

Determining Best Practice for Colonoscopy Preparation for Persons with Constipation

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Abstract

According to the American Cancer Society, colorectal cancer is estimated to affect 145,000 people and is expected to cause over 51,000 deaths in the year 2019. The way to prevent colorectal cancer is by early detection through colonoscopy starting at age 50 or, age 40 if there is a strong family history. To cleanse the bowel for this procedure, patients drink a preparation (prep) fluid that induces bowel evacuation. If the preparation is poor, polyps, abnormal tissue, or masses can be missed warranting a repeat procedure. The purpose of this project was focused on determining the best practice for bowel prep for patients with a history of constipation. The project utilized retrospective chart review and assessed the frequency of poor prep diagnoses in persons with a history of constipation and association with the type of prep prescribed for colonoscopy at two Gastrointestinal (GI) clinic locations associated with a Midwest medical center. The overall rate of poor bowel prep was 34% but there was no statistical difference between each clinic's bowel prep practice in the rates of poor prep among this population. This project also determined that the current rate of repeat colonoscopy completion due to poor bowel prep was 62.5%, 25% of patients at Clinic 1 and 37.5% of patients at Clinic 2. Clinician-perceived barriers to bowel prep standardization included barriers such as: cost to the patient, poor understanding of instructions, and fluid restrictions for comorbidities. The findings from this project determined that there is no need for bowel prep standardization across clinic sites based on prep, as best practice was not determined based on this project, however, prep should be based on patient preference, cost, price, and ability to understand instructions.

Keywords: colonoscopy prep, poor colonoscopy prep, constipation and colonoscopy prep

Table of Contents

Determining Best Practice for Colonoscopy Bowel Preparation in Persons with Constipation	4
Problem	4
Definition.....	5
Poor Bowel Prep.....	5
Literature Review.....	6
Methods	6
Recommended Pre-Procedure Bowel Preparation	6
Cost.....	7
Risks of Poor Prep.....	8
Social Determinants of Health Affecting Colonoscopy	8
Constipation and Prep Quality	9
Project Aims	9
Organizational Framework.....	10
Methods	11
Project design	11
Human Subject Protection	11
Project Setting.....	12
Sample	13
Data Collection Plan.....	13

Instruments.....	14
Results.....	14
Discussion.....	17
Conclusion.....	19
References.....	20

Determining Best Practice for Colonoscopy Bowel Preparation in Persons with Constipation

Colorectal cancer is the third most commonly diagnosed cancer in the US (Miller, Itzkowitz, Shah, & Jandorf, 2016). The United States Preventative Services Task Force (USPSTF) recommends screening for colorectal cancer beginning at age 50, or age 40 for a first degree relative with colon cancer (2015). A screening colonoscopy is used to identify abnormal growths and polyps, including adenomas which can develop into cancer (Association of Directors of Anatomic and Surgical Pathology, 2018). About one-third to one-half of all individuals will eventually develop one or more cancerous polyps (adenomas). Early diagnosis of colon cancer before it has spread has a 5-year relative survival rate of 90% (American Cancer Society, 2018). Screening can also be done with stool-based studies, these studies have an 87% specificity while a colonoscopy is considered the gold standard with a specificity rate of 91% (Issa & Nouredine, 2017). Individuals with a positive stool-based study are referred for a colonoscopy (Cohen, Kastenburg, Mount, & Safdi, 2009, as cited in Kunz & Gillespie, 2017).

The accuracy of the colonoscopy is largely dependent on the preparation (prep) of the colon so lesions can be identified. An incomplete or poor prep leads to missed polyps along with the need for repeat colonoscopy requiring a new prep (Lebwohl & Neugut, 2014). For a poor or incomplete prep, the Center for Disease and Control and Prevention's Colorectal Cancer Screening Optimizing Quality report recommends repeat screening in 2-6 months (CDC, 2019). Research shows the return rate at 18 months due to poor prep is 24.6% (Smith, et al., 2013) and the rate for patients to return within three years is under 60% (Menees, et al., 2013).

