4%, n = 10), followed by bloating (5.7%, n = 6) Less reported side effects included pain (2.8%, n = 3) and taste (2.8%, n = 3). No side effects were reported by 79.2% (n = 84) of participants. A summary of the data on the procedural related factors can be found in Table 2.

Table 2
Summary of Data: Procedural Factors

Factor	n	%
Colonoscopy Prep Type	90	84.9
Golytely/Colytely with Ducolax –	13	12.3
Golytely/Colytely Split Dosing –	3	2.8
Gatorade/Miralax –		
Presence of Side Effects from Prep		
Yes –	22	20.8
Nausea –	10	9.4
Vomiting –	1	0.9
Bloating –	6	5.7
Pain –	3	2.8
Taste –	3	2.8
No –	84	79.2

Data was also recorded on specific outcome related factors including participant compliance with colon preparation instructions, quality of colon preparation and procedure completion. Participant compliance with colon preparation was self-reported as full compliance (84.9%, n = 90), partial compliance (11.3%, n = 12) and minimal or no compliance (3.8%, n = 4). The quality of colon preparation was rated by the endoscopist on a four-point scale: excellent (22.6%, n = 24), good (67%, n = 71), adequate (4.7%, n = 5) and poor (5.7%, n = 6). The endoscopist reported completed procedures on 89.6% (n = 95) with 10.4% (n = 11) incomplete. A summary of the data related to outcome factors is located in Table 3.

Table 3
Summary of Data: Outcome Related Factors

Factor	n	%
Compliance with Prep Instructions		
Full Compliance –	90	84.9
Partial Compliance –	12	11.3
Minimal or No Compliance –	4	3.8
Quality of Prep		
Excellent –	24	22.6
Good –	71	67.0
Adequate –	5	4.7
Poor –	6	5.7
Procedure Completed		
Yes –	95	89.6
No –	11	10.4

Data was grouped to discover the relationships between specific patient related factors and different outcome indicators. The patient related factors included location of care, gender, race, age, language spoken, educational level, colonoscopy preparation type and presence of side effects from the colonoscopy preparation. The outcome indicators included compliance with colonoscopy preparation instructions, quality of colon preparation for colonoscopy and colonoscopy procedure completion. Colonoscopy preparation instruction compliance is included as a factor affecting quality of colon preparation and procedure completion. Quality of colon preparation is also included as a factor affecting colonoscopy completion. Data was analyzed using descriptive statistics and the Chi-Square test for two or more categorical variables. Where appropriate, Spearman's Correlation test was also conducted.

Factors Affecting Colonoscopy Procedure Completion

Patient related factors were compared to colonoscopy procedure completion. Quality of colon preparation was found to have a significant effect on procedure completion ($p < .001$, $R = .382$). Compliance of participants with preparation instruction

($p < .001$, $R = .394$) and presence of side effects to the colonoscopy preparation ($p = .004$, $R = .284$) were also significant. The data is summarized in Table 4.

Table 4
Factors Affecting Colonoscopy Procedure Completion

Factor	% Completed Procedures	Chi-Square ($\alpha = .05$)	Spearman's Correlation
Location of Care		p = .584	R = .53
Freestanding	90.7		
Hospital Based	87.1		
Gender		p = .574	
Female	88.1%		
Male	91.5%		
Race		p = .696	
African American	81.8%		
Asian	100%		
Hispanic	100%		
Other	100%		
White	91.1%		
Age		p = .714	R = .80
18 - 35	87.5%		
36 - 50	94.4%		
51 - 65	87.0%		
66+	87.5%		
Language		p = .836	
English	89.3%		
Other	100%		
Spanish	100%		
Educational Level		p = .643	R = -.105
Grade School Only	100%		
Some High School	66.7%		
High School Graduate	87.8%		
Some College	88.9%		
College Graduate	93%		
Colonoscopy Prep Type		p = .779	R = -.059
Golytely/Colytely with Docolax	88.9%		
Golytely/Colytely Split Dosing	92.3%		
Gatorade/Miralax	100%		
Prep Quality		p < .001	R = .382**
Excellent	23.2%		
Good	73.7%		
Adequate	3.2%		
Poor	0.0%		
Prep Side Effects		p = .004	R = .284**
Yes	72.7%		
No	94.0%		
Compliance with Prep Instructions		p < .001	R = .394**
Full Compliance	94.4%		
Partial Compliance	75.0%		
Minimal or No Compliance	25.0%		

