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Short Communication Open Access

HyGIeaCare® Preparation for Colonoscopy-A Technical Update for Success

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Abstract

Colonoscopy remains the gold standard in colon cancer prevention. An adequate prep is pivotal in allowing the colonoscopist to detect pre-cancerous lesions. Unfortunately, patients oftentimes are not adequately prepared, ultimately limiting the exam. In addition, the prep can be cumbersome and interfere with daily activities deterring many patients from undergoing colorectal cancer screening with colonoscopy altogether. HyGIeaCare® Prep offers a novel alternative to oral purgative laxatives traditionally prescribed prior to colonoscopy, which allows for adequate visualization of the colon and may ultimately lower barriers to entry for colonoscopy for colorectal cancer screening in patients who may otherwise opt not to pursue colonoscopy.

Keywords: Colonoscopy preparation; Colon cleansing; Colon irrigation; Screening; Colorectal cancer; Boston bowel preparation score

Background

The Center for Disease Control (CDC) reports that colorectal cancer is the second leading cause of cancer-related deaths and the third most common cancer in both men and women [1]. Colonoscopy remains the mainstay in colon cancer prevention with both diagnostic and therapeutic capability as it allows for direct visualization and removal of pre-cancerous polyps. Patients who undergo colonoscopy with a suboptimal prep are at higher risk for missed lesions with possible malignant potential. These missed lesions are thought to account for nearly 80% of interval cancers [2]. An estimated 20-25% of patients who present for colonoscopy are found to have an inadequate colon cleansing at the time of exam despite taking the oral preparation [3]. Consequences of an ineffective bowel preparation include lower adenoma detection rates [4], longer procedural times [5], lower cecal intubation rates [6], increased electrocautery risk, and shorter intervals between examinations [4,6,7].

The most recent literature supports the use of several different bowel preparations - with a split dose formulation now recommended as the standard of care, unless the preparation is done on the same day of colonoscopy. The inconvenience involved in the standard split dose preparation for colonoscopy causes disruption in daily routine and work commitments, which may ultimately lead to the patient opting out of their colonoscopy. In addition, while oral purgative bowel preps are generally considered safe and well-tolerated, patients and providers should be cognizant of potential associated risks. Complications include hypovolemia, nausea, vomiting and electrolyte disturbances (e.g. hypokalemia, hyponatremia, hypomagnesemia and hypermagnesemia) [8].

HyGIeaCare Prep

HyGIeaCare Prep is an emerging technology used to purge the colon by water infusion prior to colonoscopy or where medically indicated. With HyGIeaCare prep, patients are placed on a clear liquid diet the day before and the day of their colonoscopy. They are encouraged to hydrate well and to take a gentle laxative at noon and in the evening the day before their procedure. If the patient has a history of chronic constipation, they may be encouraged to take an additional gentle laxative the morning of their HyGIeaCare Prep and colonoscopy.

HyGIeaCare Prep provides an FDA cleared colon irrigation system to replace the traditional oral prep (Figure 1). It is intended for use when medically indicated, such as before radiological or endoscopic examination. The HyGIeaCare Prep is private, low-pressure, warm water, odorless, well tolerated and effective.

Figure 1: HyGIeaCare system.

The HyGIeaCare System is manually disinfected by flushing the entire system with a chlorine disinfectant solution before and after each patient. The system includes disposable tubing and a sterile, disposable rectal nozzle intended for single use only.

