

Impact of Hemostasis Methods, Electrocoagulation versus Suture, in Laparoscopic Endometriotic Cystectomy on the Ovarian Reserve: A Randomized Controlled Trial

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Objective: To evaluate the impact on ovarian reserve between two different methods of hemostasis after laparoscopic ovarian endometrioma excision.

Material and Method: A randomized controlled study was conducted from January to December 2013 in Thammasat University Hospital, Thailand. Reproductive women, age 18-45 years who underwent laparoscopic ovarian cystectomy were randomized in electrocoagulation and suture groups. Clinical baseline data and ovarian reserve outcome (anti-Mullerian hormone (AMH)) were evaluated.

Results: Fifty participants were recruited and randomized in two groups. Electrocoagulation and suture groups consisted of 25 participants. Baseline characteristics between 2 groups (age, weight, BMI, height, cyst diameter, duration and estimated blood loss) were not statistically different. There were no significant difference of AMH between electrocoagulation and suture group at pre-operative (2.90 ± 2.26 vs. 2.52 ± 2.37 ng/ml), 1 week (1.78 ± 1.51 vs. 1.99 ± 1.71 ng/ml), 1 month (1.76 ± 1.50 vs. 2.09 ± 1.62 ng/ml), 3 months (2.09 ± 1.66 vs. 1.96 ± 1.68 ng/ml) and 6 months (2.11 ± 1.84 vs. 1.72 ± 1.68 ng/ml), respectively. However, mean AMH of both groups significantly decreased since the first week of operation. Effect of laparoscopic ovarian surgery had significantly declined and sustained AMH level until 6 months.

Conclusion: Laparoscopic cystectomy of ovarian endometrioma has negative impact to ovarian reserve. Either electrocoagulation or suture method had no different effects.

Keywords: Laparoscopic ovarian cystectomy, Anti-Mullerian hormone, Endometrioma

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Ovarian endometrioma is one of the most common manifestations of endometriosis⁽¹⁾. Laparoscopic ovarian cystectomy is currently considered the procedure of choice in women with endometrioma and benign ovarian cysts⁽²⁾. The systematic review and meta-analysis demonstrated that excisional surgery for endometrioma provides for a more favorable outcome than drainage and ablation with

regard to the recurrence of the endometrioma, recurrence of pain symptoms including women who were previously sub-fertile⁽³⁾. This approach has been gaining increasing acceptance among gynecologic surgeons. However, there are some studies which demonstrated the negative impact of laparoscopic ovarian endometrioma excision on ovarian reserve⁽⁴⁻⁸⁾. The ovarian reserve testing comprises hormonal markers such as basal follicle stimulating hormone (FSH), estradiol, inhibin-B, anti-Mullerian hormone (AMH) and ultrasonographic markers (ovarian volume and antral follicle counts (AFC)). These markers have limitations in terms of which test(s) should be used to predict reliably ovarian reserve with regard to accuracy, invasiveness, cost, convenience and utility⁽⁹⁾.

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Anti-Mullerian hormone (AMH) levels represent the ovarian follicular pool and could be a prediction of quantitative and qualitative aspects in assisted reproductive technologies (ART). AMH seems to be a better marker in predicting ovarian response to controlled ovarian stimulation than age of the patient, FSH, estradiol, inhibin B and antral follicle count (AFC)⁽¹⁰⁻¹³⁾.

Hemostasis technique in laparoscopic excision of ovarian cysts has been questioned to be a part major of compromising ovarian reserve. Basically, electrocoagulation with bipolar has been used to secure bleeding after laparoscopic excision of ovarian cysts. But few studies reported the type of hemostasis associated with a significant reduction in ovarian reserve⁽¹⁴⁻¹⁶⁾. According to the questionable and inconclusive results on the impact of these hemostasis techniques in laparoscopic cystectomy on ovarian reserve in cases of endometrioma, objective of the current study was to evaluate the impact of two different methods of hemostasis after laparoscopic excision of ovarian endometriomas on ovarian reserve.

