A novel self-propelled disposable colonoscope is effective for colonoscopy in humans (with video)

Nathan Gluck, MD, PhD,[1,2] Alaa Melhem, MD,[1,2] Zamir Halpern, MD,[1,2] Klaus Mergener, MD,[3] Erwin Santo, MD[1,2]

Tel Aviv, Israel; Tacoma, Washington, USA

Background and Aims: The self-propelled disposable colonoscope (SPDC) with a 360° view is designed to enhance visualization, minimize risks of perforation and infection transmission, and shorten operator training time associated with conventional colonoscopy (CC). We evaluated SPDC efficacy for cecal intubation and safety.

Methods: Prospective patients presenting for colorectal cancer screening underwent SPDC immediately followed by CC. Initial patients necessary for SPDC operators to achieve proficiency comprised the training cohort. Subsequent enrolled patients comprised the study cohort. SPDC colonoscopy was performed up to the cecum, where anatomic landmarks were photographed and mucosal suction marks were placed. During SPDC withdrawal, polyps were recorded and similarly marked. On the second pass (by using CC), any potential mucosal damage and suction marks from the SPDC as well as polyps were recorded. Main endpoints included SPDC cecal intubation rates, confirmed by anatomic landmarks and residual marks seen on subsequent CC, and frequency and severity of adverse events and mucosal damage with SPDC. The secondary endpoint was subjective procedure proficiency, evaluated by the operator based on the training cohort. The tertiary endpoint was documenting pathologies visualized with SPDC.

Results: Fifty-six of 58 enrolled subjects completed the study. Proficiency with SPDC was attained after 8 to 10 procedures. Cecal intubation was successful in 98.2% (55/56 subjects; 95% confidence interval [CI], 90.4%-99.9%), including 100% (95% CI, 90.7%-100%) of the study cohort and 94.4% (95% CI, 72.7%-99.9%) of the training cohort. No mucosal damage or adverse events were reported. SPDC detected 87.5% of polyps seen in tandem CC, including all polyps larger than 5 mm.

Conclusions: SPDC was highly successful, simple to use, and safe in achieving complete colonoscopy (cecal intubation). (Clinical trial registration number: 0692-12-TLV.) (Gastrointest Endosc 2016;83:998-1004.)

Colorectal cancer (CRC) is the second leading killer among cancers in the Western world. The risk of the development of CRC and of CRC-related mortality is reduced by removal of adenomas and early detection and treatment of cancers. Colonoscopy is considered the criterion standard for colon inspection and removal of polyps, with recent reports suggesting a correlation between the increased adoption of screening colonoscopy and the reduced incidence of CRC.[1,2]

Conventional colonoscopy (CC) is associated with risks, albeit limited and finite, which may be life threatening. These include bowel perforation and infectious

Abbreviations: CC, conventional colonoscopy; CI, confidence interval; CIR, cecum intubation rate; CRC, colorectal cancer; SPDC, self-propelled disposable colonoscope.

DISCLOSURE: *Dr Halpern is a consultant for GI View Ltd. All other authors disclosed no financial relationships relevant to this article.*

This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

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Current affiliations: Tel Aviv Medical Center (1), Sackler Faculty of Medicine, Tel Aviv University (2), Tel Aviv, Israel, Digestive Health Services, Tacoma, Washington, USA (3).

Reprint requests: Nathan Gluck, MD, PhD, Tel Aviv Medical Center, Research Center for Digestive Disorders and Liver Diseases, 6 Weizmann St., Tel Aviv 64239, Israel.

disease transmission.[3-6] Infections may occur due to failure to meet standards of reprocessing[7] or because of inherent difficulties with complete disinfection.[8,9] Although reported infection rates associated with colonoscopy are low, such infections may go unrecognized due to a lack of appropriate surveillance and reporting as well as a lack of acute symptoms.[4,10,11] Achieving proficiency in performing CC, including consistent cecal intubation and recognition of colon pathologies, requires a substantial learning process estimated to be at least 300 to 500 colonoscopy procedures.[12,13]

