Comparison of the TINTARA Uterine Manipulator with the Cohen Cannula in Gynecologic Laparoscopy

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Objective: *To assess the efficacy of the TINTARA uterine manipulator and the Cohen cannula for gynecologic laparoscopy.*
Material and Method: *Sixty women scheduled for laparoscopy were randomized for use of TINTARA (n = 30) or Cohen (n = 30) as a uterine manipulator. The degree of anterior and lateral deviation of the uterus, operative time, surgical complications and ease of use were recorded and compared between the two groups.*
Results: *The mean ranges of anterior and lateral deviation of the uterus in TINTARA and Cohen groups were 61.17 ± 19.37 vs. 49.33 ± 22.58 degrees (p = 0.033) and 107.03 ± 39.68 vs. 85.5 ± 37.52 degrees (p = 0.035) respectively. The percentage of patients having dye leakage from the cervix in the Cohen group was greater than in the TINTARA group, but the difference was not statistically significant. Both instruments provided similar ease of use. Complications were not found in either group.*
Conclusion: *TINTARA was found to have more advantages than the Cohen in moving the uterus in both anterior and lateral directions.*

Keywords: *Cohen cannula, TINTARA, Uterine manipulator, Uterine elevator, Laparoscopy, Laparoscopic surgery*

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Laparoscopy is currently accepted worldwide as an excellent diagnostic tool and treatment options for many gynecologic problems. The uterine manipulator is the most useful tool for assisting in the control the uterus during a laparoscopic operation. As part of a gynecologic procedure, dye is injected into the uterine cavity to observe its passage through the fimbria for evaluation of fallopian tube patency. The Cohen cannula has routinely been used to inject the dye, and also for manipulating the uterus. However, manipulation of the uterus using the Cohen cannula has certain limitations, as the head and shaft of the instrument are fixed together, somewhat reducing its maneuverability. In 1978, Valtchev KL et al developed a new uterine manipulator with dye injection capability that could pivot between the head and the shaft, and ease the insertion of the distal part further into the uterine cavity[1]. This instrument provided a better view of pelvic organs and was suitable for both diagnostic and laparoscopic surgery, but it still had some disadvantages during use. There was some leakage of dye at the pivoting joint, and the locking mechanism of the instrument was difficult to operate. After the patent period of the Valtchev Uterine Mobilizer (Conkin Instruments, Toronto, Ontario) expired in 1998, a number of uterine manipulators including a pivoting head were developed. The ClearView uterine manipulator (Clinical Innovations, Utah, U.S.A.)[2], the Majoli manipulator (Cook, IN, U.S.A.), the BARD manipulator (BARD Inc., MA, U.S.A.), the Harris-Kronner Uterine Manipulator

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Injector (UNIMAR, CT, U.S.A.)[3], the Zinnanti Uterine Mani-pulator Injector (Zinnanti Surgical Instruments, CA, U.S.A.) and the Hasson balloon elevator cannula (LINVATEC, FL, U.S.A.) for instance. Most are disposable instruments.

The TINTARA uterine manipulator was designed based on the Songkla manipulator[4], an instrument which was modified from the Valtchev Uterine Mobilizer by the author (HT) as a reusable instrument to save on money, always a consideration in developing countries. The TINTARA has a pivoting head to overcome the limitations of a rigid instrument in manipulating the uterus in both anterior and lateral directions. Chromotubation can also be performed via an injection-tube connected directly to the pivoting head.

Although many other tools were developed to try to improve upon the Cohen cannula, probably its ease of use, the Cohen cannula remains a widely used tool for uterine manipulation. The objective of the present study was to compare the TINTARA uterine manipulator with the Cohen cannula in terms of efficacy, safety, and ease of use.