Material and Method

The present study, randomized controlled trial was conducted at department of Obstetrics and Gynecology in Thammasat University Hospital, Thailand during January and December 2013 after approval from ethical institute committee. We enrolled the patients with endometrioma who underwent laparoscopic ovarian cystectomy. They met all the following eligibility criteria: ages of 18-45, completely understand the process of this study with written informed consent, having regular menstrual cycles, never taking any medication such as oral pill and hormonal drugs during the 3 months before the enrollment, no previous history of adnexal surgery, no evidence of any other endocrine disorders such as diabetes mellitus, thyroid dysfunction, hyperprolactinemia, congenital adrenal hyperplasia, Cushing's syndrome, or adrenal insufficiency, pathological diagnosis of excised ovarian tissue confirmed as endometriotic cyst. They were excluded if they had polycystic ovarian syndrome according to the Rotterdam criteria⁽¹⁷⁾, pathological diagnosis of excised ovarian tissue was confirmed as non-endometriotic cyst and converted to laparotomy.

Eligible patients who provided written informed consent underwent randomization. In order to achieve comparable groups, a table of random numbers was used. Randomization was carried out

using opaque and sealed envelopes that were consecutively numbered. The details of randomization were safely and confidentially kept. Subjects withdrawn from the trial retain their identification codes (e.g. randomization number). New subjects received a new identification code. Allocation concealment was maintained until the time when hemostasis was started. All patients were blinded for the study intervention. Blinding of the surgeon and people in the operating was not feasible. The assessors of serum AMH were blinded to patients' allocated treatment group for postoperative evaluation.

The sample size was calculated based on the determination for difference in means with repeated measures includes confidence interval approach. The means of serum AMH from previous studies was used for sample size calculation. From the study of Ercan et al⁽⁶⁾, mean of preoperative AMH level in the study group was 1.62 ± 1.09 ng/ml. If estimation of the difference and power were 20% and 80%, respectively and the significance level was 0.05 by two-sided. By calculation, sample size for means with repeated measures, the number of women in each group was 25; hence the number of patients in the present study was 50.

For the operation techniques for laparoscopic cystectomy, all patients underwent the surgical procedure under general anesthesia. Laparoscopic pneumoperitoneum had been created by CO₂ in sufflation via Verres needle that was passed through a 5-mm umbilical incision until the intra-abdominal pressure reached 12 mmHg. Following pneumoperitoneum, umbilical 5-mm trocar and telescope entries were made. Then, two of 5-mm trocars were inserted from suprainguinal region or suprapubic area under direct laparoscopic observation. Successful removal of a cyst consisted of incisions of the ovarian cyst with scissors, identifying the cystic wall and removing it from the ovarian cortex by traction with grasping forceps. If the cystic content leaked, suction with irrigation of spillage content as much as possible was preferred.

In bipolar coagulation group, hemostasis was achieved with 25-30 W bipolar current forceps applied on the ovarian parenchyma. To reduce the possible damage of normal ovarian tissues, hemostatic procedure was minimally performed, as necessary. In suture group, the operated ovary was sutured for approximation of the ovarian edges and bleeding control. A single polydioxanone non-suture (2-0 Vicryl) on a CT curved needle holder would be used to re-approximate the edges and achieve satisfactory

hemostasis. The suture was performed with intra-ovarian knots and the knots were not detectable on the ovarian surface. Bleeding from ovarian hilus was resolved only by suturing, as well. All procedures were performed by one or two gynecologic laparoscopists who had experience in laparoscopic ovarian cystectomy more than a hundred cases.

After the removal of ovarian cyst, specimens were assessed by visual inspection for any evidence of malignancy such as vegetation. Histo-pathological examination of removed specimens was always done. The patients were kept under observation in the in-patient room for 24 to 48 hours after the operation to avoid any complications associated with surgery or anesthesia and then discharged.

Each patients were asked to visit the hospital on the seventh day of postoperative status, 1 month, 3 months and months 6 after laparoscopic ovarian cystectomy. At each visit and pre-operative day, blood samples would be obtained from the patients by venipuncture to measure the levels of AMH. The patient's sera were obtained from blood samples in 5-milliliter tube and centrifuged at 1,400 x g for 10 minutes to separate cellular contents and debris. The sera were transferred to sterile polypropylene tubes and stored at -70°C until assayed. Serum AMH levels were measured by enzyme-linked immunosorbent assay (ELISA, Diagnostic Systems Laboratories, Webster, TX, USA).

Statistical methods were used to assess the quality of data, homogeneity of treatment groups, endpoints and safety of the both groups. The confirmatory analysis was performed on the basis of an intention-to-treat (ITT) population and with respect

to ITT principles. Categorical data were summarized by means of absolute and relative frequencies (count and percent). Continuous data were presented by mean and standard deviation. Concentrations of serum AMH were compared between each sampling point using unpaired t-test. A *p*-value of less than 0 .05 was considered as statistically significant.

