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A simple gasless single-port laparoscopy suitable for use in middle- and low-income countries or primary hospitals

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Running Title: Gasless laparoscopy for ovarian tumors

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ABSTRACT

Objectives: The purpose of the present study is to explore the effectiveness of a modified suspension method combined with gasless single-port laparoscopy (MS-GSPL) for the treatment of benign ovarian tumors. The aim of this approach is to provide a convenient, economical, and minimally invasive method that is suitable for widespread use, even in middle- and low-income countries or primary hospitals.

Material and methods: Retrospective analysis of patients who underwent laparoscopic unilateral ovarian cystectomy due to benign ovarian tumors from January 2019 to December 2019.Thirty-six cases were treated with MS-GSPL, and 36 cases were treated with single-port laparoscopy (SPL). The patients' medical records, perioperative surgical outcomes, postoperative pain scores and complications were reviewed and compared.

Results: There are no significant differences in age, body mass index, previous pelvic surgery, tumor diameter, and tumor pathologic outcomes between MS-GSPL group and SPL group. The median operation times were 50 (Q1~Q3, 44~62.25) min in the MS-GSPL group and 60.5 (Q1~Q3, 57.25~78) min in the SPL group with a significant difference. The median estimated blood loss was 40 (Q1~Q3, 30~50) mL in the MS-GSPL group and 50(Q1~Q3, 30~60) mL in the SPL group with no significant difference. Compared with SPL group, patients in MS-GSPL group had earlier postoperative exhaust times, shorter hospital stays and lower costs, and all these differences were statistically significant ($p < 0.05$). There was a strong positive correlation between operation time and BMI in the MS-GSPL groups.
Conclusions: The patients receiving MS-GSPL treatment have quick postoperative recoveries. MS-GSPL is a novel, safe and economical surgical method that is suitable for extensive clinical development in middle- and low-income countries or primary hospitals.
Key words: gasless laparoscopy; ovarian tumor; single-port laparoscopy; suspension method; body mass index

INTRODUCTION

Ovarian tumors are among the most common tumors in gynecology. Early diagnosis and treatment can significantly improve patients' prognoses and quality of life. Laparoscopy is an important treatment method for benign ovarian tumors. Single-port laparoscopy (SPL) improves on previous laparoscopic techniques by using the natural umbilical fold to hide the single incision, which results in better cosmetic outcomes, shorter hospitalization times, fewer complications, and quicker postoperative recovery times [1]. In 2001, Kosumi et al. [2] first applied SPL to ovarian cyst surgery, and in the following years, many more scholars have proposed that SPL could be suitable for various benign gynecological tumors [3–6]. However, due to the loss of the operating triangle in single-port laparoscopy, interference between the instruments affects the operation. Furthermore, steep learning curves [7]

make it difficult for doctors in primary hospitals to carry out single-port laparoscopy. SPL also requires CO2 pneumoperitoneum to form a manipulation space. It has been reported that CO2 pneumoperitoneum can cause complications such as increased abdominal pressure, hypercapnia, and gas embolisms, and it can affect cardiopulmonary function [8, 9]. Therefore, single-port laparoscopy cannot be performed on elderly patients, patients with cardiopulmonary diseases, or pregnant women.

In 1991, Japanese scholars first proposed the method of suspension gasless laparoscopy, which was successfully applied in cholecystectomy [10]. In 1993, suspension gasless laparoscopy was first used in gynecological surgery. The method was subsequently modified to use a subcutaneous suspension technique with a single steel needle, which further promotes the application of minimally invasive surgery in gynecology. The gasless laparoscopy operation uses the abdominal wall suspension system to establish the operation space in the abdominal cavity, which avoids the effects of CO2 pneumoperitoneum on the respiratory and circulatory systems and improves the safety of the operation and the use of anesthesia. Therefore, the combination of the SPL technique and the suspension technique can not only obtain satisfactory cosmetic effects, but it can also expand the surgical indications. Ulker et al. [11] reported in 2013 that treatment of adnexal cysts with suspension gasless single-port laparoscopy resulted not only in satisfactory cosmetic effects, but also less intraoperative bleeding, shorter operation times, and fewer complications. Takeda et al. [12] reported that treatment of adnexal masses during pregnancy by suspension gasless single-port laparoscopy avoided the negative effects of carbon dioxide on the mother and fetus and results in quick post-operative recovery times. However, the application of suspension gasless single-port laparoscopy in gynecology is still in its initial stages. Previous studies have required the use of a suspension system, and due to limited availability of instruments, this prevents the widespread use of suspension gasless single-port laparoscopy, especially in under-developed areas.

The present study used a modified suspension method, which was simple and

required no special instruments. The modified suspension method is suitable for hospitals of diverse economic levels, and it contributes to a novel, economical, safe, and effective treatment for patients.

MATERIAL AND METHODS

Study design and participants

This retrospective comparative study was approved by the Institutional Research Review Board of ShengJing Hospital of China Medical University (2020PS127J). Our research complied with the guidelines for human studies. All Patients were notified of this study, and they provided written informed consent. A total of 72 patients who underwent ovarian cystectomy between January 2019 and December 2019 were enrolled in the study. Patients were categorized according to the type of surgery received, which included 36 cases of asless single-port laparoscopy (MS-GSPL) and 36 cases of SPL. Medical records including age, body mass index (BMI), the number of previous pelvic surgeries, tumor diameter, tumor pathologic outcomes and ASA physical status classification were collected for study participants. The primary outcome of the study was operation time measured in minutes. The secondary outcomes of the study included estimated blood loss, the postoperative exhaust time of patients, length of hospital stay, total hospitalization cost and Pain scores.

