

A Novel Balloon-Colonoscope and Technique for Increasing Colonoscopy Diagnostic Yield: Retrospective Review of Polyp and Adenoma Detection Rates

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Introduction: Colonoscopy is considered to be the standard of care for detecting pre-cancerous polyps (adenomas) & colorectal cancer. Though, numerous studies show that a significant number of polyps and adenomas (20%-30%) are missed at colonoscopy¹, e.g., due to polyps located at the proximal aspect of haustral folds and colonic flexures.

We investigated a new balloon-colonoscope, the NaviAid™ G-EYE™ (SMART Medical Systems Ltd, Ra'anana, Israel), which employs a permanently-integrated, reprocessable balloon at the bending section of an otherwise standard colonoscope.

During G-EYE™ colonoscopy, the balloon-colonoscope is advanced conventionally with the balloon deflated to the cecum. Once the cecum is reached the balloon is partially inflated to one of few user-selected, intermediate (non-anchoring) pressure levels, and the colonoscope is withdrawn in the conventional technique. While the colonoscope is pulled backwards, the partially inflated balloon slides along the lumen, straightening haustral folds and lumen topography, centralizing the endoscope's optics, and preventing bowel slippage. This newly available mechanism was developed to improve polyp detection. Furthermore, the balloon can be readily inflated to anchoring pressure upon interventional need, thus stabilizing the colonoscope in position, for faster and more controlled endoscopic interventions.

Aim of the current work was to determine the safety as well as the efficiency of the new available (gained CE-mark, pending FDA clearance) colonoscope.



Fig. 1: NaviAid™ G-EYE™ endoscope

Methods: A retrospective analysis of human subjects who underwent G-EYE™ colonoscopy between November 2012 and May 2013 was conducted. Patients referred to colonoscopy for screening, surveillance or diagnostic evaluation (ages 40-75 years), were included. The number of patients detected with polyps and adenomas was obtained, and correlated polyp detection rate (PDR) and adenoma detection rate (ADR) were calculated. Cecal intubation rate was also determined.

Results: A total number of 125 G-EYE™ colonoscopy procedures were included in the review, performed by 14 physicians at 6 medical centers. The G-EYE™ device and technique lead to a polyp detection rate of 51.3% (64/125) and

an adenoma detection rate of 42.1%. G-EYE™ colonoscopy's PDR was found to be roughly two-fold higher than previously reported in standard colonoscopy peer-reviewed publications², typically ranging from 25% to 35%. Moreover, G-EYE™ exhibited a significant, approximately 100% higher ADR, compared with published statistics of standard colonoscopy^{3,4}, typically 20% (range 15%-25%). A cecal intubation rate of 100% (125/125) was achieved. During G-EYE™ colonoscopy, lumen visibility was improved due to straightening of lumen folds and flexures, and elimination of bowel slippage.

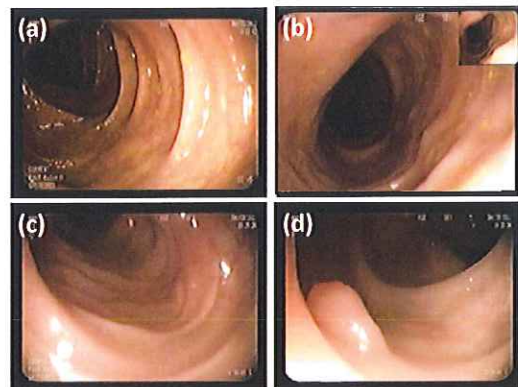


Fig. 2: G-EYE™ colonoscopy: (a) – (c) controlled withdrawal, colon view, and (d) revealing a hidden polyp

Conclusions: This (retrospective) review of the new G-EYE™ colonoscope demonstrated a substantial increase of the polyp as well as the adenoma detection rate (51.3% and 42.1%) during 125 colonoscopies. The new device and technique were found to be safe and efficient, facilitating fold-straightening, improved colon visibility, and reduced bowel slippage. Further randomized studies are ongoing to fully clarify the clinical benefit of the G-EYE™ colonoscope.

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