Results

Of the 50 participants recruited, there were 25 patients in each group, bipolar coagulation and suture, respectively. Most patients were nulliparous and never had prior lower abdominal surgery. There were no major complications related to the surgery in both groups. The postoperative courses were uneventful. Baseline characteristics between 2 groups such as age, weight, height, size of endometrioma, duration of surgery and blood loss were not statistically different (Table 1). The stage of disease and the bilateral of endometrioma presenting were also comparable. Mean of the revised American Society for Reproductive Medicine (rASRM) scores between bipolarcoagulation and suture groups were not statistically different (48.76 ± 22.83 vs. 43.52 ± 16.86 , $p = 0.36$).

There were no significant differences in AMH of electrocoagulation and suture group at pre-operative (2.90 ± 2.26 vs. 2.52 ± 2.37 ng/ml), 1 week (1.78 ± 1.51 vs. 1.99 ± 1.71 ng/ml), 1 month (1.76 ± 1.50 vs. 2.09 ± 1.62 ng/ml), 3 months (2.09 ± 1.66 vs. 1.96 ± 1.68 ng/ml) and 6 months (2.11 ± 1.84 vs. 1.72 ± 1.68 ng/ml), respectively. However, mean AMH of both groups significantly decreased since the first week of operation. Mean AMH of all participants at pre-operative and 6 months after surgery were (2.62 ± 2.27 ng/ml) and (1.91 ± 1.75 ng/ml),

Table 1. Baseline clinical profiles of the patients

Clinical profiles	Electrocoagulation (n = 25)	Suturing (n = 25)	<i>p</i> -value
Age (years)	33.6 \pm 5.2	33.6 \pm 6.6	0.96
Body weight (kg)	50.3 \pm 6.5	53.7 \pm 7.9	0.10
Height (cm)	158.5 \pm 4.5	158.9 \pm 4.6	0.76
BMI (kg/m ²)	20.1 \pm 2.8	21.3 \pm 3.5	0.17
Duration of surgery (min)	81.4 \pm 30.8	80.6 \pm 34.9	0.93
Blood loss (cc)	88.8 \pm 66.3	79.6 \pm 41.8	0.56
Stage of disease (%)			1.00
III	12 (48)	13 (52)	
IV	13 (52)	12 (48)	
Bilaterality (%)	6 (25)	5 (20)	1.00
Size of endometrioma (cm)	5.4 \pm 2.0	5.0 \pm 1.6	0.54

Numbers are mean \pm SD, or n (%)

respectively ($p<0.001$). Effect of laparoscopic ovarian surgery had significantly declined and sustained AMH level until 6 months.

The concentration of AMH was decreasing with the patients age. The distribution of some values were out of 95% confidence interval. The changes of serum AMH level at first week post-operation had much significantly decreased in coagulation group (67% vs. 31%, $p<0.001$) from pre-operative level. However, this significant decline was not apparent at one month, 3 months and 6 months.

Discussion

In the present study, the authors findings supported previous studies that the laparoscopic ovarian cystectomy or stripping technique for endometrioma had significant negative effect on ovarian reserve^(5,6,8). Several markers such as antral follicle count (AFC), FSH or AMH could be commonly utilized to assess ovarian reserve. Serum AMH level was selectively applied in the present study because it is the most sensitive and practical marker compared with the others. AMH level is not affected by gonadotropin, GnRH agonist, pregnancy or sex hormones. Moreover, the level is stable throughout menstrual cycle⁽¹⁸⁻²⁰⁾.

The reduction of AMH level in this study was significantly apparent since the first week after operation. The adverse effect had been maintained for at least six months after surgery. Mechanisms underlying the reduction of ovarian reserve in an operated ovary could be explained in the following explanations. Firstly, this damage could have occurred before surgery. Since the cyst per se can negatively affect the surrounding ovarian tissue. Secondly, in performing the cystectomy, some healthy follicles in adjacent ovarian tissue were removed during excision, stripping the capsule. Hirokawa et al⁽²¹⁾ also reported that pre-operative AMH was correlated with the number

of follicles in the cystectomy specimen. To avoid abundant effect, surgeon has to identify carefully the location of healthy follicles before starting remove the cyst wall. Bilaterality of endometrioma was determined as one of the major risk factors⁽²²⁾. However, the authors failed to demonstrate the effect of bilateral endometrioma because only one-fifth of our patients were in this group.