Operation time was defined as the time interval between umbilical incision and the completion of skin closure. Estimated blood loss was defined as the amount difference between irrigation and suction before and after surgery plus the difference of the gauze weight. Patients' pain scores were evaluated with a visual analogue scale (VAS) immediately after surgery (0 h), and at 4 h, 12 h, and 24 h post-operation. Higher scores indicate more severe pain. Postoperative management was the same in both groups. Only flurbiprofen (100 mg/day) was used for postoperative pain control, and no other analgesics were used.

Surgical technique

Gasless single-port laparoscopy

The operation was performed under general anesthesia with the patients in the Trendelenburg position. Patients were placed in the dorsal lithotomy position. After abdominal cleaning and sterile draping according to standard procedure, the surgeon made an intraumbilical vertical skin incision of about 2 cm, pulled up the umbilicus with the towel clip, and then opened the peritoneum layer and fascia. A small wound retractor was inserted through the incision providing access to the abdominal cavity, which allowed for the simultaneous insertion of multiple laparoscopic instruments into the abdominal cavity.

The modified suspension method was conducted as follows (Fig. 1): The three-point suspension method was used (Fig. 2A). Point A: the lowest point of the umbilical incision; point X: the midpoint of the navel and symphysis pubis; point B□C: The medial 1/3 between the front axillary line and X point. The anesthesia screen frame was placed between points A, B and C, and the three points were suspended on the anesthesia screen frame using a towel clip. Point A was placed above the intraperitoneal mass (Fig. 2B).

After the operation space was established, the ovarian cyst was exposed and removed under a laparoscope. When suturing, the suture line can be pulled outside the body to fix the ovarian position (Fig. 3A), and the other hand can be used for one-handed suturing to avoid interference between the instruments (Fig. 3B). Knotting can be carried out with instruments or hands in vitro, and the knot can be pushed under laparoscopy (Fig. 4). Ovarian cysts with satisfactory mobility could be pulled to the vicinity of the umbilical incision in the abdominal cavity and operated on with instruments for laparotomy. For large cysts, they can be pulled to the umbilical incision, connected to the aspirator with a puncture needle, and given puncture fluid under the protection of dry gauze. The ovarian cyst was then pulled out of the incision for resection and suture.

The abdominal cavity was carefully observed for any bleeding lesions, rinsed with 5% warm glucose solution, and then suck out the irrigation fluid in the

abdominal cavity. The peritoneum and fascia of the umbilicus and the skin were closed after confirming that there is no bleeding.

Single-port laparoscopy

For SPL, the same preparation procedure was applied as described for suspension gasless single-port laparoscopy. After general anesthesia, a 2 cm intraumbilical vertical incision was made, and the umbilical incision was used to perform the multichannel single-port procedure with a wound retractor and surgical glove. The fingers 1, 3, and 5 were placed with the corresponding trocar among the laparoscopic instruments. The abdomen was then insufflated with carbon dioxide gas to maintain intraabdominal pressure at 13 mm Hg. The surgeon then performed routine laparoscopic operations to remove ovarian cysts and suture the ovaries [13].

Statistical analysis

Statistical analysis was performed using IBM SPSS ver. 23.0. Descriptive data were expressed as mean ± standard deviation (SD), as medians with first quartile (Q1) and third quartile (Q3) and as numbers with percentages. Differences in categorical variables were examined using the Pearson chi-square test and the Fisher exact test. Differences in continuous variables were examined using the Student's T-test and the Mann–Whitney U test for parametric data. Multivariate analysis with multiple linear regression was used to identify independent predictors of outcome measures. Two-tailed P-values lower than 0.05 were considered statistically significant.

According to our previous preliminary results, for the primary end point of the change from operation time, we calculated the sample sizes. Group sample sizes of 36 and 36 achieve 90% power to detect a difference of –13.8 between the null hypothesis that both group operation time means are 51.0 and the alternative hypothesis that the mean of control group is 64.8 with estimated group standard deviations of 10.7 and 22.6 and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test. Thus, a sample size of about 72 patients was needed for this study.

We then conducted prespecified subgroup analyses of statistical effect modification by BMI [14], because research suggested that the effect of the operation may differ by BMI [15].

RESULTS

For both groups, all surgeries could be performed without conversion to conventional laparoscopy or laparotomy. The demographic characteristics of the patients are shown in Table 1. There were no significant differences in age, BMI, the number of previous pelvic surgeries, ovarian tumor diameter, or ASA classification between the two groups. The tumor pathologic outcomes included Mature cystic teratoma, Serous cystadenoma, Mucinous cystadenoma and Endometriotic cyst. There was no statistically significant difference in pathological results between the two groups.

The postoperative outcomes and complications are shown in Table 2. There was no statistically significant difference in estimated blood loss between the two groups. The operation time in the MS-GSPL group was significantly shorter than that of the SPL group. After surgery, the MS-GSPL group had significantly less time until postoperative exhaust and shorter hospitalization times than the SPL group. The total hospital costs in the MS-GSPL group were significantly less than those in the SPL group. In addition, the MS-GSPL group had a lower incidence of postoperative shoulder pain than the SPL group. There was no significant difference in postoperative pain score between the two groups during recovery (Tab. 3).