Material and Method

The present study was performed at Songklanagarind Hospital, Prince of Songkla University, Thailand, and was approved by the Ethics Committee of the Faculty of Medicine. Sixty patients having pelvic organ pathology or infertility problems for which a laparoscopy would routinely be scheduled were recruited between December 2004 and October 2005. The subjects gave their informed consent and patients' anonymity was preserved. Any patient who was considered as being medically fit was eligible for the trial. Once being scheduled for laparoscopic surgery, the patients were allocated to either the TINTARA uterine manipulator (n = 30) or Cohen cannula group (n = 30) by computerized randomization. The surgical assistants who manipulated the uterus were trained to standardize their procedures for inserting and using the two tested devices. The exposure of the operative field and lateral deviation of the uterus were video-recorded in all cases. The range of anterior motion of the uterus was evaluated by the surgeon and another physician, outside the operative field, during surgery. The exposure of the pelvic organs and the angle of lateral uterine deviation were evaluated later from the video by the first author (CC) without knowledge of the type of uterine manipulator used. The angle was recorded in degrees by applying a scale on the monitor with a vertical line of 0-degrees placed between the outlines of two uterosacral ligaments as a reference line. The degrees of right and left deviation were measured from this reference line when the uterine fundus reached the greatest angles to the right and left respectively. The operative time and surgical complications were observed and recorded. Ease of use was recorded using a visual analog scale (0-10).

The TINTARA uterine manipulator

The novel feature of the TINTARA uterine manipulator is a new locking system, with which the pivoting angle can be freely adjusted from 0-90 degrees without any ratchet mechanisms (see Fig. 1). The pertubation tube adapter is located on the pivoting head without an O-ring, and this adaptor both prevents dye leakage and makes the instrument easy to clean. The shaft of the manipulator, without an interior lumen, is stronger than instruments, which have a lumen for injecting the dye. The intrauterine insert is connected to the pivoting head with a quick-lock mechanism, which works through a push-in/pull-out manner. The pertubation tube is designed for injecting the dye when the uterus is anteverted to about 45 degrees. In this position, the uterine tube does not kink and the fimbrial end can be observed easily.

Manipulation of the uterus

After the tenaculum was applied to the cervix, the insertion part of the uterine manipulator was inserted into the uterine cavity and the uterine manipulator hooked to the tenaculum. The uterus can be mobilized freely in an antero-posterior direction by sliding the controlling knob. The manipulator can be operated with one hand. Pulling the knob with the index finger moves the uterus to an anteversion position of

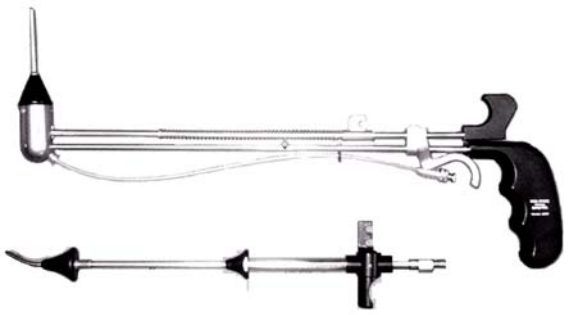

Fig. 1 The maximum uterine anteversion with the TINTARA uterine manipulator (top) and Cohen Cannula (bottom)

up to 90 degrees, while pushing the knob with the thumb moves the uterus in a retroversion direction up to zero degrees. Injecting the dye via the silicone tube, connected directly to the pivoting head, can be performed when the tubal patency test is needed (Fig. 2). The uterine position can be held by pulling the locking-lever with the middle finger (Fig. 3). Pushing the locking-lever with the middle finger will unlock the manipulator, and the uterine position can be readjusted as required (Fig. 4).

Statistical analysis

A sample size calculation was computed by using a two-tailed test with an level of.05 and a power of 95%. Based on a previous study, the mean range of lateral uterine motion of the Songkla uterine manipulator was known to be 118.4 ± 20.3 degrees[5]. The clinically significant difference of this range was estimated as 15 degrees. Therefore, to detect a difference of this magnitude required at least 60 patients or 30 patients per comparative group. The data are presented as mean ± standard deviation, the number of cases or a percentage (%) as appropriate. The SPSS v.11.0 for MS Windows was used to analyze the data. The range of uterine motion, ease of use and operative time were compared by *t*-test. Other parameters and complications were assessed by Chi-square test. The Fisher exact test was done when necessary. Statistical significance was considered if the p-value was less than 0.05.

