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Protocol for a modified vaginal pipe for total laparoscopic hysterectomies: Experimental research

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ABSTRACT

Background: The Vagi-Pipe® is a useful device for performing a total laparoscopic hysterectomy. The conventional model of the Vagi-Pipe® is unable to grasp the uterus during colpotomy for recovery of the resected uterus. However, the modified C-Type Vagi-Pipe® model has a shape that allows insertion into the vagina without removing the uterus manipulator. In this study, we will prospectively investigate the safety and efficacy of the C-Type Vagi-Pipe® in total laparoscopic hysterectomies.

Materials and methods: In total, 25 female subjects aged between 20 and 60 years with uterine fibroids or adenomyosis will be included. Patients with complications regarded as unsuitable for this study by the investigators will be excluded. The C-Type Vagi-Pipe® will be used rather than the conventional Vagi-Pipe® when performing a total laparoscopic hysterectomy. The primary endpoint will be safety and the secondary endpoints will be operation time, bleeding volume, and presence of complications.

Ethics and dissemination: The protocol was approved by the institutional review boards. Written informed consent will be obtained from all patients before registration in accordance with the Declaration of Helsinki. Results of the study will be disseminated via publications in peer-reviewed journals.

1. Introduction

Total laparoscopic hysterectomy (TLH) is becoming the standard radical surgical procedure for the treatment of common uterine tumors, such as fibroids and adenomyosis. In comparison to open surgery, a TLH is superior in terms of the degree of invasiveness and in terms of cosmetic concerns, but requires advanced surgical skills, including that for a colpotomy [1].

The Vagi-Pipe® is a widely used device when performing a colpotomy as part of a TLH. For the standard procedure of a TLH, a uterine manipulator is inserted through the cervix into the uterine cavity to manipulate the uterus, which reduces the surgical difficulty. During colpotomy, the Vagi-Pipe® is inserted into the vagina to stretch the vaginal wall and let the incision line clear. To insert the conventional model of Vagi-Pipe®, however, the uterine manipulator must be removed in advance. The conventional model is unable to grasp the uterus, requiring more effort to manipulate the uterus during colpotomy and recovery of the resected uterus through the vagina.

The C-Type Vagi-Pipe® has a modified shape that allows it to be inserted into the vagina simultaneously with a uterine manipulator grasping the uterus. The uterine manipulator does not have to be removed in advance. Therefore, the C-Type Vagi-Pipe® allows the manipulated uterus to be anteflexed and retroflexed during colpotomy and recovery procedures. This functionality can lead to reduced difficulty of the surgical procedure.

In this study, we aim to confirm the evaluate the safety and efficacy of the C-Type Vagi-Pipe®. If these aspects are confirmed, introduction of the C-Type Vagi-Pipe® is expected to allow TLH to be performed at many more medical facilities, as it would make the procedure easier to perform.

2. Materials and methods

2.1. Study design and study setting

The study is a single-arm, open, phase I trial. The protocol was approved by the clinical research review board. Written informed consent will be obtained from all patients before registration in accordance with the Declaration of Helsinki. At least annual

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independent monitoring is planned, in accordance with Japanese clinical trial guidelines.

2.2. Participants

The inclusion criteria are as follows:

(1) Patients with clinically confirmed uterine fibroids
(2) Patients with clinically confirmed uterine adenomyosis
(3) Patients able to accept surgical treatment
(4) Patients capable of participating in this study for at least a 1-week hospital stay or corresponding management
(5) Patients who are between 20 and 60 years of age (at the time of enrollment)
(6) Patients who provide written informed consent to participate in the study

The exclusion criteria are as follows:

(1) Patients with malignant tumors
(2) Patients with infectious disorders requiring treatment with antibacterial drugs or antimycotics
(3) Patients with uncontrollable diabetes mellitus
(4) Patients who have complications of a clinical concern (such as uncontrollable cardiac disease, severe cardiac arrhythmia requiring medical treatment, and sustained digestive diseases)
(5) Any other patients who are regarded as unsuitable for this study by the investigators

The following patient population will be analyzed:
All subjects enrolled in this study (full analysis set, FAS); subjects excluding patients with serious violations, such as serious protocol deviation, violation for inclusion/exclusion criteria, and violation for prohibited concomitant medication/therapy from the FAS (per protocol); and among the FAS in which the protocol treatment is provided at least once (safety analysis set).

2.3. Study endpoints and treatment regimens

The primary endpoint is safety and the secondary endpoints are operation time, bleeding volume, and presence of complications. We will utilize the C-Type Vagi-Pipe® rather than the conventional Vagi-Pipe® when performing a TLH. The C-Type Vagi-Pipe® has an improved morphology consisting of a tube-like structure with an opening only at the tip of the pipe (Fig. 1). This allows the device to be inserted through the vagina into the uterus along with the uterus manipulator.