Problem

Nationally, inadequate bowel prep is found in about 20% of colonoscopies with the highest rates amid persons with lower socioeconomic status (Lebwohl & Neugut, 2014).

Incomplete or poor preps are not only more common in patients in lower socioeconomic groups but also in patients with constipation (Cheng, et al., 2017; Corliss, 2017; Lee, et al. 2015; Mahmood, Farrooqui, & Madhoun, 2018; Lebwohl & Neugut, 2014). In regard to repeat colonoscopy, one study suggests that patients often do not return for the repeat procedure, resulting in missed lesions and increased complications (Miller et al., 2016).

This project took place in a Midwest urban medical center serving a lower socioeconomic patient population. There was a perception that persons with constipation had poorer quality bowel preps and would have a better-quality result when using a prep that contains more fluid. When patients received a diagnosis of “poor prep,” they were ordered to repeat the test within a matter of weeks or months. Not only does this result in an additional procedure with the risk of anesthesia, but, an additional night of bowel prep, an additional day off work for the procedure, and an additional prep which may not be covered by some insurance companies. Repeating the procedure due to a poor prep had significant financial implications for this patient population. The purpose of this quality improvement project was to determine the best practice in bowel prep prior to colonoscopy for patients with a history of constipation.

Definition

Poor Bowel Prep

The definition of poor prep was based on the grading scale used to determine the prep quality. The Aronchick scale grades prepping quality according to the amount of gastrointestinal lumen visible to the physician. The prep quality is rated as excellent, good, fair, or poor. An excellent prepping quality is one in which there is a small volume of clear liquid or more than 95% of the colonic lumen is seen. A good prepping quality is one in which there is a large volume of clear liquid that covers 5%-25% of the surface, but more than 90% of the colonic

lumen is seen. A fair prep includes semisolid stool that could be suctioned or washed away but more than 90% of the lumen can be seen. And finally, a poor prep includes semisolid stool that could not be suctioned or washed away and that less than 90% of the colonic lumen was seen (Aronchick et al., 2000, as cited in Kunz & Gillespie, 2017). The operational definition of poor prep is defined as the physicians rating according to the Aronchick scale of grading. The operational definition was used in this project.

Literature Review

Methods

A review of literature was performed using CINAHL and PubMed. Key words used for search engines included: recommended colonoscopy bowel preps, cost of colonoscopy, cost of bowel prep for colonoscopy, poor prep diagnosis, repeat colonoscopy completion rate, socioeconomic factors and poor prep rates in colonoscopy, and impact of poor prep and anesthesia risk. Search limits used included research articles less than eight years old and in the English language. Inclusion criteria included research specific to adults (>18 years of age). Levels of evidence preference were systematic reviews and randomized clinical control trials (RCTs).

Recommended Pre-Procedure Bowel Preparation

When patients are referred for a screening colonoscopy, there are several different types of prep solution that cleanse the bowel. The two most commonly used preparations at a Midwest urban medical center are Nulytely® with Ducolax® and Suprep®. Nulytely® contains polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, while Suprep® contains sodium sulfate, potassium sulfate, and magnesium sulfate. During the literature search of recommended bowel preps, a study was found comparing the

major ingredient in these two bowel preps. The study concluded in over 28,000 colonoscopies that sodium-sulfate based preparation solutions (i.e., Suprep®) were recommended for community settings due to higher quality bowel preparation (Martin et al., 2016).

In another study, there was a comparison of patients utilizing Nulytely® and Suprep®. The original Nulytely® was used to prep inpatients and the Suprep® was used to prep outpatients. The Nulytely®-prepped inpatients had an inadequate bowel prep rate of 44.1% compared to the Suprep®-prepped patients' inadequate bowel prep rate of 16.3% (Corliss, 2017).

Cost

The cost of a colonoscopy in 2016, prior to insurance, averaged around \$2000 (Sawhney, 2018). A consumer-based website, the HealthCare Bluebook, lists the average price of procedures without insurance, and estimates the cost of a colonoscopy prior to insurance is \$2285 (CareOperative, 2019). The Affordable Care Act mandates insurance coverage for screening colonoscopy, as well as repeat screening colonoscopy due to poor prep as recommended by the United States Preventative Task Force (2015). A poor prep diagnosis requiring a repeat procedure is costly to consumers and insurance providers.

