Investigation of the feasibility of an articulated laparoscopic camera system - Precision Robotics' Sirius Robotic Flexible Endoscopic System in gynaecological laparoscopic surgery

NCT ID not yet assigned
Unique Protocol ID: PRHK HKU-GHK IRB 2021-01
Dated 18 February, 2021

Gleneagles HONG KONG 港怡醫院

Research Protocol

Investigation of the feasibility of an articulated laparoscopic camera system - Precision Robotics' Sirius Robotic Flexible Endoscopic System in gynaecological laparoscopic surgery

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Background

Laparoscopic procedures for benign gynaecology are well established. For gynaecological oncology, laparoscopic total hysterectomy bilateral salpingo-ophorectomy is the gold standard for the surgical management of early-stage carcinoma of the corpus. Compared to laparotomy, laparoscopy is associated with reduced morbidity and quicker recovery with no compromise to overall survival.[1,2,3,4] With advancement in laparoscopic technology, minimal access surgery has progressed to single incision laparoscopy (SILS) and natural orifice surgery (vNOTEs) thus further reducing morbidity and enhancing recovery.[5,6]

Precision Robotics' Sirius System is a fully integrated compact 3D laparoscopic system with a flexible tip that can change its viewing direction. The articulated tip has three degrees of freedom enabling C and S-shaped bending providing a wider field of view compared to conventional laparoscopes. This wider field of view is of particular advantage for SILS and vNOTEs, and presently available commercial systems do not have the same field of view or degrees of freedom. In addition to the robotic flexible laparoscope, the system is an fully integrated compact system which consists of a video processor box with an integrated bright white light source, a handle and cable to connect the laparoscope to the video processor box, and a handheld joystick for control. [7,8,9,10]

From September 2019 to July 2020, three animal studies were performed by Precision Robotics in collaboration with National Taiwan University Hospital and Shanghai Ruijin Hospital. Using the Sirius System, expert surgeons successfully conducted the following procedures:

- Laparoscopic Surgery - Performed a cholecystectomy where the gallbladder was removed from an animal model laparoscopically.
- Trans-anal Surgery - A small tissue sample was removed using an electronic knife to test the system's performance in a SILS operation with a porcine model.
- Orthopaedics Surgery - Conducted a MIS-TLIF (minimally invasive surgery - Transforaminal lumbar interbody fusion) operation on an animal cadaver.

Surgeons were able to complete their full surgical workflows using the system, and feedback was incorporated in refining the system's design.

In addition to animal studies, the system's safety was demonstrated through extensive testing by qualified testing centres in compliance with electromagnetic compatibility (EMC) and electrical safety standards. Tested in accordance to IEC 60601-1-2: 2014 / EN 60601-1-2:2015, FCC 47CFR Part 15: 2018 ANSI C63.4:2014, IEC 60601-1:2005+AMD1:2012 and IEC 60601-2-18:2009, Biocompatibility test for all material in contact with patient body according to ISO 10993.

Aim of the Study

To assess the safety, reliability and efficacy of an articulated laparoscopic camera system - Precision Robotics' Sirius Robotic Flexible Endoscopic System in gynaecological laparoscopic surgery particularly for Single Incision Laparoscopic Surgery(SILS) and Vaginal Natural Orifice Transluminal Endoscopy(vNOTEs).

The aim in this pilot study is to show that the Sirius System can safely replace the conventional endoscope in the surgical workflow for gynaecological laparoscopic surgery.

Methods

Trial Design and Study Analysis

This is a pilot study to be conducted at GHK. All patient listed for gynaecological laparoscopic surgery by the principal investigator(PI) aged 18 -70 years will be invited to participate in the study. An information sheet and consent for the study in English and Chinese will be available for the patient, and an informed consent will be taken by the PI. It will be emphasized that participation in the study is voluntary, and if they do not consent to the study, it will not affect their subsequent treatment and management.

Anonymized video data of the surgical procedure will be captured for analysis and validation. The recording will be only of the surgical field and only during the surgical procedure to prevent capturing any personal identifiable details. The surgical staff will start and stop the video recording feature on the Sirius System.

The anonymized clinical outcome of the procedure will be taken from clinical records by the PI. Clinical data will be extracted from the patient records by the PI.

Study date

The study date will be from 01-03-2021 to 30-09-2021 with a target of 60 participants.

We estimate that there will be 12 patients for laparoscopic surgery per month and therefor a target of 60 patients will be recruited in 5 months. A study duration of 7 months will ensure patients have at least 6 weeks of follow-up to document postoperative complications. It is our opinion that even with a conservative estimate that only 50% of the targeted patients will agree to the study with a written informed consent, a final figure of 30 participants will be adequate for a pilot study.

Participants

All patients aged 18-70 years listed for gynaecological laparoscopic surgery by the PI will be invited to participate in the study. An informed consent for the procedure and a separate consent and information sheet for the study available in English and Chinese will be given to the patient.