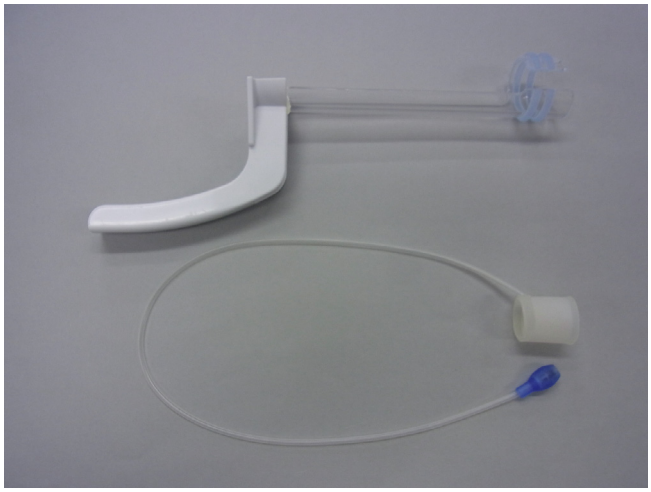

Fig. 1. The C-Type Vagi-Pipe®.

2.4. Rationale for the setting of the number of enrolled subjects

The conventional Vagi-Pipe® model has been classified as a Class I device in terms of the risk it poses to the human body. However, its safety has never been verified via a clinical study. The C-Type Vagi-Pipe® has not been subjected to a multi-center clinical study and assessments of its safety and other features are yet to be performed. As a result, its use in Japan is not yet approved. This will be the first clinical study on the C-Type device in humans conducted in Japan. It is, therefore, a pilot study whose primary endpoint is safety. The incidence of complications reported following a TLH is approximately 1.5% [2]. Therefore, we calculated that the number of subjects required to assess the safety of the device with a reliability of 95% and an error of within 5% as 23 subjects.

2.5. Statistical methods

Safety: grade and frequency of each adverse event
Operation time: total time during operation
Bleeding volume: total amount of blood loss during operation
Presence of complications: grade and frequency of each complication

2.6. Ethics and trial status

The trial received ethical approval from the ethics committee. The trial is subject to the supervision and management of the ethics committee. This study opened to recruitment in July 2016, with a planned last follow up in March 2024. As of April 2019, 8 subjects have been enrolled.

3. Discussion

Total laparoscopic hysterectomy (TLH) is currently the standard surgical procedure used in cases of benign uterine diseases, and its indications are to be expanded to include uterine malignancies, such as uterine and cervical cancers [1,3]. Furthermore, robot-assisted laparoscopic hysterectomy (LH) has begun to be performed in recent years, also leading to marked expansion of laparoscopic surgeries [4,5]. Nevertheless, the number of facilities currently able to perform a TLH on malignancies or robot-assisted LH remains limited [6]. One reason for this is the fact that the entire surgical team, including the surgical assistants, must have a certain level of expertise in the procedure of TLH.

When performing a TLH, the second surgical assistant manipulates the uterus using the uterus manipulator. When performing a colpotomy in a TLH, the uterus is displaced in the cranial direction while simultaneously maintaining a fixed degree of tension on the incision line on the vaginal wall in order to allow a keen incision. However, this process can be quite difficult to perform without the uterus manipulator.

The modified vaginal pipe that will be utilized in the present study has a morphology that differs from the conventional model in that it is not a perfect cylindrical shape. Only the tip has a cylindrical shape and there is a space on the side, making it C-shaped. This space allows the uterus manipulator to pass through along the side of the modified vaginal pipe, allowing the device to be used in the same way as the conventional device without requiring removal of the uterus manipulator prior to insertion. This modification allows the uterus manipulator to grasp the uterus during colpotomy and recover the uterus. It may lead to greater uterine mobility, making it easier for the first surgical assistant to ensure

the surgical field, allowing the surgeon to make the vaginal wall incision and the recovery of the resected uterus less difficult. As a result, the use of the modified vaginal pipe may allow the conventional TLH to be more easily performed; with a shorter surgical duration, decreased blood loss, and fewer complications.

If this study shows that the modified vaginal pipe is safe, a TLH may be performed more safely and with less difficulty using this device. This may encourage larger numbers of medical facilities to adopt the C-Type Vagi-Pipe® for TLH.

Trial registration

Japan Registry of Clinical Trials (jRCT), jRCTs052180221.

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Ethical approval

The trial received ethical approval from the Ethics Committee of Kyoto Prefectural University of Medicine, Kyoto, Japan (number: ERB-C-609-3, the last edition ver 2 17/Jun/2016). The trial is subject to the supervision and management of the Ethics Committee. This study opened to recruitment in July 2016, with a planned last follow up in March 2024. As of April 2019, 8 subjects have been enrolled.

Author contribution

F.I. and J.K. conceived and designed the study; F.I., T.K., H.M., A. K., and I.K. perform the study; F.I., T.M., and J.K. will analyze the data and interpret the results of the study; F.I., T.M., and J.K. edited and revised the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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