Comparison of the ClearView Uterine Manipulator with the Cohen Cannula in Laparoscopy

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Abstract

The ClearView Uterine Manipulator was compared with the Choen acorn-tipped cannula for efficacy and safety in patients undergoing laparoscopy at the University of Utah medical Center. Fifty consecutive patients were randomized by computer to have either the ClearView instrument or the Choen cannula used as a uterine manipulator (25 patients each). The ClearView manipulator was statistically superior to the Choen cannula for range of motion in the anterior and posterior sagittal plane ($p < 0.0001$). The Cohen cannula was consistently inserted in less time ($p < 0.02$). There was no statistically significant difference between the instruments in ease of uterine manipulation, ease of dye instillation, percentage of dye leakage from the cervix, overall ease of use, ease of device insertion, and ease of device removal. Two cervical perforations occurred during cervical dilatation in the ClearView manipulator group in patients with cervical stenosis requiring dilatation with metal dilators (os <2 mm). No patients in the Cohen cannula group had cervical stenosis. In that group two cervical lacerations occurred requiring suture ligation. The ClearView instrument provides a greater range of motion, does not require an assistant to maintain uterine position, and allows manipulation without a cervical dilatation, increasing the time of insertion compared with placement of the Cohen cannula. In patients with cervical stenosis, use of a uterine sound and cervical dilatation increase the risk of perforation.

Adequate exposure is a well-known requirement in abdominal surgery. The same is true for laparoscopic surgery, as procedures have become increasingly complex with physician experience and technologic advances. To improve exposure at laparoscopy, a number of devices have been developed to manipulate the uterus, including the Cohen cannula (Karl Storz, Culver City, CA), Majoli manipulator (Cook, Spencer, IN.), BARD manipulator (BARD Inc., Billerica, MA), Valtchev Uterine Mobilizer (Conkin Instruments, Toronto, Ontario), Harris-Kronner Uterine Manipulator Injector (HUMI) (UNIMAR, Wilton, CT), Zinnati Uterine Manipulator Injector (ZUMI) (Zinnanti Suirgical Instruments, Chatsworth, CA), and Hasson balloon elevator cannula (LINVATEC, Largo, FL). Some of these also allow dye injection for evaluating fallopian tube patency.

The ClearView Uterine Manipulator (Clinical Innovations, Murray, UT) was designed as an inexpensive, disposable instrument to allow safe and optimum uterine manipulation with the ability to perform chromotubation. In addition, the device has the ability to vary the angle of the uterine manipulation mechanically and to maintain the uterine position without the need for an assistant to hold the instrument. We prospectively compared the ClearView manipulator with the Cohen acorn-tipped cannula, in common use at our institution, for efficacy, safety, and ease of use.

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Presented at the 23rd annual meeting of the American Association of Gynecologic Laparoscopists, New York.

Materials and Methods

Between October 1993 and April 1994, 50 consecutive patients undergoing laparoscopic surgery were enrolled and randomized by a computer-generated random number table to have the ClearView Uterine Manipulator or the Cohen cannula used for uterine manipulation. Twenty-five subjects were enrolled into each arm. The variables studied were age, parity, surgical indications, operating room time, ease of uterine manipulation, range of uterine manipulation in the anterior and posterior sagittal planes, ease of dye instillation, percentage of dye leakage, overall ease of use, ease of insertion and removal, insertion time, requirement for tenaculum use, and ability to perform laparoscopy in the supine rather than the dorsal lithotomy position.

All physicians participating in the study were experienced in using the Cohen cannula and in sounding and dilating the uterine cervix. Before subjects were enrolled, the study was approved by the institutional review board, and written informed consent was obtained from each patient.

The ClearView Manipulator

The ClearView manipulators were donated by the manufacturer for this evaluation. The instrument is a disposable, plastic, single-unit device with a rotating control knob at the handle that elevates the intrauterine tip, an enclosure, a pivoting tip, an inflatable balloon, and a luer fitting for dye instillation (Figures 1 and 2). By turning the retractor control knob at the handle, the pivoting tip has a range of motion of 170 degrees in the sagittal plane, Clockwise rotation of the control knob elevates the uterus to the anteverted position, and counter-clockwise rotation causes uterine retroversion.