The difference in cost of bowel preps, noted on a consumer-friendly website was significant. The Suprep® was listed for over \$100 while Nulytely® was listed for \$12 (GoodRx, 2019). Some insurance companies will cover the cost of the prep, while other companies require copays and deductibles.

Repeat colonoscopies also result in increased cost due to anesthesia use. According to a study regarding anesthesia use, the quantity of anesthesia used during this procedure increased significantly from 2006 to 2015 during colonoscopy procedures. This results in an increased cost

of the repeat procedure for all consumers and insurance companies that would not be incurred if the bowel prep was initially successful (Krigel et al., 2019).

Risks of Poor Prep

Although colonoscopies are low risk procedures, they are not risk free as patients will undergo risk of repeat sedation. Complications of a colonoscopy includes bleeding, infection, or perforation (Fisher et. al, 2011). The risk of complications after a colonoscopy increases when a patient receives anesthesia (Cooper, Kou, & Rex, 2013; Wernli et al., 2016). Complications from anesthesia may include aspiration pneumonia, cardiac arrhythmias, stroke, or death (Cooper, Kou, & Rex, 2013).

Social Determinants of Health Affecting Colonoscopy

Lower socioeconomic status (SES) is associated with sub-optimal bowel preparations, and persons with a lower SES have increased incidence and mortality rates of colorectal cancer (Lebwohl & Neugut, 2014, Mina Suh, et al., 2015). Non-attendance for colonoscopies was identified as 42% in this population in one study (Laiyemo et al., 2015). Repeat colonoscopies often require another ride, another missed day of work, and another prep. Certain populations are more often affected by colorectal cancer than others. According to the CDC, the African American population has a higher rate of colorectal cancer at 42.2% per 100,000 people than any other race (2016). Reasons for racial or ethnic disparities in colorectal cancer are multifaceted, but echo differences in socioeconomic status. According to the American Cancer Society, “People with the least education (used in studies to estimate socioeconomic status) are 40% more likely to be diagnosed with CRC than those with the most education” (American Cancer Society, 2019).

Constipation and Prep Quality

The research correlating constipation with poor prep was evident and consistent throughout multiple studies. These studies showed that a history of constipation was independently associated with inadequate bowel preparation due to diminished or altered bowel motility (Cheng, et al., 2017; Corliss, 2017; Lee, et al. 2015; Mahmood, Farrooqui, & Madhoun, 2018). Results from one study show that sodium phosphate plus bisacodyl was the most effective preparation for constipated persons (Pereyra et al., 2013).

Project Aims

This purpose of this quality improvement project was to determine the best practice in bowel prep prior to colonoscopy for patients with a history of constipation. The project was based on the premise that providing an appropriate bowel prep for persons with constipation, would reduce the frequency of a diagnosis of poor prep necessitating a repeat colonoscopy. To support this purpose, there were three aims met:

Aim 1: Established the current rate of poor bowel prep (PBP) at each clinic site

Question 1: What was the current rate of poor bowel prep at each of the clinic sites?

Question 2: Was there a significant difference in rates of poor bowel prep rates between the two clinic sites?

Question 3: Which bowel prep practice (Nulytely® with Ducolax® or Suprep®) had lower rates of poor bowel prep?

Aim 2: Determined the current rates of repeat screening colonoscopy completion due to poor bowel prep at each clinic site

Question 4: What was the current rate of repeat screening colonoscopy completion within one year at each of the clinic sites?

Question 5: Was there a significant difference in repeat colonoscopy completion rates between the two clinic sites?

Aim 3: Assessed facilitators and barriers to bowel prep standardization.

Question 6: What were the facilitators to standardizing the bowel prep practice between the two clinic sites?

Question 7: What were the barriers to standardizing bowel prep practice between the two clinic sites?

