

論文内容要旨

A prospective study of the safety and usefulness of
a new miniature wide-angle camera: the “BirdView
camera system”

(新規小型広視野角カメラ「BirdView カメラシステム」の安全性と有用性に関する前向き臨床研究)

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Background

Endoscopic surgery for colorectal cancer has various advantages in comparison to open surgery: similar treatment effects higher esthetic outcomes, less pain, and a shorter hospital stay. On the other hand, the incidence of perioperative complications such as bleeding, bowel injury, and solid organ injury, is reportedly higher in comparison open surgery. The difficulty of endoscopic surgery due to the need to establish a 3D image based on 2D information, a diminished sense of touch, the presence of blind spots (and other issues) is the main reason for the higher incidence of perioperative complications. We therefore developed a system to compensate for the abovementioned blind spots by separately installing a miniature camera with a wide field of view in the abdominal cavity. In the present study, we conducted a clinical trial (Phase I) to confirm the safety and usefulness of our camera system, which has a wide field of view, in human patients.

Methods

This study was an open-label single institutional, nonrandomized single-arm phase 1 clinical trial that was conducted between February 2017 and June 2017 to assess the safety of the novel wide-view camera system (BirdView Camera System; SHARP Corporation, Osaka, Japan). The study was performed independently at Hiroshima University.

Patients

The inclusion criteria were as follows: (1) 20–80 years of age, (2) scheduled to undergo laparoscopic colorectal resection at our hospital, (3) performance status (PS; ECOG) of 0 or 1, (4) the patient's laboratory findings were acceptable, and (5) the patient gave their written informed consent for participation in this study. The exclusion criteria were as follows: (1) a history of abdominal surgery, (2) currently or perioperatively treated with anti-coagulants, (3) a history of myocardial infarction or cerebral infarction, and (4) judged by the research doctor to be unsuited for participation in this study.

The BirdView camera system

The BirdView camera system was designed at Hiroshima University and manufactured by SHARP Corporation (Osaka, Japan). The BirdView camera system, which is capable of providing a wide view of the internal organs during laparoscopic surgery, features a very wide viewing angle of 120° (in comparison to a normal viewing angle of 80°). This system consists of a camera unit for capturing images inside the body and a monitor to display the captured image for the surgeon. The camera unit includes a miniature wide-view camera with a color CMOS imager that captures images of the operative field, and a plastic camera lens and 2 LED lights. The BirdView camera can be inserted into the abdominal space through a 12-mm trocar. The end of the cable of this camera is pulled out through a 3-mm trocar and connected to another cable leading to a control box.

Procedures

The BirdView camera unit was placed within the patient's abdominal space in three steps. Laparoscopic surgery was performed using a medial- to-lateral approach with left colic artery-preserving lymphadenectomy to maintain a good blood supply on the oral side of the colon. The specimen was then removed through the incision, and reconstruction was performed in the abdominal cavity under laparoscopy. After the specimen had been removed, the BirdView camera was removed in two steps.

Safety and efficacy assessments and endpoints

The primary outcome was safety, which was determined by assessing the profile of all surgical adverse events during the perioperative period (within 28 days). The secondary outcomes of efficacy were the operative time, bleeding, duration of hospital stay, operator's mental stress, and the rate of mechanical failure.

Results

Ten patients who underwent laparoscopic surgery with a BirdView camera. The median age of the patients was 59 years, and the BMI values ranged from 17.4 to 26.9 kg/m². In half of the patients, the ASA score was 1 or 2. In 90% of the patients, the PS score was 0. The locations of colorectal cancer were the transverse colon in 10% of the patients, the sigmoid colon in 20%, the rectosigmoid colon in 20%, the Ra rectum in 10%, and the Rb rectum in 40%. The BirdView camera system was used for laparoscopic low-anterior resection. As expected, this system was able to achieve a wider field of view in comparison to conventional laparoscopy. Regarding the primary endpoint, the safety-evaluable population included all 10 patients. Surgical adverse events were in two cases (20%) [problems with ileus (Clavien-Dindo classification grade III) and urination (Clavien-Dindo classification grade II)]. There were no cases of device failure or damage to surrounding organs. There was no external evidence of heat-induced trauma on the abdominal wall from using an LED. Regarding the secondary endpoint, the median operative time was 299.5 min (range 220.0–393.0 min; 95% confidence interval, 233.0–356.0 min), the median blood loss was 35.5 mL (range 6.0–72.0 mL; 95% confidence interval 10–50 mL) and the median post-operative hospital stay was 8 days (range 7–11 days; 95% confidence interval 7–11 days). These values were similar to the average operative time, blood loss, and duration of hospital stay of patients who undergo conventional laparoscopic surgery in our institution. In terms of the operator's mental stress, the subjective performance increased and the subjective temporal demand decreased during laparoscopic surgery using the BirdView camera system.

Conclusions We evaluated the safety of the BirdView camera system. We believe that this camera system will contribute to the performance safe endoscopic surgery and the execution of robotic surgery, in which operators do not have the benefit of tactile feedback.