Multiple linear regression was used to analyze the effects on operate time of the following variables: BMI, tumor diameter and previous pelvic surgeries. The results showed that BMI was a significant independent predictive factor of affected operation time in the MS-GSPL group (Tab. 4). Table 5 showed the comparison results of operative time and estimated blood loss between the MS-GSPL group and the SPL group in different BMI subgroups. The results showed that in the patients with BMI<25, the operative time of the MS-GSPL group was significantly shorter than that

of the SPL group, while there was no significant difference in the operative time of the patients with BMI ≥ 25. There was no significant difference in estimated blood loss between the two groups in different subgroups.

DISCUSSION

With the development and advances in surgical instruments and technology, laparoscopy has become one of the standards for removing ovarian tumors. There is no doubt that compared with laparotomy, laparoscopic surgery has better cosmetic outcomes, shorter hospitalization times, fewer complications, less pain and quicker postoperative recovery times. However, the CO2 pneumoperitoneum would make the laparoscopic's applications to have limitations. In addition, the absence of operating triangle and interference between instruments in single-port laparoscopic surgery affect the operation, leading to a long learning curve for doctors. Therefore, our study proposed MS-GSPL which provides a safe, effective and economical technology for patients.

In both groups, all operations were performed successfully and did not require conversion to conventional laparoscopy or laparotomy. The present comparative study showed that patients in the MS-GSPL group had a shorter borborygmus recovery time and a lower incidence of shoulder pain. BMI was significant independent predictive factors of affected operation time in the MS-GSPL group.

In 1993, suspension gasless laparoscopy was first used in gynecological surgery, which has been recognized by most scholars. It has been shown to be the primary minimally invasive approach for patients who cannot perform laparoscopic surgery due to pneumoperitoneum. Meanwhile, minimally invasive surgery can be performed in remote areas or in middle- and low-income countries without support services such as bottled gases or disposable instruments [16]. After years of exploration and development, various abdominal wall suspension methods have been proposed and studied [11, 17–21]. However, existing methods all require the use of suspension systems. Due to instrument limitations, this presents a barrier to the widespread use of

gasless laparoscopy. The method proposed in this study was a major improvement, because it does not require special equipment for suspension. Our method uses existing surgical instruments and an adjustable anesthetic stent for suspension and does not require a pneumoperitoneum machine or suspension system. This makes our approach more conducive for performing gasless laparoscopy in middle- and low-income countries or primary hospitals. This method reduces the cost of hospitalization and alleviates the economic burden of patients. On the other hand, our modification of the suspension method can reduce the risk of subcutaneous hematoma and intestinal injury caused by needle passing under the skin in previous studies. The position of the suspension point can be adjusted according to the location of the cyst to broaden the field of vision. In addition, the operation method is simple, without special training, which is conducive to the development of grass-roots hospitals.

Suspension gasless laparoscopy improves the safety of the operation and the use of anesthesia. Previous studies have shown that CO2 pneumoperitoneum can potentially damage the circulatory and respiratory systems and can even cause life-threatening complications. Increased intra-abdominal pressure and hypercapnia caused by CO2 pneumoperitoneum may cause increased blood pressure, arrhythmia, increased airway pressure, and decreased lung compliance, which seriously affects the stability of the respiratory and circulatory systems [22]. CO2 pneumoperitoneum can excite the vagus nerve through the pressure and chemoreceptors of the gastrointestinal system, weaken gastrointestinal peristalsis [23], increase the probability of postoperative nausea and vomiting, and affect the recovery of gastrointestinal function [24]. Our results showed that compared with the SPL group, the MS-GSPL group had less postoperative exhaust time and lower incidence of nausea and vomiting, which was consistent with the study results of Kim et al. [25]. It can promote early enteral feeding and enhance recovery after surgery. On the other hand, CO2 pneumoperitoneum also stimulates the phrenic nerve, which can cause postoperative shoulder and back pain. It is reported that following laparoscopic surgery, in addition to incision pain, up to 80% of patients complain of

subdiaphragmatic, shoulder and back pain [26]. Often, the subdiaphragmatic, shoulder, and back pain exceed the incision pain in degree and duration, and these pains often become the main source of discomfort for patients following laparoscopic surgery. It also affects the quality of life and is one of the important reasons for delayed discharge or interference of coming back to normal activities [27]. The results of this study showed that there was only one case of shoulder and back pain in the MS-GSPL group, which was much less than 10 cases in the SPL group. The length of postoperative hospital stay in MS-GSPL group was significantly shorter than that in SPL group.