Results

Random allocation was confirmed by the similarities of the characteristics of the women between each group as shown in Table 1. The mean ages of women in the TINTARA and Cohen groups were 34.37 ± 5.17 and 33.87 ± 5.46 years and the mean parities 0.63 ± 0.93 and 0.47 ± 0.90 (range 0-3) respectively. The body mass index was approximately 22 kg/m^2 in both groups. There were no significant differences in the diagnoses and procedures between the groups, as illustrated in Tables 1 and 2. The mean ranges of anterior and lateral motions of the uterus between the TINTARA and Cohen group were 61.17 ± 19.37 vs. 49.33 ± 22.58 degrees (p = 0.033) and 107.03 ± 39.68 vs. 85.5 ± 37.52 degree (p = 0.035) respectively (Table 3); these differences were statistically significant in both directions. In terms of ease of manipulation, ease of dye injection, ease of removal and overall ease of use, both instruments had similar scores. The operative times between the groups were not different. There was no cervical dilatation required before inserting the uterine manipulator in either group. There were only 3 out of 30 cases (10%) in each group considered the use of a tenaculum. The number of patients having dye

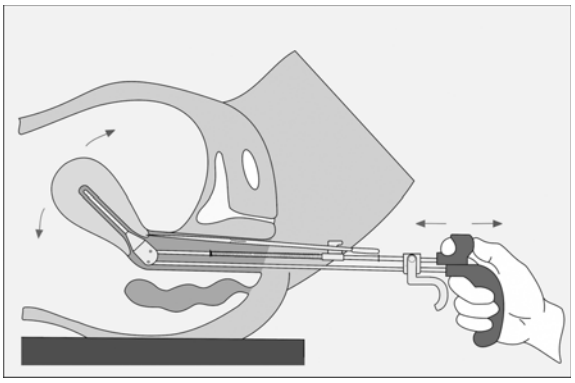

Fig. 2 Manipulation of the uterus

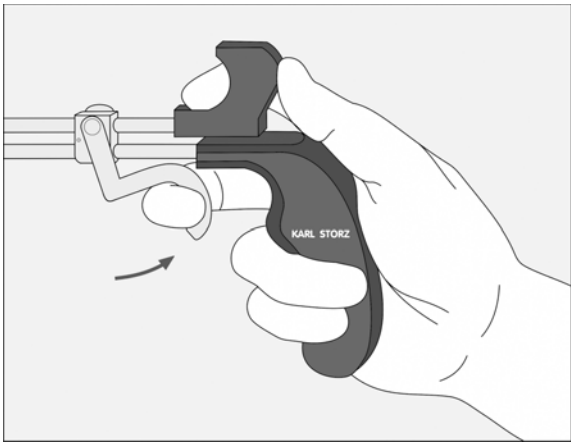

Fig. 3 Locking the uterine position

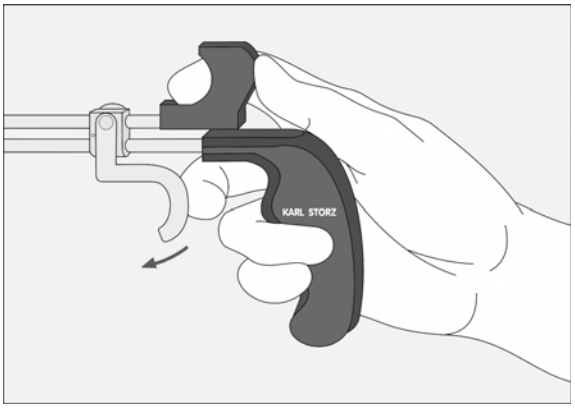

Fig. 4 Unlocking the manipulator

Table 1. Demographic characteristics

	Uterine manipulator		
	TINTARA (n = 30)	Cohen cannula (n = 30)	p-value[1]
Age (year)	34.37 ± 5.17 (27-50)	33.87 ± 5.46 (20-49)	0.717
Parity	0.63 ± 0.93 (0-3)	0.47 ± 0.90 (0-3)	0.483
BMI (kg/m^2)	21.85 ± 3.43 (17.70-32.50)	21.53 ± 2.76 (17.00-27.40)	0.688
Diagnosis[2]			
Normal study	3 (10.0)	7 (23.3)	
Uterine mass	4 (13.3)	2 (6.7)	
Ovarian mass	21 (70.0)	16 (53.3)	
Pelvic adhesion	2 (6.7)	5 (16.7)	

