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Mona Zaghoul Kandeel
Department of Obstetrics and
Gynecology, Faculty of Medicine,
Tanta University, Tanta, Egypt

Mohamed Ahmed Talat El Sharawy
Department of Obstetrics and
Gynecology, Faculty of Medicine,
Tanta University, Tanta, Egypt

Naglaa Ali Hussein
Department of Obstetrics and
Gynecology, Faculty of Medicine,
Tanta University, Tanta, Egypt

Mostafa Zein Al Abidean Mohamed
Department of Obstetrics and
Gynecology, Faculty of Medicine,
Tanta University, Tanta, Egypt

Use of Oxidized Regenerated Cellulose (ORC) in treatment of ovarian endometriomas to prevent recurrence and preserve ovarian reserve

Mona Zaghoul Kandeel, Mohamed Ahmed Talat El Sharawy, Naglaa Ali Hussein and Mostafa Zein Al Abidean Mohamed

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Abstract

Background: Oxidized Regenerated Cellulose (ORC) is used in the treatment of Endometriosis to eliminate or postpone endometriomas' recurrence and to preserve ovarian reserve subsequently increasing pregnancy rate. The aim of this research was to evaluate the benefit of ORC in surgical management of ovarian endometriomas to reduce the rate of recurrence while preserving ovarian reserve.

Methods: This prospective randomized controlled research was carried out on 60 cases, divided into two groups: Group A (drainage and ablation): 30 cases had laparoscopic drainage of ovarian endometrioma with electrocautery of the endometriomal cyst wall. Group B (drainage and ORC): 30 cases had laparoscopic drainage of ovarian endometrioma with insertion of ORC inside the cyst cavity.

Results: There was a statistically significant difference according to 3 and 6 months in anti-mullerian hormone (AMH) (ng/ml) and Antral Follicular Count (AFC) being higher in ORC group compared to ablation group while the reduction in AMH (change) was significantly lower in ORC group (P values < 0.001). The recurrence rate of ovarian endometrioma was comparable between both groups. AMH and AFC was significantly associated with the recurrence of ovarian endometrioma 3 and 6 months.

Conclusions: ORC reduces effectively the recurrence risk of endometriomas following laparoscopic drainage.

Keywords: Oxidized Regenerated Cellulose (ORC), ovarian endometriomas, ovarian reserve

Introduction

Endometriomas is defined as the presence of endometrial glands and stroma like lesions outside the uterine cavity including the Ovaries, Douglas pouch, Uterosacral ligaments, vulva, bladder and rectum. The endometrium undergoes cyclic changes [1]. In spite of analgesics and cyclic oral contraceptive pill treatment, it is linked to persistent pelvic discomfort, painful periods (dysmenorrhea), painful sexual activity (dyspareunia), painful bowel movements (dyschezia), and painful bladder emptying (dysuria). It is also associated with Infertility and intermenstrual bleeding [2].

Endometriosis is managed by: Symptomatic treatment: as Anti-Prostaglandin, Oral Contraceptive Pills. Medical treatment: as Progestrone, Gonadotropin Releasing Hormone, Oral Contraceptive Pills and Androgen analogue. Surgical treatment: cystectomy or drainage of endometriomas either by laparoscopy or laparotomy and then ablation of cyst wall using electrocautery [3].

As an efficient measure for haemostasis, especially for gushing surfaces, oxidized regenerated cellulose (ORC) has been used in surgical sectors as a topical absorbable substance. ORC works as a physical barrier that encourages platelet aggregation and clotting in addition to the mechanical compression (tamponade-like) at the bleeding sites. In addition, ORC's acidic pH (between 2 and 4) aids haemostasis through vasoconstriction, denaturation of blood proteins, and the development of a gel-like artificial clot [4, 5].

In most cases, ORC products are tolerated well and safe since they are quickly eliminated from the body after insertion [4]. Nowadays, ORC is used in treatment of Endometriosis to eliminate or postpone endometriomas' recurrence and to preserve Ovarian reserve subsequently increasing pregnancy rate [4, 5].