There are several benefits to the LESS approach, such as the potential for improved cosmetics, shorter hospital stays, fewer complications, less pain and so on. But due to loss of the "operating triangle" in single-port laparoscopy, instruments interfere with each other, which increases the difficulty of operation. Consequently, SPL needs long learning a long learning curve for doctors. This is especially true for ovarian cystectomy. In the process of cyst resection and ovarian suturing, because of the close distance between the instruments, interference is particularly serious. However, when SPL is combined with suspension gasless laparoscopy, the surgical instruments can freely enter and leave the abdominal cavity. The difficulty of the operation is further reduced by the combination of in vivo and in vitro procedures and the use of instruments for laparoscopy and laparotomy. When suturing, the suture line can be pulled outside the body to fix the ovarian position, and the other hand can be used for one-handed suturing to avoid interference between the instruments. Knotting can be carried out with instruments or hands in vitro, and the knot can be pushed under laparoscope. In addition, larger ovarian cysts can be pulled out beyond the umbilical incision, followed by removal of the cyst and suture of the ovary. This operation is the same as a laparotomy and is simple and convenient. Finally, operation times for suspension gasless SPL are short. Because the abdominal wall is suspended to maintain the operating space, the aspirator does not cause air leakage and affect the field of vision during use. In addition, smoke from electrical instruments and blood

buildup in the pelvic cavity can be quickly cleared without affecting surgical procedures. The results of this study showed that the operation time of the MS-GSPL group was significantly shorter than that of the SPL group, which was consistent with the results of Kim et al. [25]. However, there are some limitations in the implementation of gasless single-port Laparoscopy. It was reported that there was a positive correlation between operation time and tumor diameter. But BMI was negatively correlated with operation time. In this study, we studied the influencing factors of the operation time in the MS-GSPL group, and the results showed that BMI was an independent influencing factor of the operation time, while the tumor diameter and the number of previous pelvic surgeries was not correlated with operation time

Our study has some limitations. This study is retrospective design and there was potential selection bias. Overweight patients may influence the surgeon's choice of surgical approach, leading to biased results. Therefore, stratified analysis was adopted in this study. Our results showed that the patients with BMI < 25, the operative time of the MS-GSPL group was significantly shorter than that of the SPL group. Therefore, we believed that gasless single-port Laparoscopy was more suitable for thin patients. In the future, well-designed prospective, randomized controlled studies are required to verify our findings.

CONCLUSIONS

Gasless single-port laparoscopy requires no special instruments, the operation is simple, induces fewer postoperative complications, and results in quick postoperative recovery. It is a feasible, safe and economical surgical method that is suitable for widespread use even in economically under-developed countries and under-resourced hospitals.

ARTICLE INFORMATIONS AND DECLARATIONS

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial

or financial relationships that could be construed as a potential conflict of interest.

Author contributions

Y.L. designed the research; X.Y.W. performed the research; all authors read and approved the final manuscript.

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Data availability statement

The datasets used during the current study are available from the corresponding author on reasonable request.

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Table 1. The demographic characteristics of the patients

Characteristics	MS-GSPL group	SPL group	$T/Z/X^2$	p value

	n = 36	n = 36	value	
Age [year]	30 (26.25, 36.75)	33.5 (27, 39.75)	–0.940	0.350**
BMI [kg/m^2]	22.97 (21.48, 27.15)	23.44 (20.84, 27.34)	–0.271	0.787
Ovarian tumor diameter [cm]	6 (5, 8)	6 (5, 7)	–0.046	0.963
Previous pelvic surgery (n, n%)			1.416	0.234
0	23 (63.9%)	18 (50%)		
1	13 (36.1%)	18 (50%)		
ASA Classification			0.355	0.551
I	6 (16.7%)	8 (22.2%)		
II	30 (83.3%)	28 (77.8%)		
tumor pathologic			1.044	0.813**
Endometriotic cyst	11 (30.6%)	14 (38.9%)		
Serous cystadenoma	13 (36.1%)	11 (30.6%)		
Mature cystic teratoma	10 (27.8%)	8 (22.2%)		
Mucinous cystadenoma	2 (5.5%)	3 (8.3%)		

MS-GSPL — gasless single-port laparoscopy; SPL — single-port laparoscopy; BMI — body mass index; ASA Classification — ASA Physical Status Classification;

Values were presented as medians with first quartile (Q1) and third quartile (Q3) or as numbers with percentages. The differences in continuous variables were examined using the Student's T-test* and the Mann–Whitney U test. Differences in categorical variables were examined using the Fisher exact test** and Pearson chi-square test

Table 2. Comparison of postoperative outcomes and complications outcomes

Characteristics	MS-GSPL group n = 36	SPL group n = 36	T/Z/X^2 value	p value
Estimated blood loss [mL]	40 (30, 50)	50 (30, 60)	–0.531	0.595
Operation time [min]	50 (44, 62.25)	60.5 (57.25, 78)	–3.557	< 0.001
postoperative exhaust time [hour]	25 (22, 28)	28 (24, 31.75)	–2.790	0.007※※
Length of exhaust time [day]	3 (3, 3)	4 (3, 4)	–4.508	< 0.001

Total hospital cost [US dollar]	3650 (3471, 3880)	3878 (3653, 4099)	–2.450	0.017*
Complications (n, n%)				
Nausea and vomiting	2 (5.5%)	8 (22.2%)		0.085**
Shoulder and back pain	1 (2.8%)	10 (27.8%)		0.006**
Subcutaneous emphysema	0	3 (8.3%)		0.239**

MS-GSPL — gasless single-port laparoscopy; SPL — single-port laparoscopy; Values were presented as medians with first quartile (Q1) and third quartile (Q3) or as numbers with percentages. Differences in continuous variables were examined using the Student's T-test* and the Mann–Whitney U test. Differences in categorical variables were examined using the Fisher exact test** and Pearson chi-square test

