Comparative Study of the Efficacy of the Songkla Uterine Manipulator and the Hulka Controlling Tenaculum in Laparoscopic Tubal Ligation

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Abstract

Objective : To compare the efficacy of the Songkla uterine manipulator (SUM) and the Hulka controlling tenaculum for manipulation of the uterus for laparoscopy.

Method : Forty women scheduled for laparoscopic tubal ligation were randomized to the SUM group (n=20) or the Hulka group (n=20) as uterine manipulator. Laparoscopic evidence of antevertion and lateral uterine movements and organ exposure was video recorded. Assessment of organ exposure and degree of lateral uterine deviation were subsequently evaluated.

Results : The characteristics of the women were similar in both groups. Right, left and range of lateral uterine motion were greater in the SUM group than the Hulka group (59 *vs* 42 degrees, 60 *vs* 47 degrees, and 118 *vs* 89 degrees, respectively, $p<0.0001$). The SUM group had 2.4 times better cul-de-sac exposure than the Hulka controlling tenaculum (95% CI : 0.51-11.51, $p=0.475$). The SUM exposed fallopian tubes better than the Hulka tenaculum ($p=0.022$) but other structures were not significantly better visualized. There were no complications in the SUM group but two had cervical bleeding in the Hulka group.

Conclusion : The SUM has advantages over the Hulka controlling tenaculum in giving a wider angle of lateral uterine deviation and better exposure of the fallopian tubes.

Key word : Uterine Manipulator, Laparoscopic Tubal Ligation

CHOKSUCHAT C, TINTARA H, SRIPLUNG H
J Med Assoc Thai 2002; 85: 693-697

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Laparoscopic surgery is a surgical technique widely used nowadays by gynecologists in diagnosis and treatment of pelvic pathology. Its advantages include reduced post-operative pain, short hospital stay, and a short recovery period[1]. Though it has advantages, the success of laparoscopic surgery requires specialized instruments and trained personnel. Clear exposure of the pelvic organs assisted by a uterine manipulator is essential for gynecologic laparoscopic surgery to minimize operative time and complications. Several uterine manipulators have been invented. Hulka first introduced a combined uterine sound and tenaculum in 1972[2]. The Hulka controlling tenaculum (Fig. 1, top) is widely used in Thailand. However, it has a fixed angle between the handle and the intrauterine portion, so antevertion and lateral deviation of the uterus are limited by the relaxation of the vaginal orifice. Furthermore, it has no cervical plate, and when force is applied to push the uterus upward, the sound tip can perforate the uterine fundus while the tooth of the tenaculum may traumatize the cervix. To reduce this complication, the Ramathibodi uterine manipulator, which has a cervical plate and can be used without tenaculum, was developed[3,4], but the range of uterine mobilization is still limited by the vaginal orifice. Valtchev and Papsin developed their uterine manipulator with a pivoted head in 1977[5] to overcome the limitation but it is not widely used in Thailand because of its excessive size and weight and also its high cost. One of the authors (HT), designed the Songkla uterine manipulator (SUM) in 1996 (Fig. 1, bottom), which combines the features of the Valtchev's and the cervical plate of the Ramathibodi's with the additional advantages of lightweight and low cost. It can antevert the uterus up to 95 degrees and provide a full range of lateral deviation. After the preliminary good results of the SUM[6], the authors decided to use laparoscopic tubal ligation as a model to compare the efficacy of the SUM and the Hulka tenaculum for uterine mobilization in laparoscopic surgery.

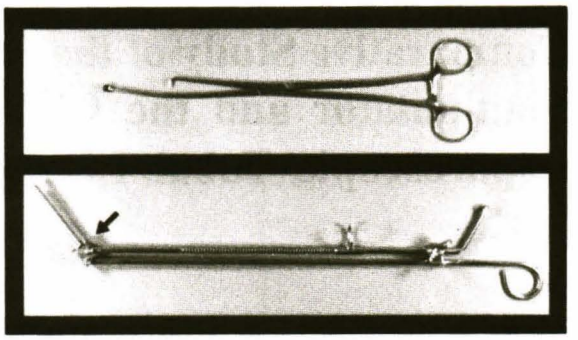

Fig. 1. The Hulka controlling tenaculum (top) and the Songkla uterine manipulator (bottom); the arrow indicates the pivoting joint.

