Multi-center clinical experience - Evaluating G-EYE™ endoscope polyp and adenoma detection rates

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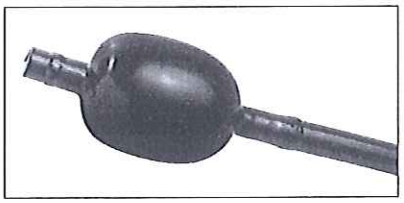
Background: Colonoscopy has been established as the method of choice for colorectal cancer (CRC) prevention by detection and removal of pre-cancerous polyps. However, clinical studies[1-4] report that a significant number of polyps and adenomas (20%-30%) are missed during routine colonoscopy. Several techniques have been recently introduced for improving polyp detection rate, such as retro-viewing optical devices that can detect polyps in the proximal aspect of colon folds and flexures.

The G-EYE™ endoscope (Smart Medical Systems, Ra'anana, Israel), is a conventional, forward viewing endoscope, comprising an integral, reusable and reprocessable balloon at its bending section. Following cecal intubation, the endoscope is withdrawn with the balloon moderately inflated, thereby straightening colon folds, smoothening colon topography and reducing bowel slippage– altogether improving bowel visualization and increasing polyp and adenoma detection rate (PDR and ADR). Previous clinical studies[5,6] reported an increase of 50% or higher in PDR and ADR with the G-EYE™ endoscope, compared with results of standard colonoscopy.

A large-scale (1,000 patients) multicenter randomized clinical study is presently being initiated to further validate the effect of G-EYE™ colonoscopy on polyp and adenoma detection. As preparation for this study, 9 assigned medical centers employed the G-EYE™ endoscope in routine screening and surveillance colonoscopy, and compared the results to results of standard colonoscopy that was performed in the same centers. The present work reports this pre-study initial experience.



Methods: From May to October 2013, Patients of age 50 years and above referred to colonoscopy for screening, surveillance, following positive FOBT, or due to change of bowel habits, were arbitrarily assigned to either conventional colonoscopy or G-EYE™ colonoscopy. The G-EYE™ endoscope was based on the same instrument as the conventional colonoscope (3890i Series HD colonoscope, Pentax Medical, Japan), thereby employing the same High Definition optics. 9 medical centers participated (Europe and Israel). Detected polyps were removed and analyzed. The polyp and adenoma detection rates were calculated.

Results: 144 patients are included in this report, 76 patients (46 male) underwent conventional colonoscopy and 68 patients (34 male) underwent G-EYE™ colonoscopy.

In the conventional colonoscopy group, polyps were detected in 34 of the 76 patients, yielding a PDR of 44.7% (34/76). PDR in the G-EYE group was 64.7%. Reported ADR was 24.2% in the conventional colonoscopy group and 44.4% in the G-EYE group. Conventional colonoscopy detected 0.70 polyps per patient and 0.38 adenomas per patient, while G-EYE™ colonoscopy detected 1.07 polyps per patient and 0.60 adenomas per patient.

Compared with conventional colonoscopy, G-EYE™ colonoscopy increased PDR by 45% and ADR by 83%. The number of polyps per patient detected by the G-EYE was 53% higher than the polyp per patient detection of the conventional colonoscopy. For adenomas per patient, the G-EYE detection was 58% higher than that of conventional colonoscopy. Cecal intubation rate was 100% in both G-EYE™ colonoscopy (68/68) and conventional colonoscopy (76/76). No adverse events were reported in either technique.

Discussion: This multicenter work presents comparative G-EYE™ and conventional colonoscopy detection data, collected in 9 medical centers. In the present work, G-EYE™ colonoscopy yielded ADR of 44.4%, which is in alignment with G-EYE™ ADR reported in previous clinical studies – 44.7% in a single-center pilot study[5] and 40.4% in a multicenter tandem study[6]. These G-EYE™ ADR values are in the range of 1.5-2 times higher than comparative standard colonoscopy ADR. With respect to PDR, the G-EYE result in this present work (64.7%) is 1.5 times higher than the comparative conventional colonoscopy PDR, and is somewhat higher than the G-EYE PDR reported in the previous G-EYE pilot[5] and tandem[6] clinical studies (53.2% and 53.8%, respectively). This can be explained by the patient population in the present work, which was limited to CRC screening and surveillance rather than a general population. This elevated PDR is exhibited in the conventional colonoscopy result as well (44.7%), which is higher than the typically reported PDR in conventional colonoscopy[2] (25%-35%).

Conclusions: This multicenter work reports substantial increase in polyp and adenoma detection rates with the G-EYE™ endoscope, compared to conventional colonoscopy. The G-EYE™ colonoscopy was found safe and efficient, and exhibited 45% and 83% increase in PDR and ADR, respectively, no adverse events, and 100% cecal intubation. A large-scale, multicenter, randomized clinical study is under initiation.

References:

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