Digestive and Liver Disease 45 (2013) 657–662

Contents lists available at SciVerse ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Digestive Endoscopy

Experimental assessment of a novel robotically-driven endoscopic capsule compared to traditional colonoscopy

Alberto Arezzo[a,*], Arianna Menciassi[b], Pietro Valdastri[c], Gastone Ciuti[b], Gioia Lucarini[b], Marco Salerno[b], Christian Di Natali[c], Mauro Verra[a], Paolo Dario[b], Mario Morino[a]

[a] Department of Surgical Sciences, University of Torino, Italy
[b] The BioRobotics Institute, Scuola Superiore Sant'Anna, Pisa, Italy
[c] STORM Lab, Vanderbilt University, Nashville, TN, USA

ARTICLE INFO

Article history:
Received 3 October 2012
Accepted 22 January 2013
Available online 28 February 2013

Keywords:
Capsule endoscopy
Colorectal cancer screening
Endoscopic robotic platform

ABSTRACT

Background: Despite colonoscopy represents the conventional diagnostic tool for colorectal pathology, its undeniable discomfort reduces compliance to screening programmes.
Aims: To evaluate feasibility and accuracy of a novel robotically-driven magnetic capsule for colonoscopy as compared to the traditional technique.
Methods: Eleven experts and eleven trainees performed complete colonoscopy by robotic magnetic capsule and by conventional colonoscope in a phantom ex vivo model (artificially clean swine bowel). Feasibility, overall accuracy to detect installed pins, procedure elapsed time and intuitiveness were measured for both techniques in both operator groups.
Results: Complete colonoscopy was feasible in all cases with both techniques. Overall 544/672 pins (80.9%) were detected by experimental capsule procedure, while 591/689 pins (85.8%) were detected within conventional colonoscopy procedure (P = ns), thus establishing non-inferiority. With the experimental capsule procedure, experts detected 74.2% of pins vs. 87.6% detected by trainees ($P < 0.0001$). Overall time to complete colon inspection by robotic capsule was significantly higher than by conventional colonoscopy (556 ± 188 s vs. 194 ± 158 s, respectively; $P = 0.0001$).
Conclusion: With the limitations represented by an ex vivo setting (artificially clean swine bowel and the absence of peristalsis), colonoscopy by this novel robotically-driven capsule resulted feasible and showed adequate accuracy compared to conventional colonoscopy.

1. Introduction

Colorectal cancer (CRC) is a major cause of mortality of the general population in the Western world [1]. Although identification and removal of precancerous adenomatous polyps during colonoscopy has been demonstrated to be highly effective in preventing CRC [2–4], the application of CRC screening is low, especially when compared with the high rate of attendance for other screening programmes [5,6]. Various reasons have been suggested to explain the disappointing compliance of the population to CRC screening programmes, including lack of symptoms, fear of detecting a tumour, difficulty in bowel preparation and even lack of knowledge or awareness of the benefits of regular colorectal screening [7]. Nevertheless, there is no doubt that the major obstacle is represented by the embarrassment and discomfort that many patients believe accompanies the procedure. Although introduction of better sedation (including use of Propofol) seems to somewhat improve patient acceptance of colonoscopy [8], colonoscopy under sedation remains limited in many countries due to economical and organization issue.

At the same time, a high-quality colonoscopy is necessary to provide all the benefits of endoscopic screening. In various studies, conventional colonoscopy seems to have a 5% polyp miss rate for polyps greater than 1 cm, which rises up to 25% for polyps smaller than 5 mm. Even the rates of missed cancers are reported as high as 6% in the right and transverse colon and 2% in the descending colon, sigmoid and rectum [9]. Known factors that influence the quality of colonoscopy in terms of polyp detection are withdrawal time, adequacy of bowel preparation and thorough inspection behind every intestinal fold [10,11].

In the recent past, availability of technologies enabled the development of wireless capsule endoscopy (WCE), which entails the ingestion of a miniaturized camera that navigates passively along the gastrointestinal tract by means of peristalsis, enabling inspection of the digestive system without discomfort or need for sedation

* Corresponding author at: Department of Surgical Sciences, University of Torino, Corso Dogliotti 14, 10126 Torino, Italy. Tel.: +39 3358378243; fax: +39 0116336641.
E-mail addresses: alberto.arezzo@unito.it, alberto.arezzo@mac.com (A. Arezzo).

1590-8658/$36.00
http://dx.doi.org/10.1016/j.dld.2013.01.025

[12,13]. A significant example for capsule colonic inspection is represented by the PillCam COLON 2 (CCE-2) [12]. Recently a European, prospective, multicenter trial including eight European sites, but a limited number of cases, was published [14]. In this paper CCE-2 was able to detect 88% of polyps at least 10 mm in size was 88% (95% CI 76–99%) compared to conventional colonoscopy. Nevertheless concerns about the necessity to rely on passive peristaltic movement persist.

In order to overcome these problems and limitations, technical improvements to conventional colonoscopes and new devices are being developed ranging from simple diagnostic cameras to complete and autonomous diagnostic and therapeutic robotic platforms [15–24], which aim to achieve a higher quality colonic exploration with reduced invasiveness. In this framework, magnetic active locomotion represents the most promising solution [25]. Recently Olympus Endoscopy (Tokyo, Japan) and Siemens Healthcare (Erlangen, Germany) joined their effort to produce a modified endoscopic capsule endoscope controlled by magnetic guidance, for the upper gastrointestinal tract [26].

In this paper, the authors present a robotically-driven colonoscopic capsule platform, which was tested in an ex vivo setting and compared to conventional colonoscopy to verify feasibility and accuracy of the proposed technology and related technique.