Data Analysis

All subjective variables were evaluated on a scale of 1 to 10 (ease of uterine manipulation, ease of dye instillation, overall ease of use, ease of device insertion, ease of device removal). Range of motion was quantified by the surgeon by defining the visual midplane as 0 degrees. Anterior and posterior range of motion was then estimated by rotating the uterus anteriorly and posteriorly from this reference point.

Between-group comparisons were evaluated by the Mann-Whitney rank sum test (original data), the unpaired Student's *t* test (interval data), and X2 analysis (percentage data) where applicable, and are reported as mean $\pm$ standard error of the mean. Statistical significance was defined as probability below 0.05.

Operative Procedures

All patients received a general anesthetic. After the patient was anesthetized, a bimanual examination was performed to determine the position of the uterus. The vagina was prepared with an antiseptic solution and a sterile speculum was inserted.

The Cohen cannula protocol was as follows. A single-tooth tenaculum was placed on the anterior lip of the cervix, and traction was employed while the Cohen cannula tip was placed through the endocervical canal. The acron tip was pointed anterior or posterior depending on the axis of the uterus. The cannula was spring-loaded onto the tenaculum to spring-loading the cannula on the tenaculum was recorded.

The ClearView manipulator protocol was as follows. The endometrial cavity was sounded for length with a plastic ClearView Sound/Dilator, and the reverse end of the sound/dilator was passed to ensure that the cervix would accept the 5-mm diameter intrauterine balloon tip. For every centimeter less than 8 cm, a spacer was placed at the base of the manipulating tip to prevent perforation of the uterine fundus. The tip of the ClearView instrument was placed through the endocervical canal and into the endometrial cavity, and the balloon was inflated with 4ml sterile water. If the manipulator tip would not pass easily through the endocervix, the cervix was dilated to the appropriate size to allow insertion, and a second attempt was made. If necessary, a single-tooth tenaculum was used to accomplish these procedures. All instruments and maneuvers used were recorded, and the

procedure was timed from start of the sounding of the cervix to completion of placement of the manipulator.

Results

There was no statistically significant difference between the two groups with regard to demographics. The mean age was 31.9 ± 4.8 years in the ClearView group and 30.9 ± 6.1 years in the Cohen cannula group. In the former group, 44% women were nulliparous compared with 60% in the latter group. Indications for uterine manipulation in the Cohen cannula group were pelvic pain or endometriosis (17 women), abnormal hysterosalpingogram or infertility (3), tubal sterilization (2), and adnexal mass (1). In the ClearView group the indications were pelvic pain or endometriosis (15), tubal sterilization (4), adnexal mass (1), and laparoscopic-assisted vaginal hysterectomy (1). Total operating times were 64 ± 31.2 minutes in the ClearView group and 61 ± 32.8 minutes in the Cohen cannula group.

Other variables evaluated are show in Table 1. Range of uterine motion in the anterior and posterior sagittal planes favored the ClearView manipulator, 120.4 ± 14.9 degrees versus 84 ± 14.4 degrees ($p < 0.0001$) and –19.6 ± 10.6 degrees versus –8.4 ± 5.5 degrees, respectively (p .0001). There was no statistical difference between the two groups with regard to ease of uterine manipulation, ease of dye instillation, percentage of dye leakage from the cervix, ease of insertion and removal, or overall ease of use. Insertion time was less with the Cohen cannula (mean 27.4 ± 31.3 sec vs 115.6 ± 160.7 sec, $p < 0.02$). In 16 (64%) of the ClearView cases, a tenaculum and dilatation were not required for device insertion. In addition, the instrument enabled the uterus to be manipulated while the patient was in the supine position in all cases.

The uterus was perforated in two patients with cervical stenosis (os<2mm) in the ClearView group. The perforations occurred during cervical dilatation using a lacrimal duct probe and a metal sound, and were not attributed to the ClearView group. The perforations occurred during cervical dilatation using a lacrimal duct probe and a metal sound, and were not attributed to the ClearView device or the ClearView Sound/Dilator. The ClearView manipulator was inserted despite the perforations, and its manipulating function was unaffected. Neither of these perforations resulted in hemorrhage or prolonged hospital stay.