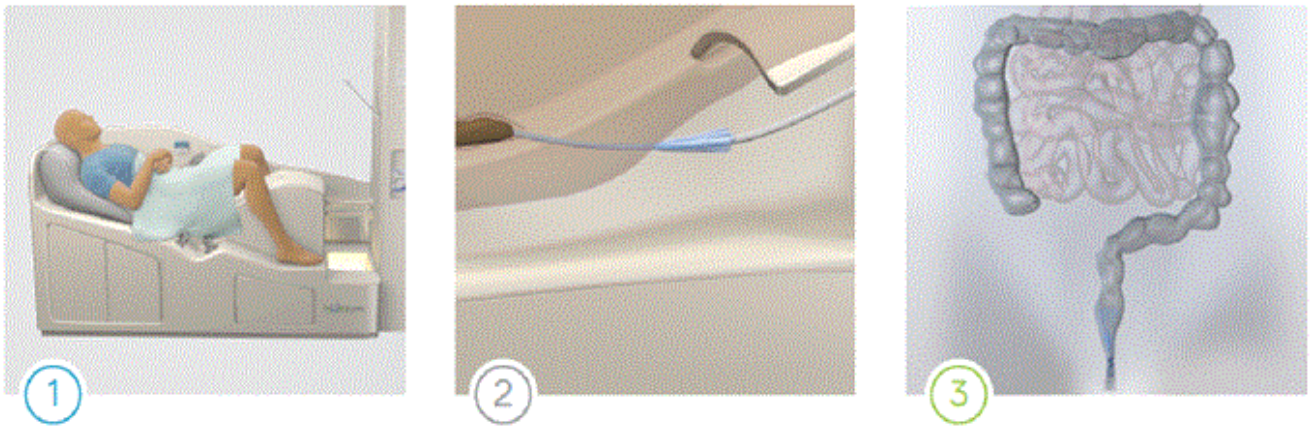

Figure 2: HyGIeaCare procedure.

The HyGIeaCare® procedure is performed by a practitioner specifically trained on the safe use of the system. The patient is seated on the disinfected basin (① in Figure 2) and a sterile, disposable nozzle (② in Figure 2) is introduced into his/her rectum. A gentle stream of warm water then flows into the bowel, loosening stool, allowing the patient to comfortably and discreetly evacuate his/her colon. Water continues to flow and gently cleans the colon (③ in Figure 2) until the practitioner instructs the patient on completion of the procedure, which routinely takes less than an hour.

Safety features of the HyGIeaCare® system

The HyGIeaCare System encompasses the following safety features:

Gently arched rectal nozzle, with a diameter of less than 1 cm

Water flows through a sediment and UV filter

Water flows gently, driven only by gravity

Temperature of the water is steadily maintained

Water automatically stops flowing into the patient if temperature of the water exceeds the safe range of 99°-103°F (37°-39°C).

HyGIeaCare Centers are strategically located in close proximity to busy gastroenterology practices. Once the physician's order for a HyGIeaCare Prep is provided, the scheduler provides the patient with an information brochure and coordinates a time for treatment with the HyGIeaCare Center. The prep takes an average of 40 minutes; the expected time a patient will spend in the HyGIeaCare Center is 1 hour and 15 minutes. The patient is seated on a sanitized basin. A sterile, disposable nozzle is introduced approximately 1 inch into the rectum. A gentle stream of warm water will flow into the bowel, loosening stool, allowing the patient to comfortably and discreetly evacuate their colon. Water will continue to flow gently until the water is clear. The certified technician will assist with noting the excrement progression-formed stool to clear water.

The timing of the HyGIeaCare Prep is coordinated with the timing of the scheduled colonoscopy to ensure the patient will arrive at the colonoscopy center within the appropriate window. Optimally, the HyGIeaCare Prep will be completed within 2 hours of the planned colonoscopy start time. The HyGIeaCare Center is staffed with a nurse manager and certified technicians to guide the patient through the process. A medical director oversees each HyGIeaCare Center.

The use of HyGIeaCare® Prep is increasing rapidly since inception (Austin TX-Sept 2015; Norfolk VA-Feb 2016; Dallas TX-April 2016; Phoenix AZ-May 2016) with approximately 2,000 patients having undergone HyGIeaCare Prep prior to their colonoscopy to date.

HyGIeaCare Preparation Results

The preps of the first 791 consecutive patients (referred to the HyGIeaCare Center in Austin, TX, by the group of physicians from Austin Gastroenterology, Austin, TX) were scored by 26 different colonoscopists characterizing each prep as adequate (defined as visualization of the colonic mucosa to exclude polyps >6 mm^3) *vs.* inadequate. Of the 791 preparations, 766 (97%) were recorded as adequate and 25 (3%) were recorded as inadequate.

The Boston Bowel Preparation Scale (BBPS) is a reliable and validated measure of bowel preparation, often used for colonoscopy-oriented research [9]. It relies on the summation of three individual colonic segment scores (ascending, transverse, descending) to indicate the degree of bowel visualization, with a score of >2 defined as an adequate preparation [9].

Total BBPS scores have been associated with clinical outcomes such as polyp detection rates, recommendations for repeat procedures, and colonoscope insertion and withdrawal times (Figure 3) [10].

A subset of 739 patients who underwent HyGIeaCare preparation prior to colonoscopy was graded using the BBPS. The median colon cleanliness was rated as a 9 with an average of 7.96; 94% scored adequate (>6 as demonstrated in Table 1).