Corresponding Author:
Mona Zaghoul Kandeel
Department of Obstetrics and
Gynecology, Faculty of Medicine,
Tanta University, Tanta, Egypt

The aim of this work was to evaluation of benefit of ORC in surgical management of ovarian endometriomas to reduce the rate of recurrence while preserving ovarian reserve.

Patients and Methods

This prospective, randomized, controlled research was carried out on 60 cases aged from 20 to 35 years with clinical criteria of endometriosis-related clinical manifestations (infertility, pelvic pain, pelvic mass), unilateral and unilocular endometrioma (≥ 5 cm), good ovarian reserve (antimüllerian hormone (AMH) > 1 ng/ml and antral follicular count AFC > 4) and candidate for conservative laparoscopic treatment of ovarian endometriomas at Tanta University Hospital – Obstetrics and Gynaecology department over 1 year from March 2021 to July 2022.

The research was done after approval from the Ethical Committee Tanta University Hospitals. An informed written consent was obtained from the case or their relatives.

Exclusion criteria were recurrent and bilateral cases, suffers chronic diseases (e.g., cardiac disease, diabetes) and has any contraindication for laparoscopic surgery (excessive anterior abdominal wall scarring).

Cases were categorized into two equal groups: Group A (drainage and ablation): had laparoscopic drainage of ovarian endometrioma with electrocautery of the endometrioma cyst wall. Group B (drainage and ORC): had laparoscopic drainage of Ovarian Endometrioma with insertion of ORC inside the cyst cavity.

All cases were subjected to: Full History, Complete Physical Examination: women had a clinical examination, including general, abdominal, and pelvic examinations, and vaginal speculum examination to exclude local causes of infertility. Laboratory Investigations: Serum antimüllerian hormone (AMH) was assayed by ELISA (enzyme linked immunosorbent assay) technique (Expected Values: 0.9–9.5 ng/ml).

Imaging techniques

Transvaginal ultrasound: Samsung H60 color Doppler (SAMSUNG MEDISON CO., LTD.42, Teheran-ro 108-gil, Gangnam-gu, Seoul, Korea) with a transvaginal 6.5 MHz probe used for: Visualisation of uterine cavity, adnexa, and ovaries. Since endometriomas can present themselves in a wide range of ways, it's important to confirm their presence and determine their size and location. Unilocular cysts are a classic case of acoustic enhancement due to hemorrhagic debris, manifesting as diffuse homogenous ground-glass echoes. Antral follicular count (AFC) is the total number of follicles, in both the diseased and healthy ovaries. Both the pre-op evaluation and the post-op follow-up ultrasounds were performed by the same doctor.

Case preparation for laparoscopy

These guidelines were instructed before coming to the hospital for the laparoscopy and the cases were informed by the surgical procedure. The surgery was done during proliferative phase of the menstrual cycle to exclude current pregnancy and to minimize bleeding at operative laparoscopy according to American Fertility Society classification.

Procedure

Under general anaesthesia, cases were put in the lithotomy position and Trendelenburg position. Small vertical umbilical incision was performed by scalpel under aspect conditions. Pneumoperitoneum was performed by a Veress needle and tested by injection of saline and aspiration then, insufflation of

peritoneal cavity by carbon dioxide gas to provide a working and viewing space for the surgeon.

Once Pneumoperitoneum was established, Veress needle was removed, and trocar 10 mm was introduced instead. 30 D or 0 Lens with One-chip Full HD camera frame rate 50/60 HZ (KARL STORZ GmbH and Co., Germany) on the end and a light source was introduced through trocar. The laparoscope (KARL STORZ GmbH and Co., Germany) transmitted images from the abdominal and pelvic cavity to high resolution video monitors in the operating room. After exploration of all abdominal cavities and when the cyst was visualized, one or two more incisions 5mm were made. Each incision was a port, where a trocar 5mm was inserted.