Exclusion criteria are:

Pregnancy

Failure to provide written informed consent for the study

Intervention, procedures and standard care

The laparoscopic procedure will be done in the usual manner. The only difference is that for the study participants, the Sirius System will be used in place of the conventional endoscope. All other procedures and instruments including the number of ports remain the same.

To further enhance safety for patients, a simulator is available on-site at GHK for the surgical team to practise on prior to operating on patients. This is to ensure every member of the surgical team including nurse assistants are familiar with the Sirius System prior to their involvement in the actual surgical procedure.

For every procedure using the Sirius System, a conventional endoscope will be on immediate standby to replace the Sirius System should there be an unanticipated equipment failure so that the procedure can be completed without delay.

Outcome measure

Primary outcome is measured by the proportion of women who successfully completed the intended procedure using the Sirius system without conversion to another camera system. The proportion of patients who completed the laparoscopic procedures successfully using the Sirius System will be measured as the primary outcome of success.

Secondary outcomes are measured by the incidence of intraoperative complications, incidence of postoperative complications during the first 6 weeks following surgery and duration of surgery. Duration of surgery is measured in minutes from urinary catheter insertion to closure of vaginal/abdominal wound. Intraoperative or Postoperative complications are classified according to Clavien-Dindo classification during the first 6 weeks of surgery.[11]

The recorded video data will be analysed for visual defects and quality. Anonymized clinical data will be taken from patient clinical records by the PI for analysis.

Study Endpoints

Main Study Parameter

The proportion of patients who successfully completed their procedure with the Sirius System without resorting to another camera system.

Secondary Study Parameters

Incidence of intraoperative complications.

Incidence of postoperative complications during the first 6 weeks following surgery.

Duration of surgery.

Results

Recruitment time frame

The tentative time for the study is from 01-03-2021 to 30-09-2021. We aim to recruit 60 participants. Only eligible women with written informed consent will participate in the trial.

Data Collection

We will collect the following baseline patient characteristics: age, diagnosis, name of surgery, date of surgery.

On discharge from hospital, we will collect the following data: date of admission, date of discharge, duration of surgery, blood loss, the successful completion of the procedure with the Sirius System without conversion to another camera system, intraoperative and postoperative complications. These data will be extracted from the hospital database by the PI and entered into a laptop computer protected by a password accessible only to the PI.

Anonymized video data of the surgical procedure will be captured for analysis and validation. The recording will be only of the surgical field and only during the surgical procedure to prevent capturing any personal identifiable details. The data will be stored for up to seven years on the secure servers of PRHK. After which, the data and all its copies will be deleted. Data can be removed at the request of participants at any time during and after the study, and the request shall be made by the participant to the Principal Investigator.

Only the PI will have access to the key to identify patients. No one from Precision Robotics will have access to the key.

Postoperatively, all patients will be seen by the PI at one week, one month and three months after surgery. Readmission to hospital and the occurrence of other postoperative complications classified according to the Clavien-Dindo classification will be recorded.

Discussions

This is a single institution prospective pilot study confined to a single surgeon(PI) and patients managed by that surgeon. This would be described as an Idea Development Exploration Assessment Long term study (IDEAL) Stage 2a development trial.[12] Confining the study to a single surgeon means that the only variable is the camera system used.

If this initial pilot trial is successful, it is our intention to continue with an IDEAL Stage 2b exploration trial involving other surgeons and disciplines as well as other institutions. The advantage of the flexible Sirius System will also be exploited in advanced laparoscopic surgeries including vNOTES where a flexible endoscope will have particular advantages. It is anticipated that results from such trials will be published as conference papers or scientific journals.

Ethics and Dissemination

The trial will be conducted in accordance with the ethical principles of the latest "Declaration of Helsinki". All patients eligible for the study will receive a consent and information sheet available in English and Chinese. A written informed consent will be required before participation in the study. It will also be emphasized that participation in the study is voluntary and non-participation will not affect their usual treatment and management. The study protocol, information sheet and consent will be submitted to the GHK Institutional Review Board for approval.

The study is sponsored by Precision Robotics(PRHK) who will provide the Sirius Camera system. However, they will not be involved in the management or recruitment of patients. They will also not have access to identifiable patient data. All records that contain names or other personal identifiers will be stored separately from study records identified by a code number. PRHK will provide the camera system as well as technical support.

At the end of the trial, the complete data set will be available to all investigators. Dr. Ng Tong Yow and Dr. Ngu Siew Fei declare that we have no conflict of interests with respect to the present study. Dr. Benny Lo is Chief Technology Adviser to Precision Robotics Hong Kong.

It is the intention that the trial results will be disseminated through scientific journals and at scientific conference presentations. All trial investigators will contribute to authorship following the International Committee of Medical Journal Editor's authorship eligibility guidelines.

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