The self-propelled disposable colonoscope (SPDC) system (Aer-O-Scope; GI View Ltd, Ramat Gan, Israel) was designed to address these concerns (Fig. 1; Video 1, available online at www.giejournal.org). The SPDC includes an external workstation with full joystick control (Fig. 1A) over the inserted, fully disposable scanner unit. The scanner comprises a soft, flexible, light-weight cable (multilumen) attached to a system of pliable polyurethane balloons (Fig. 1B). Gentle propulsion of the scanner is achieved by inflating the balloons and colon with CO_2, supplied by the workstation at a maximal pressure of 60 mbar. This minimizes the need for the operator to apply pushing force to the instrument and facilitates easy maneuvering around difficult anatomic flexures and colonic angulations. Pushing forces when applied by the operator to the soft cable of the SPDC are scattered over the entire surface area of the balloons before reaching the colon wall. This is in contrast to CC in which basal inflation pressure reaches 75 mbar, whereas forces as high as 2.5 kg are applied by the physician to the tip of the CC and are transmitted directly to the colon wall causing pressure as high as 1200 mbar.[14] An additional pulsating balloon located at the tip of the SPDC scanner further eases colonoscope intubation. The hydrophilic coating of the balloons and cable lowers friction by more than 90%, thus enhancing movement in the colon. At the scanner tip are openings for irrigation, suction, and insufflation as well as the optical head with a camera and light sources (Fig. 1C). A bending section toward the tip of the colonoscope allows full steering control of the optical head using the joystick at the workstation, which enables optimal visualization of suspected areas and easy navigation through tortuous turns in the colon. Altogether, these features have the potential to reduce the risks of colonic perforation. Because the SPDC scanner component is completely disposable, it carries no risk of infectious disease transmission and obviates the need for decontamination.

The enhanced optical system contains white-light LEDs and a CMOS high-definition digital camera, providing standard forward views with a 57° field of view as well as simultaneous complete 360° (omni) view of a cylindrical strip of the colon 18° toward the front and 26° toward the rear (Fig. 2; Video 1, available online at www.giejournal.org). This allows the operator to have continuous visualization of the colon lumen even when the optical imaging head is flush against the colonic wall, aiding in steering and advancement of the SPDC around flexures and bends.

An initial pilot study performed with a prototype model[15,16] provided proof-of-concept of the SPDC system with regard to its ability to intubate the colon.[17]

The aim of this study was to evaluate the ability of the new SPDC system to meet accepted efficacy benchmarks, specifically cecal intubation, in a group of patients referred for screening colonoscopy.

METHODS

Design

This was a prospective, single-center, noncomparative study performed at a tertiary care hospital. Subjects underwent colonoscopy examination with SPDC, immediately followed by CC, performed by the same operator. A follow-up telephone call was performed 24 to 48 hours after the procedure to query study subjects regarding delayed symptoms/adverse events.

Study subjects

Subjects were asymptomatic adults at average or increased CRC risk (based on family history) referred for screening colonoscopy. All subjects signed an institutional review board–approved informed consent. Each subject underwent an interview for relevant medical history and full physical examination before the colonoscopy procedures. As many as 10 initial subjects per operator were intended to be part of a training cohort, which was to be evaluated for device safety only. Operators could reduce the number of subjects in their training cohort if they believed that they had reached proficiency with the SPDC.

Study endpoints

The primary efficacy endpoint was documented cecal intubation with a goal of more than 90% of all study subjects. The primary safety endpoint was the frequency and severity of device-related serious adverse events, defined as resulting in death or serious injury. Because serious adverse events are rare, establishing safety requires high numbers of study subjects. Therefore, for the safety endpoint, this was a pilot study.

Secondary study endpoints included SPDC ease of use compared with physicians' experience with CC in general and overall visualization with SPDC compared with physicians' experience with CC. Data pertaining to these secondary endpoints were subjective and obtained via a questionnaire completed by the operator by using a visual analog scale immediately after the procedure.

Additional study endpoints included ascertaining the number of SPDC colonoscopies needed to acquire proficiency in device operation and documenting the number