Evaluating the Safety and Efficacy of a Novel Balloon-Colonoscope – A Prospective Study in Human Subjects

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Background and Aims: Colonoscopy is the "criterion standard" for detecting colorectal adenomas & cancers. Yet, multiple studies show significant numbers of adenomas (20%-30%) are missed at colonoscopy. This is primarily due to inadequate visualization of the proximal aspect of colonic folds and at anatomic flexures. The NaviAid™ G-EYE™ (SMART Medical Systems Ltd, Ra'anana, Israel) is a novel, balloon-colonoscope comprising a standard colonoscope with a reprocessable, permanently integrated, inflatable balloon at the colonoscope tip. The balloon is inflated (endoscopist selected inflation levels) through the endoscope internally, without any external mounted accessories. The balloon-colonoscope is advanced by the endoscopist with the balloon deflated to the cecum. At the cecum, the balloon is inflated to engage the colon walls and the balloon-colonoscope is then withdrawn as per usual technique by the endoscopist. Withdrawal of the inflated balloon-colonoscope causes mechanical straightening of colonic folds & flexures.

Aims/Methods: To establish the feasibility, usability and safety of a novel balloon-colonoscope in human subjects (ages 40-75 years) referred for CRC screening, polyp surveillance or diagnostic evaluation. Primary study endpoint was cecal intubation, additional endpoints included: time to cecal intubation, withdrawal time, total procedure time, polyp detection rate (PDR), adenoma detection rate (ADR), success of polypectomies, and adverse events. Telephone follow up with subjects was performed 24-72 hours post-colonoscopy. This study was Helsinki committee approved.

Results: From 15.11.2012 to 30.1.2013, n=50 consecutive subjects (mean age 59.0 years, range 40-74 years, 27 female) were enrolled. Three subjects were excluded due to inadequate colon prep, technical problem, and hernia, thus 47 subjects are analyzed. A 47/47 (100%) cecal intubation rate was achieved. Mean time (in minutes) to cecum was 4.3, withdrawal time 7.4, and total procedure time 16.5. We identified a total of 44 polyps in 25/47 subjects, a 53.2% polyp detection rate. There were 36 (81.8%) polyps (1-5mm), 4 (9.1%) polyps (6-9mm) and 4 (9.1%) polyps (≥10mm) in size. We found that 36/44 (81.8%) polyps were "adenomas", and 21/47 subjects had at least one adenoma, yielding an ADR=44.7%. All identified polyps were removed by cold or hot snare polypectomy. There were 2 subjects with minor adverse events (diarrhea and abdominal pain).

Conclusions: The NaviAid™ G-EYE™ balloon-colonoscope appears feasible, usable, and safe. With the balloon colonoscope there was 100% cecal intubation, a 53% PDR, a 45% ADR, and no serious adverse events. Comparative human studies are underway.

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