2. Materials and methods

2.1. Robotic platform overview and control architecture

The robotic platform used in the study (Fig. 1) includes a 6 degrees of freedom (DoF) robotic arm (Fig. 1b – RV-6SB, Mitsubishi Electric, Tokyo, Japan) with a 7th custom-DoF at the end-effector for increasing the robot dexterity to complete the endoscopic procedure (Fig. 2). The external permanent magnet (EPM) consists of a NdFeB cylindrical-shaped 1.38 T magnet fixed to the robotic arm end-effector. A human–machine interface (HMI), including an intuitive 6 DoF control peripheral (Phantom Omni, Sensable, USA) (Fig. 1c), acts as an active high-level control core. The robotic arm is used to hold, move, and orient the EPM, that establishes a magnetic link with the endoscopic capsule equipped with an internal permanent magnet (IPM). The IPM is composed by 3 NdFeB cylindrical-shaped 1.48 T magnets. A proper dimensioning of the EPM-IPMs magnetic link was addressed in order to achieve effective magnetic interaction with the capsule at an operative distance of 150 mm [27]. The user imposes robotic arm motion through the input device, which interacts with a real-time motion control system driving the robotic arm. The input device is a positional sensing compact haptic device with force feedback. The control peripheral returns translational and rotational motion commands as the difference of the joystick current position respect to a centre-zero point. These data are processed by the robotic arm as increments to be added to the actual end-effector absolute position for the execution of the next motion command.

The magnetic driven component of the platform consists of a wired endoscopic capsule (Fig. 1a) measuring 13.5 mm × 29.5 mm and embedding a wired charge-coupled device (CCD) camera (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) and 6 white light emitting diodes (NESW007BT, Nichia Chemical Europe GmbH, Nuremberg, Germany). The camera has a 550 × 582 pixel resolution and a field of view of 120°. The image stream is displayed on a dedicated video screen (Fig. 1d). Images are used not only for diagnosis, but also as feedback to manoeuvre the capsule along the colon lumen. The capsule also embeds a triaxial magnetic sensor (Hall Effect Sensor CY-P15A, Chen Yang Technologies GmbH and Co. KG) used to monitor the magnetic link magnitude, to prevent the risk to lose it, by means of a purposely developed data processing algorithm returning an acoustic alarm signal. In the current prototype, a 2 mm large soft cable, covered by a hydrophilic sheath, provides energy and allows data transmission.

2.2. Experimental setting

In order to verify the feasibility of a complete colon inspection and the accuracy compared to conventional colonoscopy, an ex vivo experimental protocol was defined including a statistical analysis of relevant control parameters (video 1). The proposed task consisted in exploring ex vivo swine large bowel tracts of animals weighing approximately 80 kg. Bowel tissue was composed of straight and curved paths inserted in a human abdominal phantom (Limbs & Things Ltd., Bristol, UK) (Fig. 2) and arranged to mimic human anatomical angles and alignments as well as mesenteric attachments of the entire colon tract, from the rectum to the cecum (850 mm in length); an anal sphincter was also simulated. In order to simulate anatomical stability and hide the tissue arrangement from the operator's view, a foam rubber layer (10 mm in thickness) was interposed between the bowel and a Plexiglas plate, used to reproduce abdominal wall constraint. A fixed constant endoluminal pressure of 1 mmHg was maintained by an endoscopic insufflator (Surgiflator-40, W.O.M. Word of Medicine AG, Germany) connected to a Foley catheter placed transanally. Several 3 mm coloured pins were placed along the colon on the internal surface and their number and position were randomly changed in each trial. For each setting, the user, unaware about the total number of pins to be identified, had first to navigate the capsule through the colon, starting from the rectum and reaching the cecum, identifying and asserting each visualized pin. The same procedure was repeated through a conventional colonoscope. In the case of capsule control, the user took advantage of the magnetic field sensors for the knowledge about the magnetic link strength. Time to complete each test was recorded from the introduction of the scope or capsule to the achievement of the cecum. Twenty-two actors participated to the study: 11 experts, defined as endoscopists with over 5 years' experience and over 1000 colonoscopies performed, and 11 trainees, chosen among residents of the School of Surgery and the School of Gastroenterology of the local University, at their first experience with flexible endoscopy. All the trials were observed by an assistant who recorded the observed target sequence. Before each session, a theoretical briefing on the capsule platform and practical training of 5 min were organized. Medical doctors involved in the tests had no previous experience with the proposed platform. At the end of the test, each user compiled a questionnaire including an evaluation in a scale from 1 (worst) to 5 (best) on how intuitive were the overall control of the robotic platform using the Phantom Omni control peripheral and the overall control with the conventional endoscopic tool in the proposed tasks.

2.3. Statistical analysis

The primary goal of the study was to test the accuracy of the proposed technique. The primary hypothesis was to test in a pilot study the non-inferiority of the proposed technique in terms of accuracy in detecting pins (simulating human polyps). We planned a study of independent cases (capsule endoscopy) and controls (conventional endoscopy). Prior data indicated that the polyp detectability rate by conventional endoscopy is 85%. If the true detectability rate for capsule endoscopy would be 80%, we would need to study at least 632 pins per group to be able to reject the hypothesis that the detectability rates for capsule endoscopy is inferior to conventional endoscopy with probability (power) 80%. The Type I error probability associated with this test of this null hypothesis is 5%. The sample size determined would allow us to detect a non-inferiority margin difference between the group rates of 11.3%. The non-inferiority