Organizational Framework

The framework for this project incorporated the Institute for Healthcare Improvement's model of Plan-Do-Study-Act (Health Literacy Universal Precautions Toolkit, 2nd Edition, 2015). The Plan portion of the model took place with receiving support from team members within the organization, IRB review, and project methodology. Team members included the clinic manager, the physicians, nurse practitioners, and the nursing staff for both clinics as these groups helped to support the research. The Do portion of the model involved the completion of an electronic record review and data collection. The Study portion of the model included review, analysis, and evaluation of the data. The Act portion of the model used what was learned from the study to make recommendations to the stakeholders in the clinic on the most effective preparation for patients with a history of constipation.

Methods

Project design

The project utilized retrospective chart review and assessed the frequency of poor prep diagnoses in persons with a history of constipation and association with the type of prep prescribed for colonoscopy at two Gastrointestinal (GI) clinic locations associated with a Midwest medical center. From those poor prep diagnoses, a rate of adherence for repeat colonoscopy was determined. The operational definition of poor prep diagnosis was used to assess the effectiveness of each prep solution based on the Aronchick scale. Clinicians were interviewed to determine perceived facilitators and barriers to prep standardization across the two clinics.

Human Subject Protection

An application was submitted to the Institutional Review Board (IRB) at the University of Kansas Medical Center (KUMC) and the IRB at the Midwest medical center prior to any project commencement. The KUMC Human Research Protection Program approved the quality improvement project and gave the project non-human subject designation. Therefore, the IRB and Research Committee at the Midwest medical center were not required to be involved. Once the process of submission for IRB approval and declaration of approval was received, project initiation began.

Human subject and health information was protected using Health Information Privacy and Protection (HIPPA) regulations. No patient consent was necessary as this quality improvement project was retrospective, no identifiable patient data was collected, and the project manager was an employee of the organization.

Project Setting

The setting took place at two GI diagnostic clinics associated with a Midwest medical center with two hospital locations. Clinic 1 was located in the main urban hospital campus serving a primarily lower socioeconomic population and Clinic 2 was located in the suburban hospital campus serving a combination of low socioeconomic and middle-class populations. The clinic averaged around 600 procedures per month (400 at Clinic 1 and 200 at Clinic 2). The lead physician and a nurse practitioner at the clinic participated in this project. The nurse practitioner assisted in the data collection process.

When a patient was referred for a screening colonoscopy by their primary care provider, a message was sent to the nursing staff of the Gastrointestinal (GI) clinic to order a prep for the patient. The prep was ordered by either the nurses working in the clinic or by the nurse practitioner, if he or she saw the patient first prior to scheduling the procedure. There was no standard prep solution for patients with a history of constipation and information about a history of constipation was not routinely passed on to the nursing staff. However, other specific information about patients had been passed to the nursing staff through the message system. For example, when a patient was on a blood thinning medication the message would include “patient is on blood thinner”-warranting special attention or actions. If a patient was seen by a nurse practitioner in the GI clinic and scheduled for a screening colonoscopy, the nurse practitioner ordered a prep for the patient. The traditional cleansing prep prescribed at the medical center was Nulytely®, consisting of 4 liters of solution in combination with 2, 5 mg Ducolax® tablets (Nulytely® with Doculax®). The second prep used for about four years, was Suprep®, consisting of two 6-ounce bottles of solution. This prep was more commonly prescribed and preferred by patients due to the reduced fluid amount when compared to the Nulytely® with

Ducolax® amount. At this facility, there were currently no standards for ordering a prep for patients with constipation. However, for the last 2-3 years, the Nulytely® with Ducolax® preparation had been used exclusively Clinic 1 while the Suprep® had been used more often at Clinic 2.

Sample

The sample consisted of adults who received a screening colonoscopy, ICD-10-CM code Z12.11, and concurrently had a diagnosis of constipation or a past diagnosis of constipation, ICD-10-CM code K59.00.