The effects of hemostasis technique had showed precisely only at the first week. The AMH level in bipolar coagulation group was significantly diminished and much more decreased from prior baseline level than the suture group, on whom had been used only the suturing technique to stop bleeding. The electrical coagulation was presumed to be an important role in terms of damage to ovarian stroma and vascularization. This finding was consistent to the study of Zoitoun et al⁽²³⁾. In their study, the only suturing for hemostasis was performed in cases of laparotomy. Most of gynaecologists prefer to stop bleeding by suturing in open laparotomy. Because hemostasis for the active bleeding in laparoscopic field needs much more time and expertise, endoscopic suturing and knotting are among the highest skills used in laparoscopic surgery.

The recovery of ovarian reserve was reported by Suksompong et al⁽²⁴⁾. The mechanisms of the event are still not exactly understood. Vascular vasculature and rescue from atretic follicles could be the most possible explanations. Our findings also found this effect after 3 months post-operation. But there was no statistically significance between the different haemostatic methods (Fig. 1).

European Society of Human Reproduction and Embryology recommended the ovarian cystectomy when the size of cyst more than 3 cm to histologically confirm⁽²⁾. However, clinicians must outweigh the risk of the reduced ovarian function and possible loss of

Table 2. Serum anti-Mullerian hormone (AMH) level (ng/ml) in patients undergoing electrocoagulation or suturing, difference and 95% confidence interval

Time	Electrocoagulation (n = 25)	Suturing (n = 25)	Difference	95% CI	p-value
Preoperative	2.90±2.26	2.52±2.37	0.38	-0.93, 1.70	0.56
Day 7	1.78±1.51	1.99±1.71	-0.21	-1.13, 0.71	0.65
Month 1	1.76±1.50	2.09±1.62	-0.33	-1.35, 0.69	0.50
Month 3	2.09±1.66	1.96±1.68	0.13	-0.91, 1.18	0.52
Month 6	2.11±1.84	1.72±1.68	0.39	-0.66, 1.44	0.47

Numbers are mean ± SD

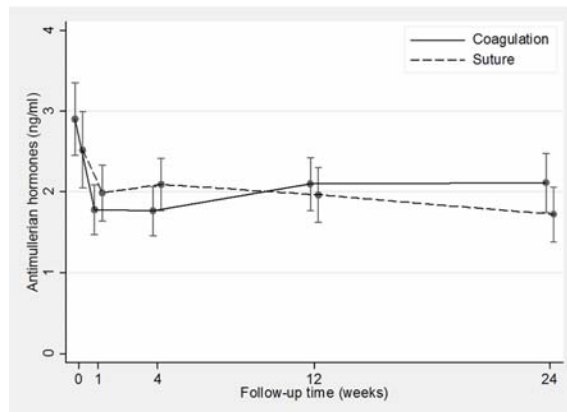


Fig. 1 The changes of serum AMH level at preoperative, post op day 7, month 1, month 3 and month 6 in coagulation group versus suturing group.

the ovary after surgery, especially in infertile patients.

There are several limitations of this study. Firstly, only one marker of ovarian reserve was used. Application of more ovarian reserve markers, associated with numerous of confounders, would be carefully interpreted. Secondly, although only two surgeons were involved in the study, the variation of techniques and the operating field in case by case are still the key factor which cannot be accurately controlled. Thirdly, the study was only prospectively investigated for 6 months. Long-term outcomes assessment such as response to infertility treatment, pregnancy outcomes could be the best end points.

Conclusion

The laparoscopic ovarian cystectomy for endometrioma had significant adverse effect on ovarian reserve, assessed by AMH level. The suturing technique for hemostasis has had a tendency to lessen this effect rather than the electrical coagulation by bipolar cauterization. However, this had only been shown in the short term, the first week visit. In the intermediate term, 6 months follow-up, the effects of hemostasis technique were showed to be insignificantly different.

What is already know in this topic ?

Excisional surgery for endometrioma provides for a more favorable outcomes than drainage and ablation with regard to the recurrence of the endometrioma, recurrence of pain symptoms including women who were previously sub-fertile.

There are some studies which demonstrated the negative impact of laparoscopic ovarian

endometrioma excision on ovarian reserve.

