A Modified Technique to Simplify TLH with New Developed Uterine Manipulator; Anurach Uterine Manipulator (AUM)

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Objective: *Total Laparoscopic hysterectomy (TLH) has became more commonly procedures for gynaecological surgery, but high incidence of complications and the technical challenges are still problematic among less-experienced surgeons. To accomplish these difficulties, we developed the new uterine manipulator; Anurach uterine manipulator (AUM) to simplify TLH with the modified technique. Our objective was to evaluate the feasibility of the new uterine manipulator, AUM, with the modified total laparoscopic hysterectomy in an initial cohort of patients.*
Material and Method: *From October 2007 though September 2008, one hundred cases of hysterectomy were done by modified technique of TLH using AUM. After installation of AUM, a modified technique of TLH was started by posterior colpotomy, then extended to anterior colpotomy. The operation was performed using bipolar and harmonic scapel for coagulation and cutting the vascular pedicles and ligaments. The entire procedure was done laparoscopically and the uterus was removed vaginally. The vaginal cuff was closed by continuous suture, double layers with PDS material.*
Results: *Most common indication was symptomatic leiomyoma, the uterine size was 64-620 grams. Mean operation time was 98 $\pm$ 27.1 minutes. Estimated blood loss was 188 $\pm$ 87.5 ml. There were no bowel or ureteric injuries, except 2 cases of bladder injury which had been repaired laparoscopically.*
Conclusion: *The modified technique using AUM could be the option to simplify TLH, in reducing the complications and having more favorable operative outcomes.*

Keywords: *Total laparoscopic hysterectomy, Uterine manipulator*

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Currently, total laparoscopic hysterectomy (TLH) is used to treat a number of benign gynecological disorders. However, the technical challenges, such as positioning of instruments, bleeding and prolonged operative times involved remain important issues for the laparoscopic gynecologist[1]. In addition, among less-experienced surgeons, there is a high incidence of serious complications with TLH[2].

For these reasons, many techniques and several kinds of equipments have been developed to improve the procedure such as positioning the ports of entry or vascular sealing systems[1]. In addition, several types of uterine manipulators have been developed to improve the TLH operation[3-7]. However, most of the uterine manipulators are not reusable. The use of uterine manipulators is very expensive relative to patients' income in developing countries.

We have developed a new uterine manipulator; Anurach uterine manipulator (AUM) to improve the TLH outcomes and remove many of the above mentioned difficulties. The instrument has been used in TLH procedure at the Department of Obstetrics and Gynecology, Pranangklao Hospital, Nonthaburi, Thailand since October 2007.

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Objective

To evaluate the feasibility of the new uterine manipulator, AUM, with the modified total laparoscopic

hysterectomy in an initial cohort of patients.

Material and Method

This prospective descriptive study was conducted at Pranangklao Hospital, Nonthaburi, Thailand from October 2007 to September 2008. The study was approved by the Pranangklao Hospital Ethical Committee. Written informed consent was obtained for every patient evaluated. Patients with benign gynecologic diseases who needed hysterectomy were recruited. Excluded were patients for whom the diagnosis of gynecologic cancers was suspected. Age, weight and BMI of each patient were recorded. All three participating surgeons were well experienced in laparoscopically assisted vaginal hysterectomy, LAVH[8] and had a minimum experience of 30 conventional TLH cases. Each surgeon received instruction on how to use the AUM device and the modified technique for the operation.

The Anurach uterine manipulator (AUM) was made in house from a 40 cm stainless steel shaft. It was shaped as a rod with a thread at the distal end (Fig. 1). The proximal end of the shaft was the handle. Diameter of the shaft at the distal end was thinner than the rest of the shaft. The vaginal balloon was adapted from a No. 26 Foley catheter had been placed at the distal end near the thread to function as a pneumo-occluder when in place in the vagina. An eye hole near the handle was designed to receive a spring hook so that the AUM would be retained within the cervix.

The obturators were 5 mm in diameter and come in 7, 9, 11 cm lengths respectively (Fig. 2). Each had an upward 15 degrees angle and was connected to the shaft thread. The tubular cervical cups were made of blue ceramic. Each was 20 mm in height and came in different diameters of 25, 30, 35 and 40 mm respectively. Each cup had a roll out rim like the mouth of the bottle. This design makes a clearer visualization of the cervico-vaginal fold when the cup is placed in the vaginal fornices. The higher rim was designed to fit the posterior fornix.

The cervical plates were 10 mm in width and were made in the lengths of 30, 35, 40, and 45 mm. The cervical plate must be connected to the shaft before the obturator.