Table 3. Postoperative pain score

Pain scores	MS-GSPL group n = 36	SPL group n = 35	t value	p value
Immediately after operation	3.25 ± 0.55	3.19 ± 0.58	0.417	0.678
4 hours postoperation	2.28 ± 0.61	2.08 ± 0.44	1.544	0.127
12 hours postoperation	1.78 ± 0.48	1.56 ± 0.56	1.804	0.075
24 hours postoperation	1.11 ± 0.32	1.03 ± 0.17	1.390	0.169

MS-GSPL — gasless single-port laparoscopy; SPL — single-port laparoscopy; Pain scores were evaluated using visual analogue scale (VAS) after surgery. The differences in pain scores were examined using the Student's T-test. Values were presented as mean ± standard deviation (SD)

Table 4. Multiple linear regression analysis of influencing factors of Operation time in gasless single-port laparoscopy group

Variable	Coefficient B	Standard error	95% CI for B	t value	p value
Previous pelvic surgeries	–0.285	3.509	–7.433~6.863	0.081	0.936
Tumor diameter	–0.380	1.109	–2.638~1.878	–0.343	0.734

BMI	3.880	0.476	2.910~4.850	8.151	< 0.001

CI — confidence interval; BMI — body mass index; R2 = 0.681; Adjusted R2 = 0.651

Table 5. The analyses of statistical effect modification by body mass index (BMI)

	BMI < 25				BMI ≥ 25			
	MS-GSPL group (n = 21)	SPL group (n = 22)	z value	p value	MS-GSPL group (n = 15)	SPL group (n = 14)	z value	p value
Estimated blood loss [mL]	30 (30, 50)	45 (30, 50)	–0.345	0.730	50 (30, 80)	50 (30, 82.5)	–0.446	0.656
Operation time [min]	45 (42, 50)	60 (59.25, 70.5)	–5.273	0.000	66 (60, 91)	62 (54.75, 90.5)	–0.461	0.645

MS-GSPL — gasless single-port laparoscopy; SPL — single-port laparoscopy; Values were presented as medians with first quartile (Q1) and third quartile (Q3).The differences in continuous variables were examined using the Mann–Whitney U test

