

High-volume colon irrigation bowel prep is safe, effective, and preferred by IBD patients

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Introduction

- Colonoscopy serves a fundamental role in the diagnosis, management, assessment, and treatment of inflammatory bowel disease (IBD).
- Oral purgative bowel prep (BP) is hypothesized to cause preparation-induced mucosal inflammation, which can be a significant confounding variable in both assessment and diagnosis of IBD, as well as evaluation for response to treatment.
- Oral colon prep for IBD patients may be more difficult to tolerate given predisposed issues.



Figure 1 - The FDA-cleared, prescription-only, Hygieacare® system for high-volume colon irrigation system, operating under stringent standard operating procedures (SOP). This high-volume colon irrigation bowel prep, replacing the traditional oral prep

Methods

- This retrospective analysis includes a demographic and meta-analysis of high-volume colon irrigation BPs of IBD patients at four US Hygieacare® Inc. centers during September 2016 - September 2020.
- All BPs were performed using an FDA-cleared high-volume colon irrigation prep system.

Results

- The IBD patients population consisted of 283 patients that underwent 304 BPs. See Table 1 for more demographic and IBD-related information.
- The BPs were prescribed by 61 physicians and performed by 15 nurses and technicians in four different sites.
- 97% of the patients were reported to have an adequate BP for colonoscopy.
- No adverse events were reported in over 93% of the BPs, and no serious AE was reported.
- Patients satisfaction was very high, with a favorable rating of over 94%.
- 274 patients reported taking an oral purgative prep prior to colonoscopies; 57% reported having difficulties with it.
- Open-ended responses revealed high satisfaction with the high-volume colon irrigation BP and dissatisfaction with past oral preps (Figure 2).

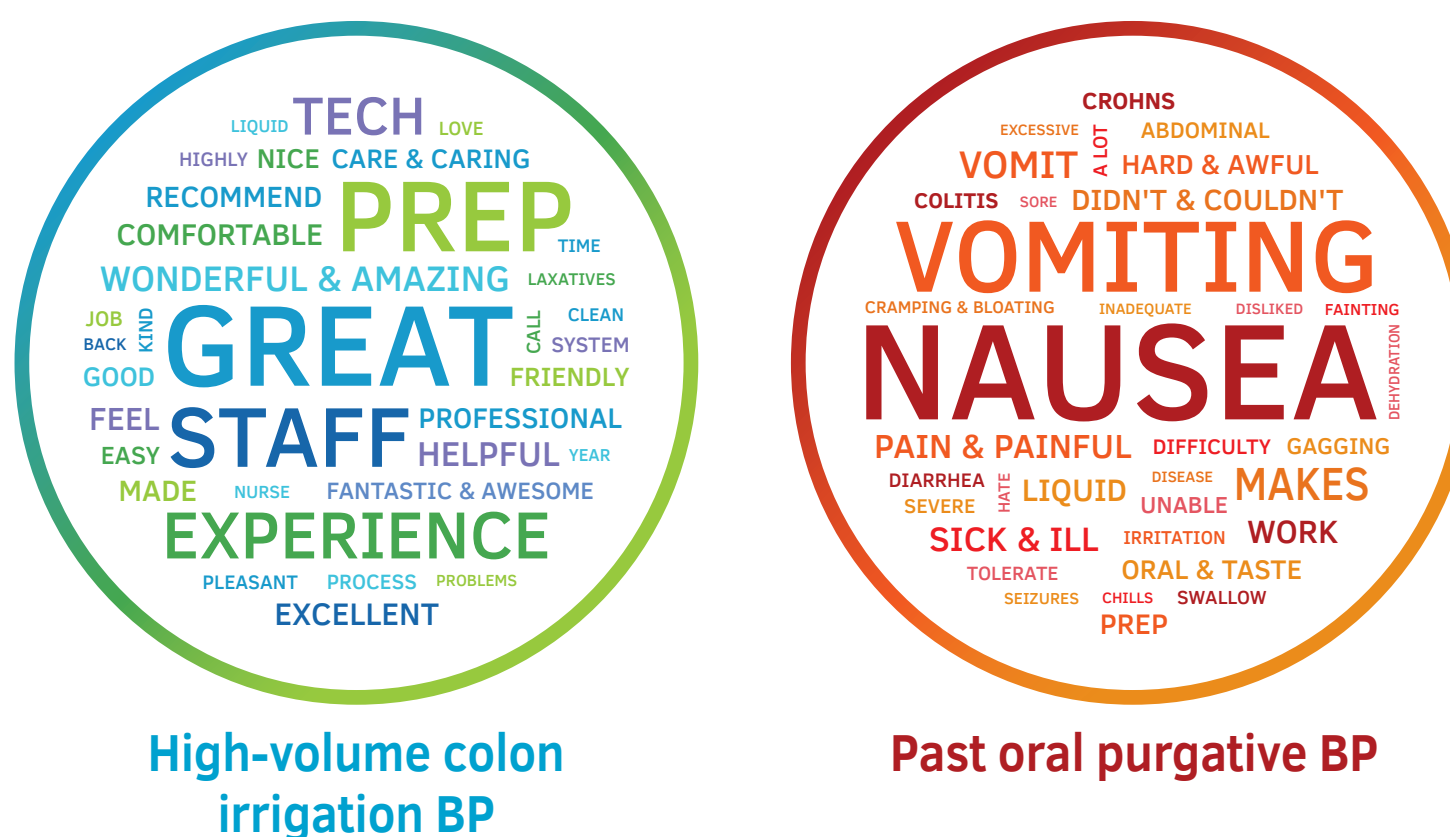


Figure 2 - Word-cloud analysis of free text open-ended responses of the reported IBD population. On the left – responses from patients asked about their past experience with oral preps (n=171). On the right - responses from patients asked about their experience with the high-volume colon irrigation bowel prep (n=98).

Conclusions

- Patients' tolerance is key for quality bowel preparation for colonoscopy.
- In patients with IBD, tolerance, adequate preparation and avoidance of prep-related macroscopic inflammation, is pivotal for informative decision management.

Parameter	Summary of demographic data and key results
BP performed	304
Number of patients	283
Number of referring physicians	61
Number of performing nurses and technicians	15
IBD indications	UC- 167 (57%), CD - 101 (35%) Unspecified IBD – 24 (8%) [n=298]
Age of patients	Min - 21; Max - 85; Average - 57.7±14.2 [n=270]
Gender of patients	Male – 58 (24%), Female – 180 (76%) [n=238]
Adequacy	All patients [n=267] – 260 (97%) UC patients [n=161]- 156 (97%) CD [n=95]- 94 (99%)
Adverse events (rated “quite a bit” or “a lot”)	Nausea – 20 (7%), Vomiting – 10 (3.5%) Dizziness – 5 (2%), Abdominal cramping – 13 (5%) [n=279]

Table 1 - Demographic and meta-analysis of inflammatory bowel disease (IBD) patients undergoing an FDA-cleared high-volume colon irrigation bowel prep (BP). UC- Ulcerative colitis; CD- Crohn's disease