Material testing

The main component of AUM has been made from the same materials as the Songkla Uterine Manipulator (SUM)[7]. The ceramic stoneware cervical cup was specially ordered from local manufacturer. The cups were fired at 1,250°C and tested to ensure no electrical conductivity. Tissue toxicity had been tested and approved for human safety by the Department of Science Service, Ministry of Science and Environment, Thailand.

Fig. 1 A stainless steel shaft with modified Foley catheter as a replaceable vaginal balloon

Fig. 2 Components of Anurach uterine manipulator are demonstrated; The first row from top (C)-ceramic cervical cups, the second row (P)-cervical plates, the third row (O)-obturators and the fourth row (S)-spring

Surgical technique

Each patient received general anesthesia, which was maintained for the duration of the operation. The patient was then prepared in the lower Trendelenburg position. The size, position and mobility of the uterus were established by vaginal examination. This information was used to select the appropriate obturator length and cervical cup size for the procedure. The No. 26 Foley catheter was replaced for each operation. All AUM components were sterilized prior to each operation. The patient's bladder was then emptied and the catheter retained.

After the cervical canal was dilated with the Hegar dilator, its anterior lip was sutured and ligated at

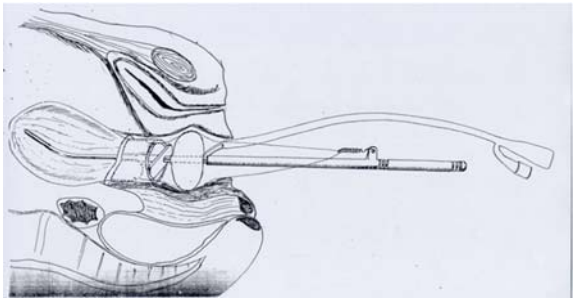

Fig. 3 Drawing picture showed the position of AUM after installation; the shaft with obturator was inserted along uterine cavity axis, the spring was locked into the suture loop and the eye hole. The sterile water was used to inflate the vaginal balloon.

the 12 o'clock position. The excess length of suture material was left outside the vagina. The posterior cervix was then sutured in the same manner. Both ends of the suturing materials were then tied together outside the vaginal wall to make a loop. The cervical cup was then pushed inside the vagina to cover the cervix until the roll of the cervical cup was placed into both anterior and posterior sides of the cervico-vaginal fornices.

Size of the cervical plate was selected according to the cervical cup size. The cervical plate and the obturator were then connected to the distal end of the shaft to complete the AUM equipment. To install AUM in place, the equipment was carefully inserted into the uterine cavity along its axis until the cervical plate attached to the cervical cup. The spring was then locked into the suture loop and the eye hole near the shaft handle to maintain the AUM in an established position (Fig. 3). Finally, 50-75 cc of sterile water was used to inflate the vaginal balloon to be used as a vaginal occluder. One 10-mm subumbilical port for the optical telescope and three 5-mm ports were used during the operation. One 5-mm port was placed in the lower left abdomen. Two 5-mm ports were located on the lower right abdomen.

A pair of bipolar diathermy forceps, harmonic scalpel, graspers, a laparoscopic needle holder and a monopolar needle were required for the following surgical procedure. The incision was first started with a posterior colpotomy until the blue cup was clearly seen. Then the vesicouterine fold was incised to further anterior colpotomy. Note that in classical TLH, this is among the final steps of the procedure rather than the first. The AUM device provided the precise location for the cervico-vaginal fold. When the ovaries were to be preserved, the fallopian tube and the ovarian ligaments were then desiccated and cut. The infundibulopelvic ligaments would be cut if the ovaries were to be removed. The uterine vascular pedicles were also excised with the harmonic scalpel after bipolar diathermy. The blue cup at the anterior and posterior fornices made a direct clear marking for lateral incision. The instrument with the uterus and/or adnexa was then completely removed. Finally, continuous laparoscopic suturing of the vaginal vault was carried out to complete the closure of the vagina. Total operating time was recorded. All patients were followed-up for 6 weeks after the surgery.

Results

The one hundred women were participating in the research from October 2007 to September 2008. Patients were between the ages of 35 and 64. Their average age and BMI were 45.4 years and 24.5 kg/m^2. All patients underwent the modified TLH procedure using AUM. Indications for hysterectomy were symptomatic leiomyoma, adenomyosis, hypermenorrhea and endometrial hyperplasia in 72, 12, 8 and 8 patients respectively. Patient characteristics and the operative outcomes are shown in Table 1.