Values are expressed as mean ± standard deviation (range) or n (%)
[1] t-test
[2] Chi-square test, p-value = 0.540
BMI: Body mass index

Table 2. Laparoscopic procedure[1]

	Uterine manipulator	
	TINTARA (n = 30)	Cohen cannula (n = 30)
Diagnostic laparoscopy	9 (30)	13 (43.3)
Adnexal surgery	11 (36.6)	6 (20.0)
Myomectomy	0	1 (3.3)
Adhesiolysis	4 (13.3)	4 (13.3)
Electrocauterization	4 (13.3)	6 (20.0)
Hysterectomy	2 (6.6)	0

Values are expressed as n (%)
[1] Chi-square test, p-value = 0.617

Table 3. Comparison of the performance between the TINTARA and Cohen cannulae

	Uterine manipulator		
	TINTARA (n = 30)	Cohen cannula (n = 30)	p-value[1]
Anterior motion (degrees)	61.17 ± 19.37 (15-90)	49.33 ± 22.58 (10-80)	0.033
Lateral motion (degrees)	107.03 ± 39.68 (30-180)	85.50 ± 37.52 (20-150)	0.035
Ease of insertion	8.48 ± 1.12	8.80 ± 1.28	0.307
Ease of manipulation	8.53 ± 1.08	8.50 ± 1.23	0.920
Ease of dye instillation	8.20 ± 2.18	7.62 ± 2.44	0.381
Ease of removal	9.12 ± 0.97	9.38 ± 0.75	0.257
Overall ease of use	8.61 ± 1.00	8.87 ± 1.02	0.323
Operative time (min)	64.17 ± 44.61	51.23 ± 39.78	0.241
Dye injection[2]	22 (73.3)	26 (86.7)	0.333
Dye leakage[2]	10 (45.5)	18 (69.2)	0.146

Values are expressed as mean ± standard deviation (range) or n (%)
[1] t-test
[2] Chi-square test

leakage from the cervix in the Cohen group was greater than in the TINTARA group, but not to the point of statistical significance. Neither device resulted in any complications.

Discussion

The present study compared the TINTARA uterine manipulator with the Cohen cannula in laparoscopic surgery. The uterine movement in both anterior and lateral directions was significantly greater in the TINTARA group. There were no significant differences in the other parameters.

The pivoting head of the TINTARA uterine manipulator does not have the limitations of the Cohen cannula in manipulating the uterus to the antero-posterior and lateral directions. The vaginal orifice of obese or nulliparous patients limited the motion of the Cohen cannula, but had no effect on the movement of the pivoting head of the TINTARA manipulator. The axis of the shaft of the Cohen manipulator had to be changed in order to move the uterus to the desired direction, but only the pivoting head of the TINTARA manipulator had to be moved without changing the axis of the shaft while controlling the uterus.

Approaching the operative field is a major concern in laparoscopic gynecologic surgery[6]. Manipulating the uterus plays an important role in providing the good exposure of the pelvic organs. The Cohen can be used in diagnostic laparoscopy but the TINTARA manipulator may be better for laparoscopic surgery. In the present study, the mean ranges of uterine motions were significant greater in both the antero-posterior and lateral directions. The greater the range of motion of the uterus, the better the exposure of the pelvic organs would be expected. Adequate exposure can shorten the operative time and minimize intraoperative complications. However, the operative time in the present study was not different. There were more cases of adnexal surgery and hysterectomy in the TINTARA group which may influence the mean operative time since the sample size was limited.

The evaluation of the range of anterior motion in the present study was from two physicians in the operation. This may limit the accuracy of the anterior angle since the fact that the results were from subjective evaluations. However, two physicians assessing this parameter did not consult each other.

Most currently used uterine manipulators are either fully or partially composed of disposable materials[2,7,8], but the new uterine manipulator, the TINTARA, was reusable. It also had several other features the other models lack - the pivoting head was able to prevent leakage when the dye test was performed, and the locking system was simple to operate, and required only the simple moving of a locking lever.