** Correlation is significant at the 0.01 level (2-tailed).

Factors Affecting Colonoscopy Preparation Compliance

Patient related factors were also compared to compliance with colonoscopy preparation instructions. Full compliance with instructions was reported by 84.9% (n = 90) and 15.1% (n = 16) reported partial or no compliance with preparation instructions. The only factor studied with a significant impact on compliance with colonoscopy preparation instructions was presence of preparation side effects ($p < .001$, $R = .510$). Side effects included nausea (9%), vomiting (0.9%), bloating (5.7%), pain (2.8%) and taste (2.8%). Bloating ($p = 0.40$), pain ($p = .022$) and taste ($p < .001$) were found to have the most significant effects on compliance. Data related to colonoscopy preparation compliance is summarized in Table 5.

Table 5
Factors Affecting Colonoscopy Prep Compliance

Factor	% Compliance w/ Prep	Chi-Square ($\alpha = .05$)	Spearman's Correlation
Location of Care		p = .063	R = .201
Freestanding	67%		
Hospital Based	23%		
Gender		p = .240	
Female	88.1%		
Male	91.5%		
Race		p = .828	
African American	16%		
Asian	3%		
Hispanic	1%		
Other	1%		
White	69%		
Age		p = .494	R = -.199
18 - 35	7.5%		
36 - 50	34%		
51 - 65	50.9%		
66+	7.5%		
Language		p = .969	
English	87%		
Other	2%		
Spanish	1%		
Educational Level		p = .413	R = -.033
Grade School Only	1%		
Some High School	2%		
High School Graduate	35.8%		
Some College	15%		
College Graduate	37%		
Colonoscopy Prep Type		p = .690	R = .050
Golytely/Colytely with Ducolax	77%		
Golytely/Colytely Split Dosing	11%		
Gatorade/Miralax	2%		
Prep Side Effects		p < .001	R = .510**
Yes	11%		
No	79%		

** Correlation is significant at the 0.01 level (2-tailed).

Factors Affecting Quality of Colon Preparation

Finally, patient related factors were compared to quality of colon preparation.

The quality of colon preparation was rated on a 4-point scale by the endoscopist with a rating of excellent or good considered adequate for colonoscopy completion. An

excellent rating ($n = 24$) was noted for 22.6%, good ($n = 71$) for 67%, adequate ($n = 5$) for 4.7 % and poor ($n = 6$) for 5.7%. Significant factors related to quality of colon preparation included the presence of side effects ($p = .018$, $R = .230$) and compliance with preparation instructions ($p < .001$, $R = .325$). Participant age, while considered a significant factor ($p = .003$), no significant correlation with bowel preparation quality was demonstrated ($R = -.001$). Other demographic factors did not have a significant impact on the quality of colon preparation. Table 6 contains the summary of this data.

Table 6
Factors Affecting Colonoscopy Prep Quality

Factor	% Prep Quality Excellent or Good	Chi-Square ($\alpha = .05$)	Spearman's Correlation
Location of Care		p = .602	R = -.008
Freestanding	90.6%		
Hospital Based	87.1%		
Gender		p = .907	
Female	53%		
Male	42%		
Race		p = .607	
African American	86.4%		
Asian	100%		
Hispanic	100%		
Other	100%		
White	89.9%		
Age		p = .003	R = -.001
18 - 35	62.5%		
36 - 50	91.7%		
51 - 65	49%		
66+	100%		
Language		p = .962	
English	86.8%		
Other	1.9%		
Spanish	0.9%		
Educational Level		p = .675	R = .049
Grade School Only	0.9%		
Some High School	1.8%		
High School Graduate	34.9%		
Some College	15.1%		
College Graduate	36.7%		
Colonoscopy Prep Type		p = .339	R = .052
Golytely/Colytely with Ducolax	76.4%		
Golytely/Colytely Split Dosing	11.3%		
Gatorade/Miralax	1.9%		
Prep Side Effects		p = .018	R = .230*
Yes	15.1%		
No	74.5%		
Compliance with Prep Instructions		p < .001	R = 0.325**
Full Compliance	95%		
Partial Compliance	66.7%		
Minimal or No Compliance	25%		

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

Chapter V

Discussion

This study demonstrated a significant correlation between compliance with colonoscopy preparation instructions and the quality of bowel preparation for the colonoscopy procedure. In addition, a correlation was found between the incidence of bowel preparation side effects and compliance with preparation instructions. With these findings, a question arises on whether treating the side effects, e.g. Reglan for nausea and bloating, would increase compliance with bowel preparation instructions. In addition, the failure to follow instruction may be related to the instructions themselves. The study did not address whether participants clearly understood the instructions or whether participants received verbal reinforcement of the instructions and had an opportunity to ask questions of their caregiver.