The mean operating time was 98.4 minutes. The mean uterine weight was 287 g, ranged from 64-620 grams. There were no ureteral or bowel injuries occurring in any of the patients. However there were two cases with bladder injuries which occurred intraoperatively. The incidences were repaired laparoscopically. There was no case of further complications in the postoperative period of all 100 cases.

Discussion

The laparoscopic hysterectomy has been developed to have low complications at the same level as vaginal hysterectomy[9]. The major complication risks of laparoscopic hysterectomy are substantial decreased and a good operative outcome is directly dependent on the experience of surgeons[10]. A learning curve for surgeons suggests that experience in approximately 20 to 40 procedures is required in order to reduce the complication rate[2,10].

The use of a uterine manipulator is one of the successful key factors for improving TLH[11]. The good uterine manipulator must be able to accommodate a wide range of uterine motions, easy assembly and reusable and can be served as a colpo-pneumooccluder. The range of uterine motions from different uterine manipulator are presented in Table 2.

There are many types of uterine manipulators such as Clemont-Ferrand's, Hohl's, SUM[5-7]. They can be used to manipulate the uterus in anterior-posterior position very well. However, most of them lack the function of a pneumooccluder, with exception of the Hohl instrument[5] and RUMI manipulator[3]. Hohl instrument and RUMI manipulator have effective pneumo-occluder function but they are only partially reusable and very expensive relative to the local standard health care cost in Thailand.

The AUM was developed to alleviate most of available uterine manipulators' drawbacks as seen in a developing country health care environment. The rim of blue cup can clearly be seen and set as the landmark for the lateral incision. The cervico-vaginal fornices can be easily identified when pressure is applied to the uterine manipulator handle. Also, the distal part of the ureter can be dissociated, reducing the risk of ureteral injuries. We found that modified Foley catheter gave AUM an effective pneumo-occluder function in the vagina without any trauma. A modified technique of starting with posterior and anterior colpotomy respectively resulted in no pneumoperitoneum loss.

Major complications reported in TLH were injury to the bladder, ureter, or bowel; hemorrhage or hematoma requiring transfusion; unintended laparotomy; and major anesthetic problems[1,2]. The number of cases with AUM had much less complications compared to the conventional TLH[12-14]. This is resulted in low complication; 2% bladder injuries and no ureter or colon injuries (Table 3). The two bladder injuries were the result of severe bladder adhesions due to prior cesarean child birth in the patients' history. The use of AUM showed a much improved result compared to previous

Table 1. Characteristics of patients and operative outcomes

Characteristics and operative outcomes	mean ± SD
Age (years)	45.4 ± 4.6
Bodyweight (kg)	56.7 ± 6.3
BMI (kg/m^2)	24.5 ± 3.1
Uterine size (grams)	287 ± 101
Operative times (min)	98.4 ± 27.1
Estimated blood loss (ml)	188 ± 87.5

Table 2. Movement ranges of selected uterine manipulators currently available compared to AUM (Adapted from Matter et al[11])

	Reusable	Anteversion movements	Lateral movement	Vaginal fornices	Easiness of use and assembling	Pneumoperitoneum maintenance
1. Clemont-Ferrand	Yes	++++	++++	+++	+	+++
2. Hohl	Yes	+++	+++	++	+	++
3. RUMI with Hohl cup	Partially	++++	+++	++++	+	+++
4. Vcare	No	++	++	++++	+++	+++
5. AUM	Yes	+++	++	++++	++	+++

Movement ranges: 140 degrees = ++++, 130 degrees = +++, 90 degrees = ++, restricted = +

Table 3. Intraoperative major complications in TLH and AUM assisted operation

	No. of patient	Bladder injury	Ureteric injury	Bowel injury	Pulmonary embolus
Walsh et al[12]	98	1 (1%)	2 (2%)	0 (0 %)	0 (0%)
Garry et al[13]	584	12 (2.1%)	5 (0.9%)	1 (0.2%)	1 (0.2%)
Luang et al[14]	143	2 (1.4%)	1 (0.7%)	0 (0%)	1 (0.7%)
Our study	100	2 (2%)	0 (0%)	0 (0%)	0 (0%)

Table 4. The advantages and disadvantage of AUM

Advantages
Movement ranges + 130□, 90□in the posterior plane
Reusable instrument
Pneumoperitoneum is well maintained
Good delineation of the vaginal fornices
Low cost device; 210 USD each,
Average cost per operation less than 7 USD in this study
Modified operation technique resulted in low complication rate
Disadvantages
Elevation of the uterus is slightly restricted
Required 3-5 minutes installation time

reports[12-14] which stated that urinary tract injuries were the most common intraoperative risks for the operation of this nature. We believed that more preservation of the vaginal and uterosacral ligament length might have contributed to lower complications.