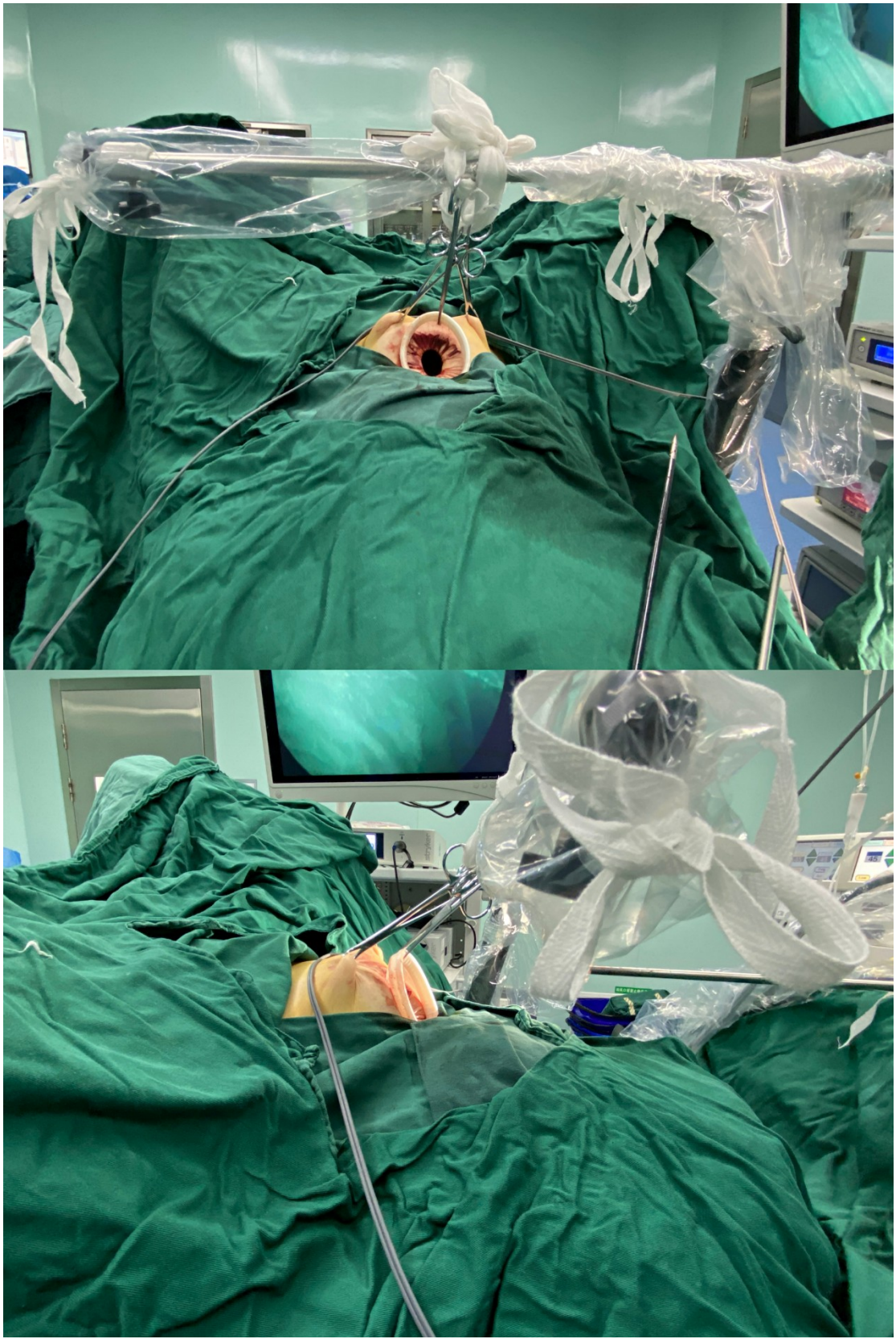
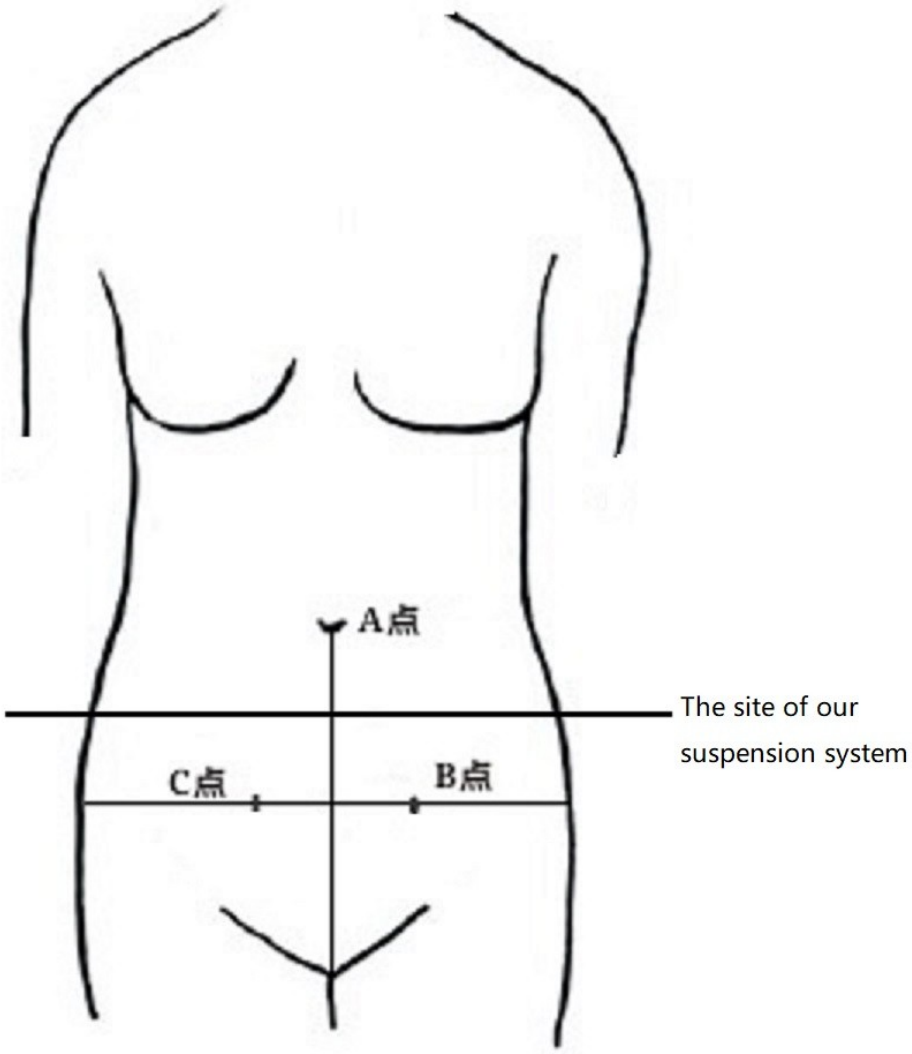


Figure 1. Modified suspension method

A.