If any adhesion or band was found between ovary and other pelvic organs, adhesiolysis was performed. Grasping of ovary and ovarian ligament by Maryland grasper introduced through the trocar 5mm. A small window 1cm was done in the cyst wall using monopolar diathermy. The window was made on the thinnest part of the cyst. Avoid making the incision close to the fallopian tube or fimbrial end. Aspiration of the chocolate material from the cyst and then irrigation of the cyst cavity with normal saline solution till complete elimination of the chocolate material.

In ablation group, haemostasis and ablation of the remaining endometriotic cyst wall was done by 60W electrodes (Erbe REF 20195-145 max. 250Vp) of bipolar electrocautery (Erbe Elektromedizin GmbH Waldhoernlestr. 1772072 Tuebingen, Germany). In ORC-treated group, each ORC knitted fabric with area measuring 5×10 cm (SURGICEL®–Ethicon US, LLC.) It was separated into quarters. Depending on the size of the endometrioma, four to eight surgical parts were placed inside the cyst's interior. Sutures of 4/0 polydioxanone (PDS® Suture–Ethicon US, LLC) were used to approximate the ovarian margins if they were gapping. During the procedure tissue may be removed for histopathology.

All cases were followed up after 3 months and 6 months following the laparoscopic surgery by: Serum antimüllerian hormone (AMH) was assayed by ELISA (enzyme linked immunosorbent assay) technique (Expected Values: 0.9–9.5 ng/ml). Transvaginal ultrasound: Samsung H60 color Doppler (SAMSUNG MEDISON CO., LTD.42, Teheran-ro 108-gil, Gangnam-gu, Seoul, Korea) with a transvaginal 6.5 MHz probe used for identification of recurrence of endometrioma in the same ovary (ovarian cyst with homogeneous low-level ground glass echogenicity of the cystic fluid) and for antral Follicular Count (AFC): Number of visible follicles from 2 to 10 ml in the same ovary.

One doctor performed both the pre-op assessment and the post-op follow-up ultrasounds. During the postoperative follow-up period, no subjects received any hormonal therapies.

Primary outcome was the presence of sonographically confirmed endometrioma-like cysts in the ipsilateral ovary (recurrence was defined as the occurrence of such cysts) at a size of more than one centimeter. As a secondary endpoint, we reevaluated ovarian reserve (AMH and day 2 AFC) after the laparoscopy.

Statistical analysis

SPSS v28 (IBM Inc., Chicago, IL, USA) was used for the statistical analysis. Quantitative variables were compared between the two groups using unpaired Student's t-test and followed-up measurements were compared to baseline measurements within the same group using paired Student's t-test. When applicable, the Chi-square test or Fisher's exact test was used to analyze qualitative variables provided as

frequencies and percentages. In this study, statistical significance was defined as a two-tailed P value below 0.05. For this reason, we analyzed the diagnostic efficacy of each marker using a Receiver Operating Characteristic (ROC) curve. The area under the curve (AUC) is a statistical measure used to assess test efficacy (with an AUC of 50% indicating satisfactory

results and an AUC of 100% indicating optimal results).

Results

Regarding Age, BMI, Manifestations, side, and size of endometrioma of the studied groups, there was no statistically significant difference between research groups. Table 1

Table 1: The demographic characteristics, Manifestations, Side, and size of endometrioma of the studied groups

	ORC group (n= 30)	Ablation group (n=30)	95% CI	P
Age (years)	29.33 ± 3.133	30.00 ± 2.613	-2.2, 0.8	0.374
BMI (kg/m ²)	26.39 ± 2.298	27.02 ± 2.016	-1.7, 0.5	0.268
Manifestations				
Primary Infertility	26.7% (8)	26.7% (8)	-	0.224
Secondary infertility	13.3% (4)	33.3% (10)		
Pelvic Pain	43.3% (13)	23.3% (7)		
Pelvic Mass	16.7% (5)	16.7% (5)		
Side				
Right	60.0% (18)	53.3% (16)	-	0.602
Left	40.0% (12)	46.7% (14)		
Size (cm)	6.58 ± 1.566	6.60 ± 1.552	-0.8, 0.8	0.967

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. BMI: Body mass index; ORC: oxidized regenerated cellulose; P is significant when < 0.05.