Boston Bowel Preparation Score(N=739)		
Area Scored	Median Score	Average Score
Ascending colon	3	2.47
Transverse colon	3	2.71
Descending colon	3	2.78
Total score	9	7.96

Table 1: Boston Bowel preparation scores after HyGIeaCare preparation.

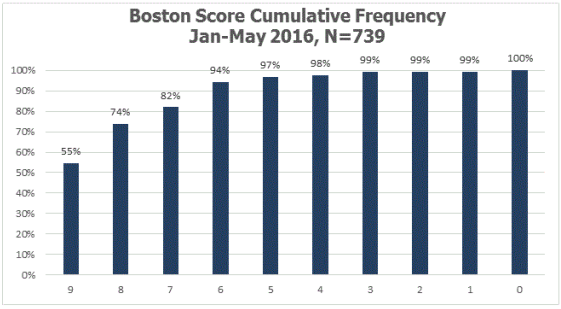

Figure 3: Cumulative frequency of BPSS after HyGIeaCare preparation January-May 2016.

Patient satisfaction and validation of the hygieacare value proposition

In order to assess the perceived value of the HyGIeaCare Prep and the patient's satisfaction with the process, a survey was conducted where each patient treated at the center was given a feedback form to provide information on their individual experience. A total of 859 patients (60%) completed the questionnaire. 95% of these patients stated that they preferred use of HyGIeaCare prep over the standard oral prep and would be willing to pay for the HyGIeaCare prep rather than perform the standard oral prep (patient's paid for their HyGIeaCare prep out of pocket, but in many cases this amount was charged to their Health Savings Account) owing largely in part to simplicity, comfort, and convenience.

HyGIeaCare safety

To date, there have been no serious adverse events in patients referred by their gastroenterologist who underwent HyGIeaCare Prep in the U.S.

All known adverse events have been classified as minor according to the Common Terminology Criteria for Adverse Events (CTCAE v.4), the most common adverse events were nausea, vomiting, generalized weakness, and rectal abrasions [11]. It should be noted, however, that in the study by Professor Michel Delvaux at the University Hospital in Strasburg, France, patients who underwent the standard oral prep experienced more nausea (statistically significant) compared to HyGIeaCare Prep, whereas rectal abrasions unique to the HyGIeaCare Prep arm of the study were clinically insignificant. No changes in electrolytes were noted [12].

Over-distention of the colon occurring with colonoscopy has the potential for perforation, with reported rates ranging from 0.05% to 0.3% in large studies [13-15]. The right colon is more susceptible to barotrauma-induced perforation due to compliance, i.e. as the intraluminal pressure increases so does the diameter of the right colon at a higher rate compared to the left colon. Human cadaveric studies evaluating the safety of sustained intraluminal pressures found that the upper limit of safety was approximately 80 mmHg (equivalent to 1.55 psi) [16]. Given that a large volume of water was being infused per rectum, the hydrostatic pressure effect with HyGIeaCare prep has been investigated. Recognizably, this system is an open system whereby the water and stool effluent return is via the rectum without resistance. Calculated pressures of water infused during the HyGIeaCare Prep found that pressures do not exceed 1.20 psi. No colon barotrauma type changes have been noted in any of the 2,000 patients who have undergone HyGIeaCare prep to date.

Conclusion

HyGIeaCare Prep represents a paradigm shift from the standard per oral purgative laxatives traditionally prescribed prior to colonoscopy. This innovative approach provides a safe and highly effective preparation, a requisite for performance for high quality colonoscopy and detection of colonic lesions. Patient satisfaction is universally high with 95% of patients willing to pay for a HyGIeaCare prep in the future, despite the additional charge. Integration into a gastroenterology practice is fluid with scheduling of the colonoscopy coordinated with the time of the HyGIeaCare Prep, so as to allow prompt and timely arrival of all patients to the colonoscopy suite.

By providing options to what otherwise might be barriers specifically related to the intolerance or refusal to take oral purgatives, HyGIeaCare Prep offers a new exciting advance in colonoscopy preparation. It is expected that the use of the HyGIeaCare Prep will clearly lower these barriers to entry for colonoscopy for colorectal cancer screening.

Since commencing operations in 2015, 4 HyGIeaCare Centers have been established in the U.S. (Austin, TX; Norfolk, VA; Dallas, TX; Gilbert, AZ). Additional information can be found on the company website at www.hygieacare.com.

HyGIeaCare is a registered trademark of HyGIeaCare, Inc.

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