What this study add ?

Laparoscopic cystectomy of ovarian endometrioma has negative impact on ovarian reserve.

To stop bleeding during surgery, neither electrocoagulation nor the suture method had different effects on ovarian reserve.

Acknowledgement

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Potential conflict of interests

None.

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ผลของวิธีหยุดเลือด ระหว่างการจี้ไฟฟ้าห้ามเลือดและการเย็บผูก ในการผ่าตัดส่องกล้องเลาะถุงน้ำรังไข่ชนิดเอนโดเมทรีโอมา
ต่อการทำงานของรังไข่: การศึกษาแบบทดลองสุ่ม

ชำนานู แท่นประเสริฐกุล, โสภภาพรณ เอกรัตนวงศ์, โอภาส เศรษฐบุตร, ชีระพร วุฒยวนิช

วัตถุประสงค์: เพื่อประเมินผลของวิธีหยุดเลือด ระหว่างการจี้ไฟฟ้าห้ามเลือดและการเย็บผูก ในการผ่าตัดส่องกล้องเลาะถุงน้ำรังไข่ชนิดเอนโดเมทรีโอมา
ต่อการทำงานของรังไข่

วัสดุและวิธีการ: ได้ทำการศึกษาโดยวิธีทดลองสุ่มในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติระหว่าง เดือนมกราคม ถึง เดือนธันวาคม พ.ศ. 2556
โดยเลือกผู้ป่วยสตรีอายุระหว่าง 18-45 ปี ที่ได้มาทำผ่าตัดส่องกล้องเลาะถุงน้ำรังไข่ชนิดเอนโดเมทรีโอมา และสุ่มเลือกวิธีการหยุดเลือดระหว่างการผ่าตัด

โดยวิธี จี้ไฟฟ้าห้ามเลือดและการเย็บผูก เก็บรวบรวมข้อมูลพื้นฐานและประเมินผลต่อการทำงานของรังไข่โดยใช้ระดับของฮอร์โมนแอนติมูลเลอเรียน

ผลการศึกษา: ได้ผู้เข้าร่วมวิจัย 50 ราย โดยสุ่มเป็น 2 กลุ่ม คือ 25 ราย ในกลุ่มจี้ไฟฟ้าห้ามเลือด และ 25 ราย ในกลุ่มเย็บผูกเพื่อห้ามเลือด

ข้อมูลพื้นฐานทั้งสองกลุ่ม ได้แก่ อายุ น้ำหนัก ส่วนสูง ดัชนีมวลกาย ขนาดของก้อน เวลาการผ่าตัดและปริมาณการเสียเลือดระหว่างการผ่าตัด ไม่แตกต่างกัน
ระดับของฮอร์โมน แอนติมูลเลอเรียนก่อนผ่าตัด ไม่มีความแตกต่างกันระหว่างสองกลุ่ม (2.90 ± 2.26 และ 2.52 ± 2.37 นาโนกรัมต่อมิลลิลิตร)

และไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างสองกลุ่ม หลังการผ่าตัดที่ 1 สัปดาห์ (1.78 ± 1.51 และ 1.99 ± 1.71 นาโนกรัมต่อมิลลิลิตร)

ที่ 1 เดือน (1.76 ± 1.50 และ 2.09 ± 1.62 นาโนกรัมต่อมิลลิลิตร) ที่ 3 เดือน (2.09 ± 1.66 และ 1.96 ± 1.68 นาโนกรัมต่อมิลลิลิตร) และที่ 6 เดือน

(2.11 ± 1.84 และ 1.72 ± 1.68 นาโนกรัมต่อมิลลิลิตร) ตามลำดับ อย่างไรก็ตามระดับเฉลี่ยของฮอร์โมนแอนติมูลเลอเรียน ลดลงอย่างมีนัยสำคัญทางสถิติ
ภายหลังการผ่าตัดที่ 1 สัปดาห์ และผลการลดลงนี้คงอยู่อย่างต่อเนื่องจนกระทั่ง 6 เดือน

สรุป: การผ่าตัดส่องกล้องเลาะถุงน้ำรังไข่ชนิดเอนโดเมทรีโอมา มีผลเสียต่อการทำงานของรังไข่ โดยที่วิธีการหยุดเลือดระหว่างการจี้ไฟฟ้าห้ามเลือด
และการเย็บผูกไม่มีผลต่างกัน