There was a statistically significant difference according to 3 and 6 months AMH (ng/ml) being higher in ORC group compared to ablation group as the reduction in AMH (change)

was significantly lower in ORC group. There was a statistically significant higher count of Antral Follicular Count in ORC group after 3 and 6 months of laparoscopy compared to ablation group as the AFC reduction (change) was significantly lower in ORC group (P values < 0.001). The recurrence rate of ovarian endometrioma was comparable between both groups. Table 2

Table 2: Basal and follow-up of Anti Mullerian hormone (ng/ml), Antral Follicular Count and recurrence in the studied groups

	ORC group (n= 30)	Ablation group (n= 30)	95% CI	P value
AMH				
Basal AMH (ng/ml)	6.16 ± 1.04	5.77 ± 0.97	-0.124: 0.915	0.133
Three months	6.05 ± 1.06	4.83 ± 0.95	0.696: 1.737	<0.001*
Six months	6.04 ± 1.07	4.6 ± 0.98	0.903: 1.966	<0.001*
AMH change	-0.13 ± 0.41	-1.16 ± 0.44	0.818: 1.259	<0.001*
Comparison of follow up to basal AMH	P1= 0.129 P2= 0.107	P1<0.001* P2<0.001*	---	---
95% CI	-0.036: 0.266 -0.029: 0.279	0.803: 1.074 1: 1.319	---	---
AFC				
Antral Follicular Count	7.57 ± 0.86	7.33 ± 0.96	-0.237: 0.704	0.325
Three months	7.2 ± 1.27	5.73 ± 1.72	0.684: 2.25	<0.001*
Six months	7.1 ± 1.47	4.77 ± 2.01	1.423: 3.244	<0.001*
AFC change	-0.47 ± 1.28	-2.57 ± 1.74	1.312: 2.888	<0.001*
Comparison of follow up to basal AFC	P1= 0.054 P2= 0.055	P1<0.001* P2<0.001*	---	---
95% CI	-0.007: 0.74 -0.011: 0.944	1.091: 2.071 1.921: 3.175	---	---
Recurrence				
Recurrence	9 (30%)	4 (13.3%)	---	0.209

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. P1: comparison between basal and three months values, P2: comparison between basal and six months values. P is significant when < 0.05. P is significant when < 0.05. AMH: Anti-Mullerian Hormone; ORC: oxidized regenerated cellulose, AFC: Antral Follicular Count.

According to ORC and ablation groups, in terms of AMH, it was significantly associated with the recurrence of ovarian

endometrioma 3 and 6 months after laparoscopy being lower in cases who suffered from recurrence than those who didn't while there was no relation between the recurrence and AMH at the start of the research. Regarding AFC, there was a statistically significant relation between AFC 3 and 6 months after laparoscopy and the recurrence of ovarian endometrioma as AFC was significantly lower in cases who suffered from recurrence than those who didn't. There was no relation between the recurrence and AFC at the start of the research. Table 3

Table 3: Relationship between recurrence of ovarian endometrioma and AMH, AFC in ORC group