Data Collection Plan

A retrospective chart review was used for data collection. The electronic chart review began with a search of patients with a current diagnosis (K59.00) or history of constipation and a screening colonoscopy between January 2018-July 2018 at both clinic locations. The data collection was completed by the project manager (Michele Smith). A yield of 200 patients from each clinic was generated. From the 200 charts, 50 patients were randomly selected from each clinic using a random number generator. Once a sample from each clinic was identified, the following data were collected: prepping solution ordered, the post procedure diagnosis of prep quality, the recommendations on when to repeat the colonoscopy, and whether the colonoscopy was repeated within the recommended time frame.

Data were collected regarding facilitators and barriers by interviewing the staff at each clinic including nurses, nurse practitioners, and physicians. Questions posed include:

Question 1: Why was a specific prep ordered at a specific clinic?

Question 2: Do you feel strongly that one prep works better than the other?

Question 3: In your opinion, have patients had an adverse experience with one prep or the other?

Question 4: What do you feel would be a barrier to practice change regarding prep ordering habits?

Instruments. Data were collected on an Excel spread sheet in REDcap, a secure server. Facilitator and barrier data were displayed as a word document in REDcap.

Evaluation Plan

Pearson's Chi-square test of independence was used to compare the number of patients with poor prep by prep type and by clinic. Of those who received the poor prep diagnosis, a percentage of patients who received repeat colonoscopy recommendations and completed a repeat colonoscopy within that recommended timeframe was calculated. From this percentage, a comparison was made to determine if one clinic has a higher repeat colonoscopy rate than the other. Facilitators and barriers were evaluated by comparing and summarizing answers from staff.

Results

The project was carried out over a two-month period including data collection and analysis of data. Of the sample, the total number of patients who experienced excellent prep at Clinic 1 was two patients (4.0%) while excellent prep was only experienced by one patient (2.0%) at Clinic 2. The majority of patients at Clinic 1 were diagnosed with good prep (22 patients or 44%), while the majority of patients at Clinic 2 were given a diagnosis of fair prep (21 patients or 42%). Only eight patients (16%) experienced a poor prep at Clinic 1 while only

nine patients (18%) experienced a poor prep at Clinic 2 ($\chi^2(1, N=100) = 0.07, p=0.79$). See

Table 1.

Table 1

Prep Quality by Location

	Total	Excellent Prep	Good Prep	Fair Prep	Poor Prep
Clinic 1	50 (50%)	2 (4.0%)	22 (44%)	18 (36%)	8 (16%)
Clinic 2	50 (50%)	1 (2.0%)	19 (38%)	21 (42%)	9 (18%)

During the 6 months when the sample was collected, Suprep was ordered more often than Nulytely. In terms of prepping solution, the most common prep quality grades were good prep or fair prep. There was no statistically significant difference in rates of poor prep between the two prep solutions ($\chi^2(1, N=100) = 0.09, p=0.77$). See Table 2.

Table 2

Prep Quality by Prep Type

	Total	Excellent Prep	Good Prep	Fair Prep	Poor Prep
Nulytely	38 (38%)	0 (0%)	18 (4.7%)	13 (3.4%)	7 (1.8%)
Suprep	62 (62%)	3 (4.1%)	23 (3.7%)	26 (4.2%)	10 (1.6%)

Completion of repeat colonoscopy due to poor prep results varied only slightly by location. From the total number of patients, 16 patients (32%) were recommended for repeat colonoscopy procedure due to poor prep within one year. Of the eight patients from Clinic 1, only two (25%) completed the procedure within the recommended timeframe. Of the eight patients from Clinic 2, only three (37.5%) completed the procedure within the recommended timeframe. there was no difference in the completion rates between the two clinics ($\chi^2(1, N=16) = 0.29, p=0.59$) See Table 3.