The limited sample size in the present study was not large enough to accurately state that there were no complications from the tested instruments. The serious complications of laparoscopic surgery involved uterine perforation; however, this is a relatively rare occurrence[9-11]. Also the authors were very cautious in the present study, and specifically avoided uterine perforation. After the diagnostic laparoscopy was finished and the uterine position was determined, the surgeon carefully inserted the uterine manipulator under visual guidance. In general, insertion of the manipulator should be performed carefully especially in nulliparous patients. Furthermore, less experienced surgeons may have a greater risk of uterine perforation. Although the head of the TINTARA uterine manipulator was larger than the head of the Cohen cannula, overall ease of use was similar.

In conclusion, the TINTARA uterine manipulator is appropriate for uterine manipulation with chromotubation during diagnostic laparoscopy and laparoscopic surgery. The ease of use is comparable with the Cohen cannula.

Acknowledgements

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การเปรียบเทียบประสิทธิภาพเครื่องโยกมดลูกแบบ TINTARA และเครื่องโยกมดลูกแบบ Cohen ในการผ่าตัดผ่านกล้องส่องช่องท้องทางนรีเวช

ชัยณรงค์ โชคสุชาติ, ชัชปวิตร เกตุพุก, ศรันญา วัฒนกำธรกุล, ธนพันธ์ ชูบุญ, เกรียงศักดิ์ ธนวรวิบูล, หเทิญ ถิ่นธารา

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิภาพระหว่างเครื่องโยกมดลูกแบบ TINTARA และเครื่องโยกมดลูกแบบ Cohen เพื่อโยกมดลูกในการผ่าตัดผ่านกล้องส่องช่องท้องทางนรีเวช*

วัสดุและวิธีการ: *ผู้ป่วยหญิงที่เข้ารับการผ่าตัดด้วยกล้องส่องช่องท้องทางนรีเวชที่โรงพยาบาลสงขลานครินทร์ ระหว่างเดือนธันวาคม พ.ศ. 2548 ถึง เดือนตุลาคม พ.ศ. 2549 จะได้รับการสุ่มให้ใช้เครื่องโยกมดลูกแบบ TINTARA หรือเครื่องโยกมดลูกแบบ Cohen กลุ่มละ 30 ราย บันทึกข้อมูลเกี่ยวกับมุมของมดลูกที่ถูกโยกไปได้มากที่สุดทางด้านหน้าและด้านข้าง, ระยะเวลาที่ใช้ในการผ่าตัด และความยากง่ายของการใช้เครื่องมือ วิเคราะห์ข้อมูลเปรียบเทียบระหว่างเครื่องโยกมดลูกทั้งสองชนิด*

ผลการศึกษา: *ค่าเฉลี่ยของมุมของมดลูกที่ถูกโยกไปได้มากที่สุดทางด้านหน้าและด้านข้างเมื่อใช้เครื่องโยกมดลูกแบบ TINTARA และ Cohen คือ 61.17 $\pm$ 19.37 กับ 49.33 $\pm$ 22.58 องศา (p-value = 0.033) และ 107.03 $\pm$ 39.68 กับ 85.5 $\pm$ 37.52 องศา (p-value = 0.035) ตามลำดับ อัตราร้อยละของผู้ป่วยที่มีการรั่วของสีจากปากมดลูกในการฉีดสี เพื่อทดสอบท่อรังไข่ในกลุ่มที่ใช้เครื่องโยกมดลูกแบบ Cohen มากกว่ากลุ่มที่ใช้เครื่องโยกมดลูกแบบ TINTARA แต่ความแตกต่างนี้ไม่มีนัยสำคัญทางสถิติ ความยากง่ายในการใช้เครื่องโยกมดลูกทั้งสองชนิดไม่แตกต่างกัน รวมทั้งไม่พบภาวะแทรกซ้อนจากการผ่าตัดในทั้งสองกลุ่มการศึกษา*

สรุป: *เครื่องโยกมดลูกแบบ TINTARA สามารถโยกมดลูกไปทางด้านหน้าและด้านข้างได้ดีกว่าเครื่องโยกมดลูกแบบ Cohen*