		Recurrence		95% CI	P
		Yes	No		
ORC group					
AMH (ng/ml)	Basal	5.67 ± 0.99	6.37 ± 1.01	-1.518: 0.125	0.094
	Three months	5.39 ± 0.99	6.33 ± 0.98	-1.747: -0.138	0.023*
	Six months	5.37 ± 0.99	6.32 ± 0.99	-1.764: -0.145	0.022*
AFC	Basal	7.33 ± 0.71	7.67 ± 0.91	-1.034: 0.368	0.338
	Three months	6.33 ± 0.71	7.57 ± 1.29	-2.178: -0.298	0.012*
	Six months	5.56 ± 0.88	7.76 ± 1.14	-3.079: -1.333	<0.001*
Ablation group					
AMH	Basal	5.13 ± 0.55	5.9 ± 0.98	-1.809: 0.271	0.141
	Three months	3.83 ± 0.57	5.02 ± 0.9	-2.145: -0.235	0.016*
	Six months	3.3 ± 0.57	4.84 ± 0.88	-2.474: -0.599	0.002*
AFC	Basal	6.75 ± 1.5	7.48 ± 0.89	-1.798: 0.335	0.171
	Three months	3.25 ± 0.5	6.19 ± 1.52	-3.761: -2.109	<0.001*
	Six months	2 ± 1.41	5.26 ± 1.75	-5.137: -1.381	<0.001*

Data is expressed as mean and standard deviation. P is significant when < 0.05. AMH: Anti-Mullerian Hormone; AFC: Antral Follicular Count; 95% CI: 95% confidence interval of the mean difference between both groups; ORC: oxidized regenerated cellulose.

AMH at 3 and 6 months after laparoscopy can significantly predict the recurrence of ovarian endometrioma with AUC of 0.682 and 0.677, respectively. At cut off ≤5.1 and ≤5.02 ng/ml, respectively, with sensitivity of 69.23% and 61.54%, respectively, specificity of 59.57% and 57.45%, respectively, PPV of 32.1% and 28.6%, respectively and NPV of 87.5% and 84.4%, respectively. (P value of 0.038 and 0.048, respectively). Figure 1

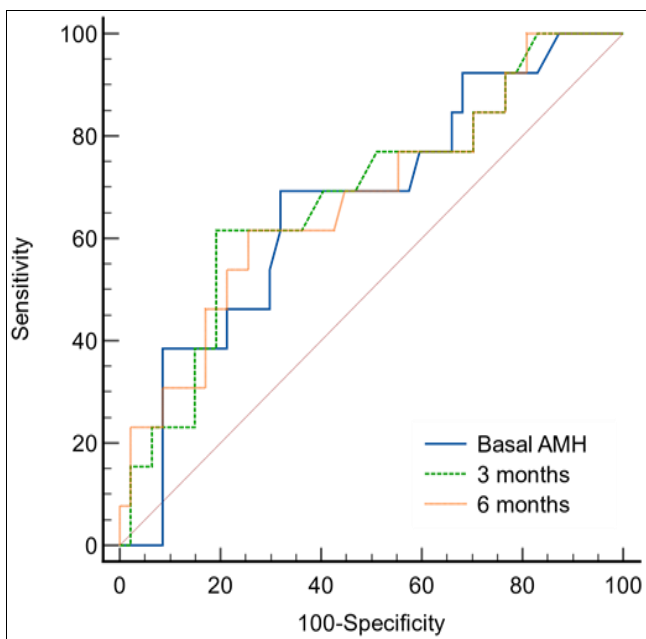


Fig 1: Comparison of ROC curves of AMH measurements in predicting the recurrence of ovarian endometrioma

AFC at 3 and 6 months after laparoscopy is a significant predictor of the recurrence of ovarian endometrioma with AUC of 0.732 and 0.76, respectively. At cut off ≤6, with 69.23% and 92.31% sensitivity, respectively, 61.7% and 59.57% specificity, respectively, 33.3% and 38.7% PPV, respectively and 87.9% and 96.6% NPV, respectively. (P value <0.001). Figure 2