Table 3

Repeat Recommendation Completion by Location

	Repeat Colonoscopy Required >1 Year	Repeat Colonoscopy \leq 1 year	Compliance with Repeat Colonoscopy \leq 1
Clinic 1	42 (84%)	8 (16%)	2 (25.0%)
Clinic 2	42 (84%)	8 (16%)	3 (37.5%)

Regarding barriers and facilitators to change of practice, staff at both locations had similar answers to posed questions. Five registered nurses and one doctor participated in the discussion. The majority of answers to the question of why a specific prep was ordered at a specific clinic revolved around financial ability to afford each prep as the patients seen at Clinic 1 are often of lower socioeconomical status than at Clinic 2. One nurse also states, “That’s just what we do” (C.E. personal communication, July 15, 2019). Many of the nurses felt that

Nulytely® worked better for patients with constipation due to the required fluid amount contained in the dosage when compared to the fluid amount in Suprep®. Regarding adverse experiences with one prep over the other, the doctor participating stated, “Suprep is often less tolerated due to nausea than the Nulytely” (F.N. personal communication, July 16, 2019). Staff agreed that patients often prefer the Suprep however, due to the lesser fluid amount.

In regards to barriers specific to standardization, the most common answers for this question included: poor patient understanding of instructions, patient fluid restriction for some comorbidities (i.e. congestive heart failure, renal failure), physicians will not be completely supportive unless prep was FDA approved for specific population, a method to assess for constipation in patients prior to procedure, and affordability of the prep. Facilitators included better patient outcomes with a standardized prep for this population including more time between recommended repeat colonoscopies with less frequent exams leading to higher patient satisfaction and lower cost to insurance companies. These results were disseminated to the clinic stakeholders at the conclusion of the project.

Discussion

Of the patients who were referred for a repeat colonoscopy due to poor prep, there was no statistical significance in the number of completions per clinic. We found that the frequency of poor prep diagnoses at Clinic 1 was similar in number (8) to the frequency of poor prep diagnoses at Clinic 2 (9). There was no significant difference in the frequency of poor prep dependent on type of prep.

When compared to the literature, these clinics had a higher rate of adherence with repeat colonoscopy recommendations at 31.3% within 12 months, when compared to a study that cited a return rate of 24.6% within 18 months (Smith, et al., 2013). In this project there was no

statistical significance between the prep with bisacodyl tablets and without bisacodyl tablets compared to a study by Pereyra which results showed that sodium phosphate plus bisacodyl tablets were more effective in patients with a history of constipation (2013). The results of this project showed no statistical significance in type of prep and poor prep rates compared to a study by Corliss which showed that the Suprep® had lower poor prep rates (16.3%) than the Nulytely® prep (44.1%) (2017).

In assessing facilitators and barriers, clinicians mentioned that cost was an issue in standardizing a bowel prep for this or any specific population as the Nulytely® prep often cost around \$12 while the Suprep® cost up to \$100. Clinicians also felt that many patients would prefer to have the Suprep® bowel prep over the Nulytely® bowel prep due to the fluid consumption required with Nulytely® at 4 L of fluid while Suprep® is simply 332 milliliters of fluid.

Implications for current practice included using the prep that is cost effective or covered by insurance and tolerated by the patient. The next steps for continuous improvement include surveying patient preference for the type of prep, common adverse effects from each type of prep, other factors influencing poor prep such as certain medications, co-morbidities or health literacy, and poor prep rates in this population when compared to non-constipated populations.

Limitations of this project included the small sample size which was limited within one hospital system which inhibits generalizable findings. Another limitation is that, although the patients were chosen with the diagnosis of constipation, there was no control of the effects of patient characteristics, medications, or other comorbidities. One final limitation is that this was a quality improvement project looking at the need for standardizing a prepping solution across the two clinics, therefore, patients were not randomized to a treatment.

Conclusion

In closing, the purpose of the project was to determine if one bowel prep was more effective than the other, establish the poor prep rates between the two clinics, and establish repeat procedure rates between the two clinics. There was no difference between the two bowel preps for this population. We found that there was no difference found in the rates of poor bowel prep rates between the two clinic sites. Lastly, we found no difference in the repeat colonoscopy completion rates between the two clinic sites. Therefore, there are no recommendations for standardizing a bowel prep between these two clinics for this specific population. Further recommendations include prescribing bowel prep specific to patient preference. Further implications for study include bowel prep preference, adverse effects from each prep, health literacy, and other factors that could affect which prep to use in this population when compared to populations with no history or diagnosis of constipation.

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