MATERIAL AND METHOD

Between March 2000 and August 2001, sixty women were scheduled for laparoscopic tubal ligation using Falope ring under general anesthesia in the Department of Obstetrics and Gynecology, Faculty of Medicine, Prince of Songkla University. Forty women who had a body mass index less than 30 kg/m^2 and voluntarily joined this study were recruited. The women were randomized to the Hulka group (n=20) and SUM group (n=20), by opening sealed envelopes containing group allocation based on computer-generated random numbers in the operating room. Five surgical assistants (obstetrics and gynecology residents) who manipulated the uterus had been trained and standardized for full range of uterine manipulation with the two different devices. During the laparoscopy, the operating table was adjusted to 15-degree Trendenlenburg position in all cases. The exposure of the operative field and lateral deviation of the uterus were video recorded with a fixed 5-cm distance between the laparoscope tip and the uterine fundus in all cases. The operating time was recorded from the application of the first Falope ring to the time of finishing skin suture. The surgical complications were observed and recorded. The exposure of pelvic organs and the angle of lateral uterine deviation were later evaluated from the video by the author (CC) without knowledge of the type of uterine manipulator used. The exposure of pelvic organs was assessed as clear visibility, partial visibility, and invisibility. The exposure assessed was modified from staging of cul-de-sac obliteration for pelvic endometriosis[1]. The angle was recorded in degrees by applying a scale on the monitor with the vertical line of 0-degree placed between the outlines of the two uterosacral ligaments as a reference line. The degree of right and left deviation was measured

from this reference line when the uterine fundus reached the greatest angles to the right and left respectively.

Data are presented as mean ± standard deviation or number of cases. Statistical analysis was performed with STATA 7.0 (StataCorp., Texas, USA). The ability to achieve pelvic organ exposure by SUM and Hulka tenaculum was compared by the Cuzick test for trend. The differences of the two devices in degrees of uterine deviation and in operating time were evaluated by Student's *t*-test. Adjustment for unequal variance was done if needed. Complication rates were compared using Fisher's exact test. A p-value of less than 0.05 was considered statistically significant. The study was approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University (EC 28/2543).

RESULTS

Random allocation was confirmed by similarity in the characteristics of the women in the two groups as shown in Table 1. The age of the women in the SUM and Hulka groups was 32.2 ± 5.1 and 34.1 ± 5.4 years and the mean body mass index was 22.8 ± 3.2 and 23.3 ± 3.0 kg/m^2 respectively. The median number of parity was 2 in both groups. The angle of lateral uterine deviation made by the SUM and the Hulka tenaculum for right side, left side, and range of lateral deviation was 58.9 ± 13.8 *vs* 42.0 ± 8.5 degrees, 59.5 ± 9.9 *vs* 46.5 ± 5.4 degrees, and 118.4 ± 20.3 *vs* 88.5 ± 11.8, respectively (p<0.0001, all comparisons) (Table 2). The SUM has a 2.4 times better cul-de-sac exposure than the Hulka tenaculum but statistical significance was not achieved (95% CI : 0.52-11.51, p=0.475) (Table 3). The operating times in both the SUM and Hulka groups were equal, 7.4 ± 2.6 *vs* 7.3 ± 2.3 minutes, respectively (p= 0.848). No complications developed in the SUM group, whereas, two women in the Hulka tenaculum group had cervical bleeding at the tenaculum site (p=0.487). Tubal ligation was successful in all cases.

Table 1. Characteristics of women in the SUM and Hulka controlling tenaculum groups.

	SUM (n = 20)	Hulka tenaculum (n = 20)
Age (years)	32.2 ± 5.1	34.1 ± 5.4
Weight (kg)	54.4 ± 7.4	57.0 ± 7.3
Height (cm)	154.6 ± 3.9	156.6 ± 4.9
Body mass index (kg/m^2)	22.8 ± 3.2	23.3 ± 3.0
Parity	2.3 ± 0.4	2.2 ± 0.8

DISCUSSION

Operative laparoscopy is now becoming popular and more extensive. Uterine mobilization for exposure of the uterus and both adnexae is an essential technique for operative laparoscopy in gynecology. It can avoid the suprapubic port for laparoscopic forceps used for uterine mobilization. After successful development of the SUM, the authors used laparoscopic tubal ligation as a model to evaluate the efficacy of this new device for uterine mobilization compared to the Hulka tenaculum. The results showed that SUM was significantly superior to the Hulka tenaculum in lateral uterine deviation and had a tendency to better antevertion of the uterus. This reflects the significance of the adjustability of intrauterine obturator of the SUM which enables a free motion of the uterus independently when the shaft is rotated along its axis. The ability to antevert the uterus by the SUM was better than that of the Hulka tenaculum but not statistically significant. This may be due to the study population who were multiparous women with some degree of relaxation of the vaginal orifice. The effect of the limited space of the vaginal

Table 2. Angles of uterine deviation in the SUM and Hulka controlling tenaculum groups.

	SUM (n=20)	Hulka tenaculum (n=20)	P-value*
Right deviation	58.9 ± 13.8	42.0 ± 8.5	<0.0001
Left deviation	59.5 ± 9.9	46.5 ± 5.4	<0.0001
Range of lateral deviation	118.4 ± 20.3	88.5 ± 11.8	<0.0001

* Student's *t*-test with unequal variance.