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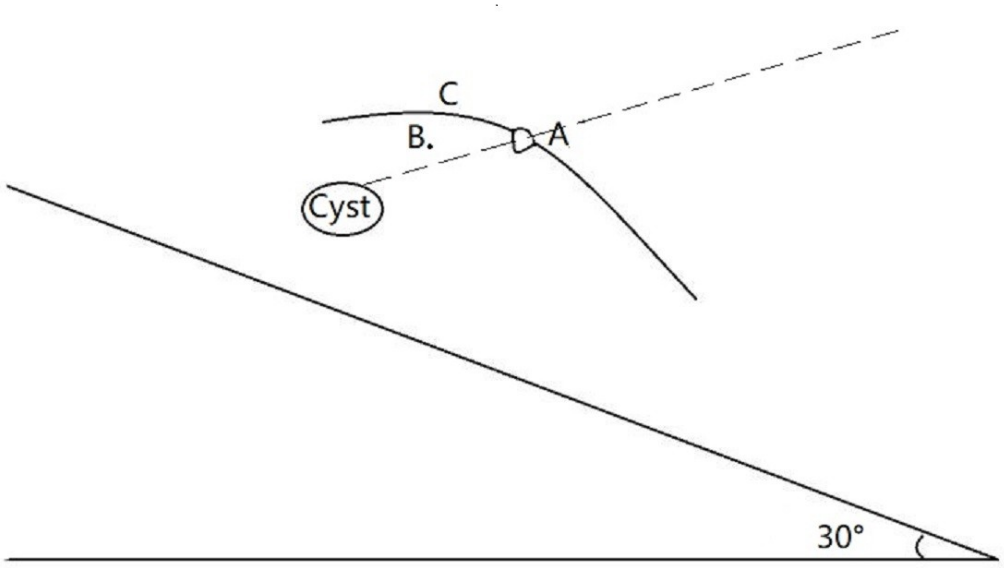
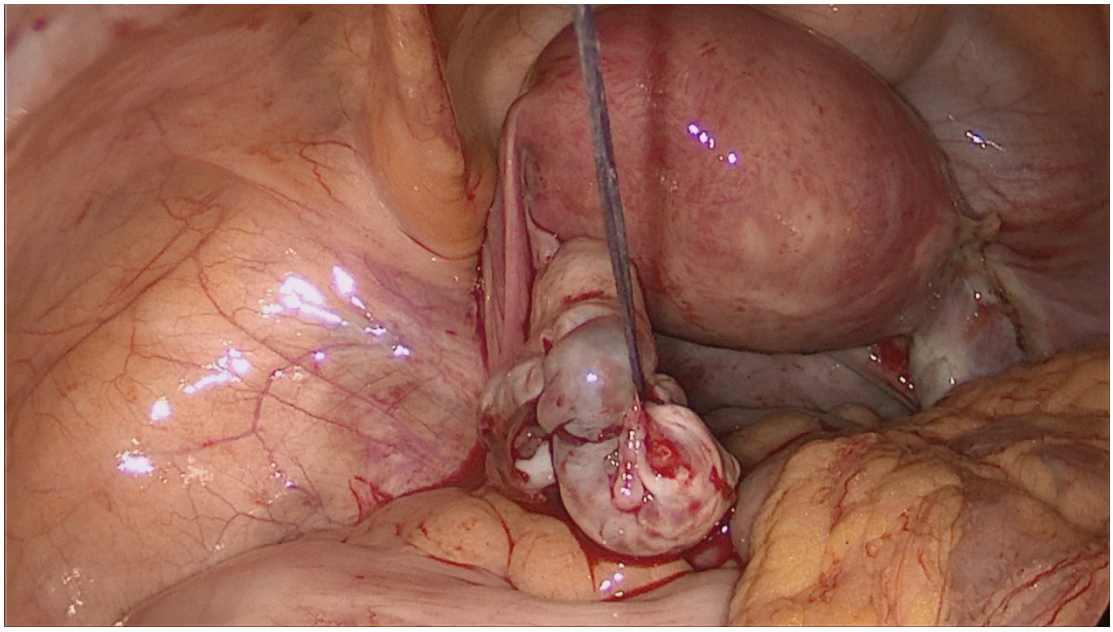


Figure 2. A. Schematic diagram of abdominal suspension points; **B.** Suspended lateral view. The height of suspension point A was higher than that of the intraperitoneal ovarian cyst

A.