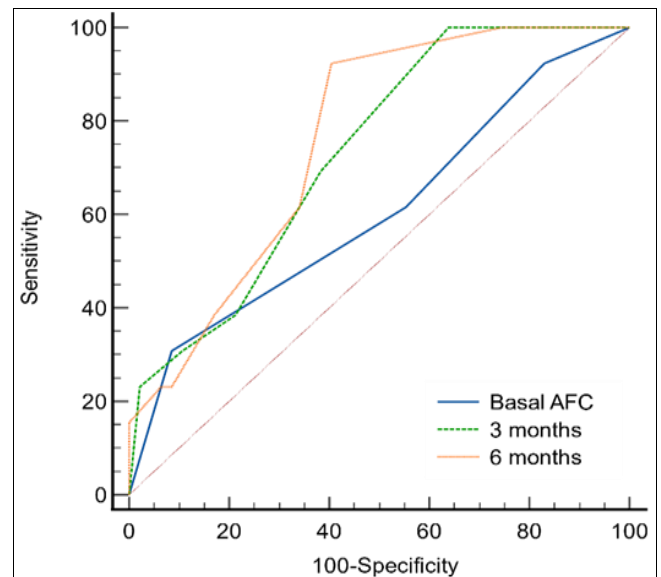


Fig 2: Comparison of ROC curves of AFC measurements in predicting the recurrence of ovarian endometrioma

Discussion

In this research, the most common manifestation in the ORC group was pelvic pain in 43.3% of cases vs 23.3% in the ablation group, while the most common manifestation in the ablation group was secondary infertility in 33.3% of cases vs 13.3% in the ORC group. The most affected side was the right side in 60% of the ORC group and 53.3% of ablation group.

Shaltout *et al.* [6] found that the most common manifestations was secondary infertility in 36% of the ORC group and in 32% of the ablation group with most affected right side in 52% of the ORC group and 52% of ablation group.

This is because endometriosis is characterized by the formation of adhesions in ectopic endometrial tissue. Adhesions lead to infertility, pelvic or abdominal pain, and bowel obstruction [7].

In this research, the mean size of endometrioma was (6.58 ± 1.566 cm) in the ORC group, and (6.60 ± 1.552 cm) in the ablation group, without statistically significant difference between the two groups (p= 0.967).

Our research agrees with Shaltout *et al.* [6] research, in which the mean size of endometrioma was (6.5 ± 1.1 cm) in the ORC group, and (6.4 ± 1.1 cm) in the ablation group, without statistically significant difference between the two groups.

Similar to Sönmezer *et al.* [8] who reported that the median size of endometrioma of hemostatic matrix group was 5 cm, of the bipolar coagulation group it was 5.5 cm.

Loss of ovarian reserve can be due to ovarian endometriosis that may reduce the amount of healthy tissue, leading researchers to believe it may have a negative effect on a woman's fertility. Serum AMH levels are known to drop significantly after invasive procedures like ovarian cystectomy due to stress to the ovarian vasculature and excessive removal of ovarian tissue [9].

Our research results have revealed that there was a statistically significant difference according to 3 and 6 months in AMH (ng/ml) and Antral Follicular Count being higher in ORC group compared to ablation group while the reduction in AMH (change) was significantly lower in ORC group (P values < 0.001). The recurrence rate of ovarian endometrioma was comparable between both groups. AMH and AFC was significantly associated with the recurrence of ovarian endometrioma 3 and 6 months.

We assume in our research that laparoscopic drainage of ovarian endometrioma with insertion of ORC inside the cyst cavity is a good alternative to laparoscopic drainage of ovarian endometrioma with electrocautery of the endometrioma cyst wall and excellent choice for cases with poor ovarian reserve. In our research, we choose the third and sixth month postoperative follow up to assess the extent of recovery after management.

Sharma *et al.* [10] concluded that the use of ORC as a hemostatic agent is simple and very effective. Additionally, the risk of compromising ovarian reserve with use of energy sources for hemostasis is also minimized.

Contrary to our research results, Chung *et al.* [11] found that in both hemostatic sealant and bipolar coagulation group, one month and three months after surgery, the AFC was higher than it had been before. The 3-month change in AFC of the afflicted ovaries was substantially (P = 0.013) larger in the hemostatic sealant group (2.36±0.37) compared to the bipolar coagulation group (1.08±0.36).