The AUM device could be adjusted and accommodate vagina of various diameters. AUM device is reusable. The same set of manipulator was used in all 100 cases during our study. The fixed cost per operation was 2.10 USD (210 USD /100 operations). The variable cost was only 4 USD per each operation including the replacement of the Foley catheter. It is a low cost medical device which can fit in any hospital's budget. The slight disadvantage of using AUM is a slightly less uterine motion than in the other types of uterine manipulators (Table 2). This modified technique for AUM is not preferable in the case of severe adhesion or obliterated cul-de-sac. The advantages and disadvantage of AUM are summarized in Table 4.

Conclusion

AUM is a new reusable uterine manipulator with a replaceable pneumo-occluder function. The use of AUM simplified the TLH procedure, shortened the operation time, lowered the equipment cost as well as hospital operating budget and reduced complication rate. The ease of use of the AUM device and the superiority of the modified operating procedure should allow beginners and less experienced surgeons to perform a successful TLH with more confidence and better outcomes. This makes the use of AUM-type device a practical choice for local healthcare providers in developing countries. These results will need to be warranted, confirmed and evaluated in a larger numbers of patients.

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การใช้เครื่องมือยกมดลูกของอนุราชร่วมกับการปรับเปลี่ยนเทคนิคเพื่อช่วยการผ่าตัดมดลูกผ่านกล้อง

ชำนาญ แท่นประเสริฐกุล, อนุราช กุลวานิชไชยนันท์

วัตถุประสงค์: *ปัจจุบันการผ่าตัดมดลูกผ่านกล้องเป็นที่แพร่หลายอย่างมาก แต่สำหรับแพทย์ผ่าตัดที่เริ่มต้นยังอาจไม่คุ้นเคย กับเทคนิคการผ่าตัดที่ซับซ้อนและพบว่าเกิดภาวะแทรกซ้อนตามมาสูง ผู้นิพนธ์จึงได้คิดประดิษฐ์และพัฒนาเครื่องมือยกมดลูก (Anurach uterine manipulator) เพื่อช่วยทำให้การผ่าตัดสะดวกและง่ายขึ้น การศึกษาครั้งนี้ต้องการประเมินประสิทธิภาพของเครื่องมือช่วยยกมดลูกหลังจากได้ใช้เครื่องมือนี้ช่วยในการผ่าตัดมดลูกผ่านกล้อง*

วัสดุและวิธีการ: *ได้ใช้เครื่องมือยกมดลูกของอนุราชเพื่อช่วยการผ่าตัดมดลูกผ่านกล้อง ในช่วงระหว่างเดือนตุลาคม พ.ศ. 2550 ถึงกันยายน พ.ศ. 2551 จำนวน 100 ราย โดยได้ปรับเปลี่ยนเทคนิคการผ่าตัด ทั้งนี้เริ่มจากการตัดสู่ช่องคลอด ด้านหลังเป็นอันดับแรกต่อมาผ่าตัดเข้าสู่ช่องคลอดด้านหน้าแล้วจึงตัดปีกมดลูกหรือเนื้อเยื่อรอบตัวมดลูกโดยการใช้เครื่องจี้ตัดไฟฟ้าหลังจากนั้นได้นำมดลูกออกทางช่องคลอด การผ่าตัดทั้งหมดและการเย็บปิดช่องคลอดกระทำผ่านกล้อง*

ผลการศึกษา: *ข้อบ่งชี้สำหรับการผ่าตัดที่บ่อยที่สุดคือ เนื้องอกมดลูกโดยมีขนาดมดลูกตั้งแต่ 64-620 กรัม เวลาเฉลี่ยที่ใช้ผ่าตัด 98 $\pm$ 27.1 นาที คะเนปริมาณเสียเลือดเฉลี่ย 188 $\pm$ 87.5 มิลลิลิตร ไม่พบการบาดเจ็บของลำไส้หรือท่อไตแต่พบการบาดเจ็บต่อกระเพาะปัสสาวะ 2 ราย ได้แก่ไขโดยทำการเย็บซ่อมกระเพาะ ปัสสาวะผ่านทางกล้อง*

สรุป: *การใช้เครื่องมือยกมดลูกของอนุราชร่วมกับการปรับเปลี่ยนเทคนิคการผ่าตัดมดลูกผ่านกล้อง เป็นทางเลือกในการผ่าตัดมดลูกแบบหนึ่ง ซึ่งพบว่ามีส่วนช่วยทำให้การผ่าตัดง่ายขึ้น ลดภาวะแทรกซ้อน และมีผลการผ่าตัดที่น่าพึงพอใจ*