Study Limitations

This study was limited by its small scope. The small number of participants prevented obtaining quota sampling to ensure the study population resembled the general population in the area as closely as possible with regard to race, language, and educational level. In addition the population studied was obtained primarily from a single site which further limits its scope.

Conclusion

The greatest value from this study is that it leads to additional questions for further research. The lack of significance on outcomes of general patient demographics indicates that other factors may influence patient compliance with colon preparation for colonoscopy and procedure completion. A study examining pre-procedure education or

other nursing interventions would be useful in determining causes of non-compliance with colon preparation instructions. Additional studies may be useful to discover reasons patients fail to schedule or follow-through with recommended colonoscopy for colon cancer screening and prevention.

Appendix A

Gardner-Webb University IRB Approval

Appendix B

Office of Research
INSTITUTIONAL REVIEW BOARD

**MEMORANDUM**

To: Rebecca Truett
WFUP Clinical Operations

From: Vice Chair, Institutional Review Board

Date 9/16/2011

Approved:

Subject: Expedited Review: IRB00018353
What patient related factors negatively impact patient and procedure outcomes in screening colonoscopy?

Study Documents:
Protocol Version: General Protocol - Factors Affecting Colonoscopy 08.22.11; Other Documents: Data Gathering Tool, Gardner-Webb University IRB Application - R. Truett

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)].

This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d).

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 5.

IRB approval is for a period of 12 months from 9/15/2011. Please notify the Office of Research when the project is complete.

Sally A. Bulla, PhD, RN

Sally Bulla

Appendix C

Thesis Project – R. Truett
Data Gathering Tool

Colonoscopy Prep Study

DATE: _____ MRN: _____ AGE: _____

Previous Colonoscopy or previously diagnosed gastrointestinal disease process:

- YES – exclude from study
- NO

Race:

- White, Non-Hispanic
- Hispanic
- African American
- Asian
- Native American
- All others

Primary Language:

- English
- Spanish
- Other

Procedure Location:

- Freestanding center
- Hospital-based center

Educational Level (patient reported)

- Grade School only
- Some High School
- High School Graduate
- Some College
- College Graduate

BEHAVIORAL FACTORS: (Check all that apply)

Colon Prep Utilized:

- Golytely/Colytely w/Duocolax**
- Golytely/Colytely w/Duocolax Split Dose**
- Miralax/Gatorade Prep**
- Moviprep**

Patient reported Colon Preparation Compliance

- Full compliance** – All instructions followed and at least 75% of prep dose taken.
- Partial compliance** – All instructions followed and at least 50% of prep dose taken.
- No compliance** – Dietary or dosing instructions not followed or <50% of prep dose taken.

PHYSICAL FACTORS

Select all reported by patient.

- Nausea** – related to bowel preparation not present prior to beginning of prep.
- Vomiting** - related to bowel preparation not present prior to beginning of prep.
- Bloating** - related to bowel preparation not present prior to beginning of prep.
- Abdominal Pain** - related to bowel preparation not present prior to beginning of prep.
- Taste** – Unable to tolerate prep solution due to taste.

COLON PREPARATION QUALITY (Select one (1) as reported by endoscopist)

- Excellent** – No fecal residue present.
- Good** - minimal fecal residue present no interfering with interpretation of colonoscopy.
- Adequate** - moderate fecal residue present easily removed by suction
- Poor** - solid or semisolid stool beyond the cecum and ascending colon that could not be suctioned or washed away
- Very Poor** - substantial fecal residue requiring a repeat examination

COLONOSCOPY COMPLETION (Select one (1) as reported by endoscopist)

- Complete** - The cecum is reached and all colonic and rectal mucosa is examined.
- Partially Complete** - Unable to reach the cecum and/or all colonic and rectal mucosa cannot be examined
- Procedure Cancelled** - Procedure is cancelled either prior to start or after start but without sufficient examination of any part of the colon.

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