

Outcome of the First Large Consecutive Series of Patients Using HyGieaCare Prep Prior to Colonoscopy

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Background

Bowel preparation formulations are intended for colon cleaning prior to colonoscopy. Unfortunately, oftentimes patients are not adherent to traditional oral preparations as they can be cumbersome and impede on daily activities. Patients will often cite intolerance of large volume oral purgatives as a reason for unwillingness to do colonoscopy. As a result, many patients will opt to postpone or even deny their screening colonoscopies because of the inconvenience of traditional preparations.

Additionally, nearly ¼ of all colonoscopies performed are reported to have an inadequate bowel preparation. Adverse consequences of ineffective bowel preparation include lower adenoma detection rates, longer procedural time, lower cecal intubation rates, increased electrocautery risk, and shorter intervals between examinations. The HyGieaCare Prep offers a novel alternative to traditional prep that overcomes these barriers.

Methods

The HyGieaCare Prep utilizes a slow stream of water drained by gravity that is infused into the rectum via a nozzle that ultimately induces natural peristalsis allowing for effective excretion of stool. A total of 791 consecutive patients underwent the HyGieaCare Prep and their preparations were characterized as adequate or inadequate using the guidelines set forth by the United States Multi-Society Task Force (USMSTF). A subset of 739 patients were also graded using the Boston Bowel Preparation Score (BBPS).



Figure 1 - The HyGieaCare Prep System

Boston Bowel Preparation Score (N=739)

Area Scored	Max Score	Median Score	Average Score
Ascending Colon	3	3	2.47
Transverse Colon	3	3	2.71
Descending Colon	3	3	2.78
Total Score	9	9	7.96

Figure 2 - BBPS after HyGieaCare Prep

Boston Score Cumulative Frequency

Jan-May 2016, N=739

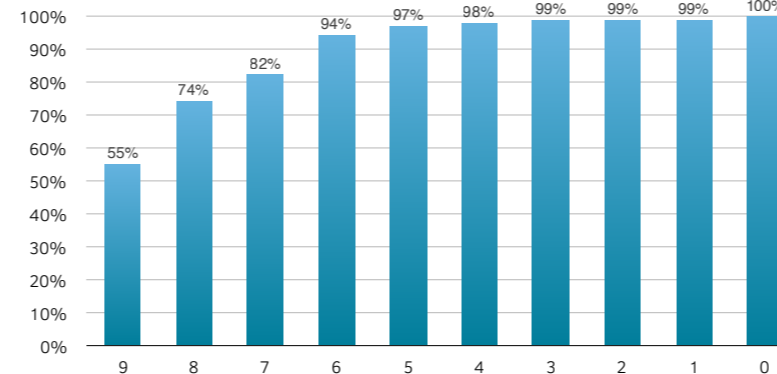


Figure 3 - Cumulative frequency of BBPS after HyGieaCare Prep Jan-May 2016

The HyGieaCare® procedure is performed by a practitioner 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 Prep 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, at 1 psi; 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)

Results

Using the USMSTF guidelines, of the 791 consecutive patients 766 (97%) of preparations were considered adequate preps versus 25 (3%) that were considered inadequate. Of the 739 patients graded using the BBPS, the median colon cleanliness score was 9, with an average of 7.96. 94% of preps were considered adequate (defined as having a BBPS score >6).

The most common adverse events were nausea, vomiting, and generalized weakness, which occurred in less than 1% of patients. Other adverse events included minor superficial and clinically insignificant rectal abrasions. There have been no severe or serious adverse events reported to date. Further randomized controlled trials comparing HyGieaCare Prep to split PEG are recommended.

Conclusion

The colon irrigation preparation appears to be an effective, well tolerated, and low-risk alternative to standard oral prep prior to colonoscopy.

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