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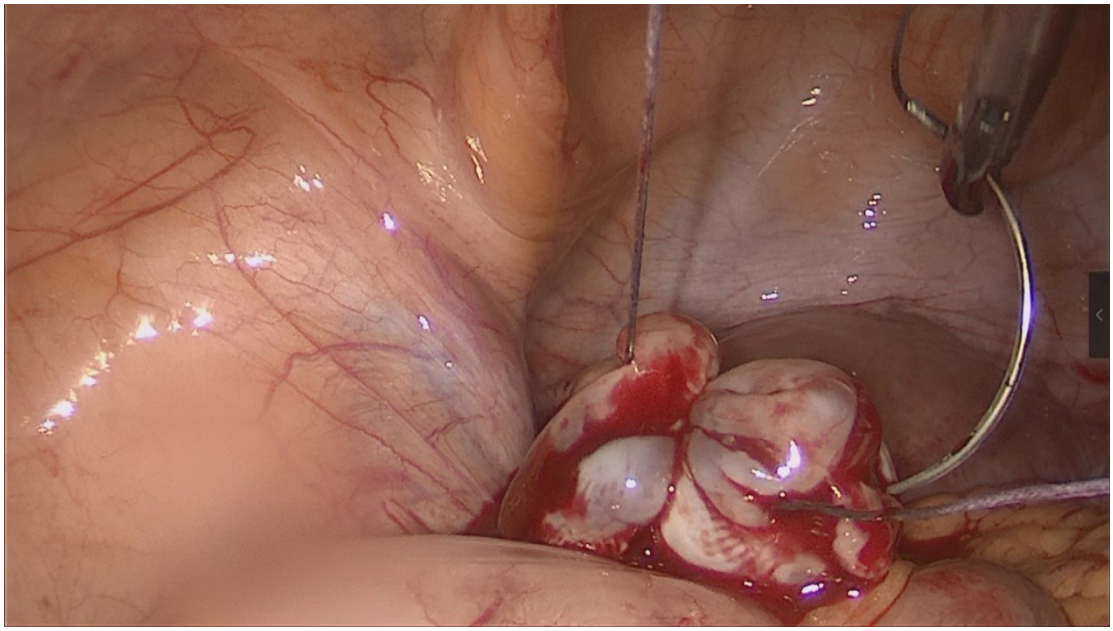
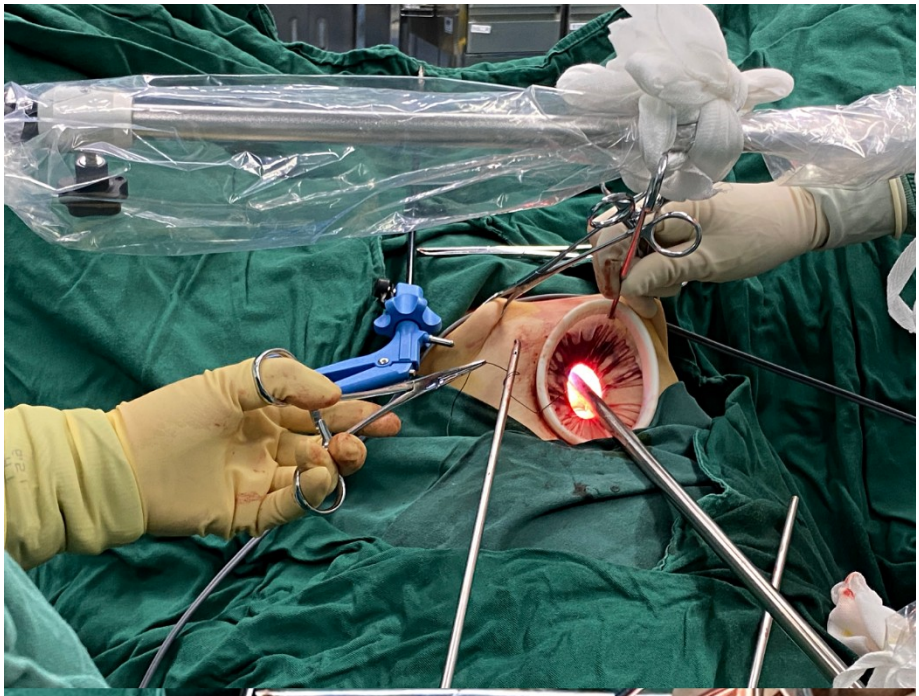
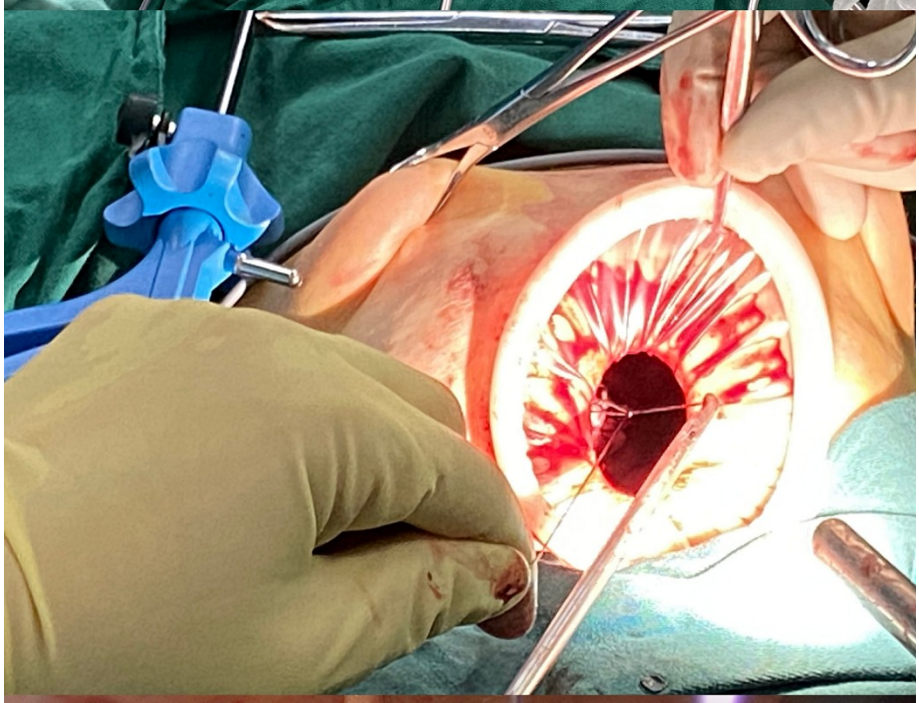


Figure 3. A. The suture line can be pulled outside the body to fix the ovarian position; **B.** *In vivo* and *in vitro* procedures were combined to suture ovaries





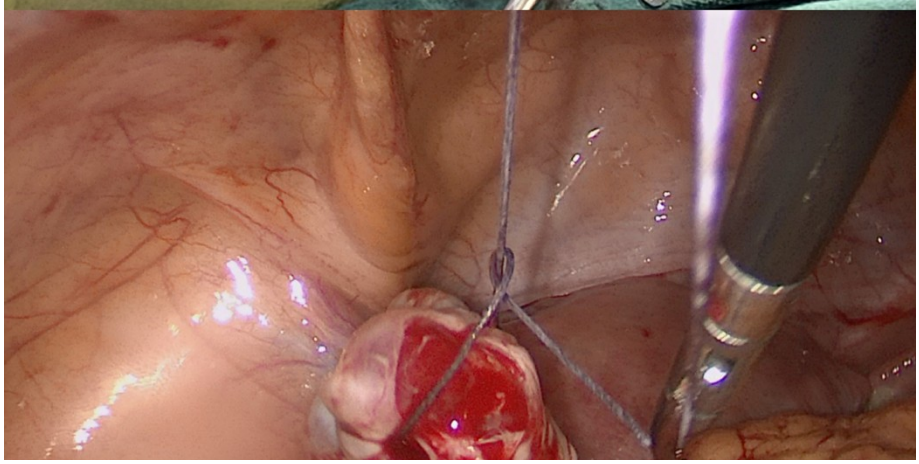


Figure 4. Knotting operation