Since it takes at least three months for little preantral and antral follicles to emerge from quiescent primordial follicles, this is the time point we will initially examine in our research. During ovarian surgery, it is crucial to protect the ovarian reserve.

[8].

There is a wide range of reported recurrence rates for ovarian endometrioma following laparoscopic ovarian cystectomy, from 9.6 percent to 45 percent. Furthermore, up to 40-45% of cases may have a risk of symptom recurrence following initial surgery, necessitating either another surgery or even more drastic treatments, such as hysterectomy [12, 13].

Although Shaltout *et al.* [6] filling the remaining cavity with ORC after drainage management has been shown to lower recurrence risk and improve overall results compared to drainage and ablation. They hypothesized that ORC (Surgicel) is able to exert a form of chemical destruction by creating a highly acidic environment (pH 2-4) and triggering severe vasoconstriction within the endometrioma, killing the remaining endometrial cells and lowering the recurrence rate.

Chen *et al.* [14] confirmed that ORC products have been confirmed safe because they are sterile and bioabsorbable. There have been reports of problems (such as foreign body granulomatous development, persistent inflammation, and infection) that occurred on the long run. However, there is still a shortage of evidence-based data on the best ways to use ORC (surgicel) and any risks associated with doing so.

Cost of treatment is an important factor to consider from an economic view. The equipment required for ORC is less expensive than that required for electrocauterization. The operational duration can be reduced without sacrificing the

precision and skill required for intracorporeal suturing [6].

In contrast to Pergialiotis *et al.* [15] research which found that AFC hadn't improved following endometrioma surgery.

In the current research, AMH at 3 and 6 months after laparoscopy can significantly predict the recurrence of ovarian endometrioma with AUC of 0.682 and 0.677, respectively. At cut off ≤5.1 and ≤5.02 ng/ml, respectively. AFC at 3 and 6 months after laparoscopy is a significant predictor of the recurrence of ovarian endometrioma with AUC of 0.732 and 0.76, respectively. At cut off ≤6.

In their research, Ozaki *et al.* [16] patients with AMH values 1.1 ng/mL 3 or 6 months prior to surgery and 3 or 6 months after surgery were reported to have an unfavorable DOR (aDOR). At 3 months following surgery, the optimal cut-off points of the pre-surgical AMH concentrations were 2.1 ng/mL [0.83 (95% CI, 0.68-0.97)]; and 3.0 ng/mL [0.72 (95% CI, 0.57- 0.87)], and at 6 months following surgery, were 2.1 ng/mL [0.85 (95% CI, 0.73-0.97)]; and 3.5 ng/mL [0.80 (95% CI, 0.67-0.93)].

Furthermore, Tang *et al.* [17] noted that the AUC of the predictive value of serum AMH for postoperative abnormal ovarian reserve function was 0.866 (95% CI, 0.801-0.923), with a sensitivity of 88.10% and specificity of 88.30% when the best cut-off value was 0.621.

We acknowledge that there are some potential pitfalls in our research, the first limitation of our analysis was that the pelvic pain improvement and case satisfaction rate were not in our scope during the follow up period. Secondly, the small sample size. Thirdly, we didn't assess the AMH and AFC, one month postoperative to test the effect of two methods on ovarian reserve. Lastly, the lack of evidence about long-term recurrence and ovarian performance (due to the short duration of follow-up).

Conclusions

ORC reduces effectively the recurrence risk of endometriomas following laparoscopic drainage. Furthermore, laparoscopic drainage with filling of the remaining cyst cavity with ORC is an effective alternative for laparoscopic drainage of ovarian endometrioma with electrocautery of the endometrioma cyst wall that minimally impairs the case ovarian reserve as measured by AMH and AFC.

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Conflict of Interest: Nil

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