No uterine perforations occurred in the Cohen cannula group; however, no patients in this group had cervical stenosis. Two cervical lacerations occurred in this group and required suture ligation or coagulation. No laceration occurred in the ClearView group.

Ten physicians participated in inserting the manipulators; nine evaluated the ClearView instrument and seven evaluated the Cohen cannula.

Discussion

Adequate exposure is vital in pelvic surgery. During laparoscopic procedures, uterine manipulation is an integral part of obtaining exposure. The ideal uterine manipulator would be inexpensive (whether reusable or disposable), convenient and quick to use, safe (especially by avoiding the need for dilatation and a tenaculum), and have the ability to inject solutions into the uterine cavity as weel as offer optimum range of motion of the uterus while avoiding the need for an assistant. No one device appears to have all these attributes. Most uterine manipulators are essentially rigid instruments that are attached or fixed to the uterus and protrude from the vagina. 1-3 Some are part of the instrument (Majoli manipultor) or separate (Cohen cannula).

Bleeding from tenaculum site is usually not significant, but may occasionally require suturing. A class of uterine manipulators has been developed that does not rely on a tenaculum during manipulation, such as the BARD, HUMI, ZUMI, and Hasson balloon elevator. These are held in place by a balloon inflated within the uterine cavity with counter-pressure applied against the external cervical portion by a second balloon (BARD), a friction-adjustable (ZUMI) or spring-loaded platform (HUMI) on the handle of the manipulator, or an

attachable weight and chain (Hasson). These instruments also allow intrauterine instillation of liquid for chromotubation.

Some manipulators, including the tenaculum-free types, have affixed curves in their shafts to assist in flexing the uterus. The handle of the instrument is grasped 4 to 6 inches outside the vagina, allowing approximately 45 degrees of anterior motion and 15 degrees of posterior motion. The external vaginal orifice is the fulcrum for these manipulators whether or not they have straight or curved shafts. The ClearView device's pivot point is at the external cervical os, and therefore the effects of obesity and other anatomic impediments to the range of uterine flexion are diminished.

A limitation of uterine manipulators in general has been the need for an assistant to decrease bias. In addition, several observers concurred on the apparent improvement in anterior and jposterior range of uterine manipulation as well as the increased time required for insertion.

Cervical perforations occurred in 2 of the 25 patients assigned to the ClearView group. These occurred during dilatation with a set of small dilators due to cervical stenosis. No perforations were attributed to the instrument itself or to the sound-dilator. The molded ClearView Sound/Dilator was of such a diameter and flexibility that pressure sufficient to dilate the cervix could not be achieved, and thus metal dilators were required, and these resulted in perforation. No perforation occurred during the insertion phase or use of the ClearView Uterine Manipulator, and no lacerations from cervical tenacula occurred with the device.

Although the ClearView manipulator takes longer to insert than the Cohen cannula and may require sounding and dilating, the increased range of uterine motion, capability for chromotubation, ability to perform laparoscopy in the supine position without an assistant, and maintain uterine positioning. The ClearView instrument enables the surgeon to manipulate the uterus without an assistant, with the patient in the supine (legs together and flat) position. This is an advantage when there are no extra support staff in the operating room, and obviates the use of stirrups that can reduce the amount of hip flexion and leg compression for extended periods of time. The Valtchev Uterine Mobilizer uses the cervix as a pivot point, which allows manipulation over a wide range of motion. It is reusable device that requires a cervical tenaculum.

Due to obvious differences between the Cohen cannula and the ClearView Uterine Manipulator, blinding of operators in this study was not possible. However, consecutive patient assignment and randomization were included to reduced requirement for a cervical tenaculum may outweigh that disadvantage. We recommend caution in patients with cervical stenosis who require cervical dilatation. The evaluators found the ClearView manipulator to be of particular assistance in patients with sever cul-de-sac adhesions and retroverted uteri, as the increased anterior range of motion allowed better exposure posteriorly.

Referneces

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