Table 3. Exposure of pelvic organs in the SUM and Hulka controlling tenaculum groups.*

	SUM (n=20)			Hulka tenaculum (n=20)			P-value†
	Clear	Partial	Invisibility	Clear	Partial	Invisibility	
Cul-de-sac	17	2	1	14	3	3	0.24
Round ligaments	17	3	0	17	3	0	1.00
Fallopian tubes	16	4	0	9	11	0	0.02
Ovaries	16	3	1	11	7	2	0.10
Uterosacral ligaments	17	2	1	15	2	3	0.39

* Data are presented as number of women.
† Cuzick test for trend.

orifice may be significant in nulliparous women. Furthermore, the efficiency of antevertion of the uterus with the Hulka tenaculum is also limited by the position of the patient. The movement is limited when the patient lies with the buttocks not hanging on the edge of the operating table which is not a problem with the SUM.

The Hulka tenaculum has no cervical plate and when force is applied to push the uterus upward, the sound tip can slide into the uterine cavity and may perforate the uterine fundus, and may also traumatize or cause bleeding to the cervix by the tooth of the tenaculum. The cervical plate of the SUM is sufficiently large to minimize the likelihood of uterine perforation. In addition, the intrauterine obturator can be selected depending on the uterine size. The Hulka tenaculum may be adequate for laparoscopic sterilization because the procedure is performed on the fallopian tube, but for laparoscopic adnexectomy or hysterectomy, in which the infundibulopelvic ligament needs to be cut, it is necessary to deviate the uterus to stretch the infundibulopelvic ligament before desiccation and cut to avoid trauma to the ureter. For this procedure, the SUM may be necessary. A trial based on the more extensive long procedures is needed to show the role of the SUM for gynecologic laparoscopic surgery.

In conclusion, the SUM clearly showed an advantage over the Hulka controlling tenaculum in lateral uterine deviation and fallopian tube exposure and also had a tendency of better antevert of the uterus.

ACKNOWLEDGEMENT

The authors wish to thank Alan Geater, Ph.D., of the Epidemiology Unit, for his valuable comments and manuscript amendment. This study was funded by the Faculty of Medicine, Prince of Songkla University.

(Received for publication on December 24, 2001)

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การศึกษาเปรียบเทียบประสิทธิภาพการโยกมดลูกของเครื่องโยกมดลูกสงขลาและเครื่องโยกมดลูกฮัลก้าในการทำหมันด้วยกล้องส่องช่องท้อง

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การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อศึกษาเปรียบเทียบประสิทธิภาพการโยกมดลูกของเครื่องโยกมดลูกสงขลาและเครื่องโยกมดลูกฮัลก้าในการทำหมันด้วยกล้องส่องช่องท้องแบบใช้ยางรัดท่อนำไข่ ผู้รับบริการทำหมันทั้งหมด 40 ราย จะได้รับการสุ่มแบ่งเป็น 2 กลุ่ม ๆ ละ 20 ราย เพื่อใช้เครื่องโยกมดลูกแต่ละชนิด บันทึกภาพวิดีทัศน์ขณะส่องกล้องทำหมันเพื่อประเมินขอบเขตของการเคลื่อนไหวของมดลูกและการมองเห็นคัลเดอแซคในภายหลัง ผลการศึกษาพบว่าลักษณะของผู้รับบริการทั้งสองกลุ่มไม่ต่างกัน เครื่องโยกมดลูกสงขลาสามารถโยกมดลูกไปด้านข้างได้มากกว่าเครื่องโยกมดลูกฮัลก้าอย่างมีนัยสำคัญทางสถิติ ($p<0.0001$) และในกลุ่มที่ใช้เครื่องโยกมดลูกสงขลาสามารถมองเห็นคัลเดอแซคได้ดีกว่ากลุ่มที่ใช้เครื่องโยกมดลูกฮัลก้า 2.4 เท่า ($p=0.475$) เครื่องโยกมดลูกสงขลาช่วยให้มองเห็นท่อนำไข่ได้ดีกว่า ($p=0.022$) แต่มองเห็นอวัยวะอื่นในอุ้งเชิงกรานได้ไม่ต่างกัน ไม่พบภาวะแทรกซ้อนในกลุ่มที่ใช้เครื่องโยกมดลูกสงขลา แต่พบมีเลือดออกจากรอยเขี้ยวเครื่องมือจับปากมดลูก 2 รายในกลุ่มที่ใช้เครื่องโยกมดลูกฮัลก้า เครื่องโยกมดลูกสงขลาสามารถโยกมดลูกทางด้านข้างได้มากทำให้มองเห็นท่อนำไข่ได้ดีกว่าเครื่องโยกมดลูกฮัลก้า

คำสำคัญ : เครื่องโยกมดลูก, การทำหมันด้วยกล้องส่องช่องท้อง

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