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Laparoscopic continuous seromuscular circumsuture for myomectomy: a real-world, retrospective, East-Asian cohort study

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ABSTRACT

Objective This study aimed to introduce a novel laparoscopic haemostasis for myomectomy and investigate the independent risk factors for uterine fibroid recurrence.

Design A retrospective cohort study.

Setting Following strengthening the reporting of observational studies in epidemiology (STROBE) criteria, a retrospective study of prospectively collected available data of the consecutive patients who underwent the myomectomy in the department of obstetrics and gynaecology of the single centre between February 2018 and December 2020.

Participants 177 patients who underwent laparoscopic myomectomy resection were enrolled in the present cohort study.

Materials and methods Patients were classified into two groups according to their different methods of haemostasis in laparoscopic surgery. Recurrence-free survival was compared between the groups during an average follow-up of nearly 2 years.

Results Of the 177 patients from 672 consecutive patients in the retrospective cohort, laparoscopic circular suture and baseball suture were carried out in 102 (57.6%) and 75 (42.4%) patients, respectively. The total amount of blood lost during surgery varied significantly (37.6 vs 99.5 mL) (p<0.001). Univariable analyses identified that age ≥40 years, position at intramural myoma, multiple fibroids and largest fibroid volume ≥50 mm^3 (HR 2.222, 95% CI 1.376 to 3.977, p=0.039; HR 3.625, 95% CI 1.526 to 6.985, p=0.003; HR 3.139, 95% CI 1.651 to 5.968, p<0.001; HR 2.328, 95% CI 0.869 to 3.244, p=0.040, respectively) are independent risk factor of the recurrence of uterine fibroids. The formula of the nomogram prediction model was established as the practical clinical tool.

Conclusion The laparoscopic continuous seromuscular circumsuture for myomectomy can effectively reduce the amount of surgical bleeding and accelerate the perioperative recovery for surgical safety. The main factors affecting the recurrence of uterine fibroids were age, location, number and volume of uterine fibroids. The nomogram can more straightforwardly assist clinicians to determine the risk of recurrence after laparoscopic myomectomy.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study introduces a new safe method of circumsuture of the peritumour seromuscular layer for laparoscopic hysteromyomectomy and compares it with traditional baseball suture.
⇒ Through Cox regression analysis, age, location of fibroids, number of fibroids and maximum fibroid diameter are identified as independent risk factors for uterine myoma recurrence.
⇒ The first nomogram to predict the recurrence of laparoscopic fibroids was established to predict the risk of recurrence.
⇒ Main disadvantages of this study are that the study is not a randomised controlled clinical trials and is only the single-centre retrospective cohort; therefore, possible bias may not be avoided.

INTRODUCTION

Uterine fibroids, also known as leiomyomas, are the most common genital tract tumour in women of middle age worldwide.[1 2] These tumours can cause significant morbidity, including heavy menstrual bleeding, pelvic pressure or pain and infertility.[3 4] Uterine fibroids are among the most common reasons for uterine surgery worldwide, with approximately 200 000 hysterectomies being performed each year for symptomatic fibroids alone.[5 6] Treatment options for uterine fibroids include medical therapy, non-surgical methods and surgery. Medical therapy, such as hormonal contraceptives or gonadotropin-releasing hormone agonists, can relieve symptoms but may lead to adverse effect and be ineffective in reducing fibroid size.[7 8] Non-surgical methods, such as uterine artery embolisation, focused ultrasonography or radiofrequency ablation, can be used as alternatives to surgery, but data about their long-term outcomes and safety are limited.[9 10]

Surgical treatment, including hysterectomy or myomectomy, remains the most definitive and effective treatment for symptomatic

uterine fibroids.[11 12] Myomectomy removes the fibroids while preserving the uterus and is commonly performed in women who wish to maintain fertility.[13 14] However, myomectomy can be associated with significant blood loss and prolonged operative time, and the recurrence rate is relatively high.[15] Open abdominal myomectomy is still the gold standard for myomectomy, while the laparoscopic or robotic-assisted myomectomy allows for better visualisation and control of bleeding, and may be preferred for larger, more complex fibroids.[16 17] Nevertheless, the amount of blood lost during surgery is uncontrollably low due to the abundant blood supply to the uterus and the duration of the operation is long.

Laparoscopic surgery technology has been recently rapidly developed, and the progress of surgical technology has provided a further guarantee for the safety of myomectomy.[18 19] These technological advances often include the development of new surgical modalities, innovations in perioperative management and the manufacture of new related endoscopic instruments.[20 21] However, there are concerns about the safety and efficacy of these approaches, and there are limited long-term data on recurrence rates and fertility outcomes.[22–24] Therefore, the surgical treatment of uterine fibroids must rely on existing methods of diagnosis and treatment to facilitate new progress and improvement.

In this study, we assessed a new technique to perform laparoscopic continuous fibroid circumsuture in myomectomy with the approval of the surgical centre. We have previously performed similar operations to successfully prevent refractory postpartum bleeding and explored the safety of this type of such surgeries.[25] In this report, we comprehensively discuss the application of this procedure to treat uterine fibroids, describe the complete surgical procedure and review the clinical data. While examining the safety and efficacy of this approach, we particularly focused on surgical blood loss and perioperative complications. We also explored the effect of myomectomy on fertility outcomes and discussed strategies for minimising recurrence rates. We aimed to provide clinicians with new surgical options for myomectomy and help guide clinical decision-making in myomectomy management.

METHODS

Study design and oversight

In this retrospective cohort study, we prospectively collected available data of consecutive patients who underwent myomectomy from an obstetrics and gynaecology centre between February 2018 and December 2020 (online supplemental figure 1). All patients diagnosed with uterine fibroids were included in the study. The researchers' surgical group performed the new technique of laparoscopic circumsuture, whereas another surgical group continued to perform the traditional baseball suturing. Both groups of patients received the same standard of clinical management. Demographic data and surgical and prognostic outcome data were collected at the end of treatment and during follow-up.

Preoperative preparation

Surgical risks were fully assessed in both groups. After successful induction of general anaesthesia, patients were placed in the 15° low-head position, and 1–3 cm laparoscope was inserted in the umbilical hole or the upper edge of the umbilical hole based on the fibroid size. Trocar was placed at the second and third puncture points in the left lower abdomen and the vascularless area of 4 cm beside the umbilical hole, respectively, to explore the location and number of uterine fibroids. A 6-U quantity of pituitrin was diluted with 20 mL of normal saline and injected into the uterine body to reduce uterine vessel bleeding and induce uterine contractions and vessel ischaemia. Blood pressure was closely monitored during the operation. Myomectomy started when the blood vessels appeared white or grey after uterine contraction and the onset of ischaemia.

Surgery

Laparoscopic circumsuturing of the peritumour seromuscular layer

Laparoscopic circumsuturing of the peritumour seromuscular layer is a new surgical method that was approved for use by our centre in 2018 (figure 1). In our patients, the suture needle was first injected into the serous layer at the starting point 1–2 cm outside the fibroid. The needle was drawn around the edge of the tumour without penetrating the mucosa. After the first needle was drawn, the knot was tied without cutting the tail to continue the suture. Stitches were spaced 2–3 cm apart each time, and the thread was knotted after each stitch. The suture encompassed approximately 75% of the area around the tumour in a 'C' shape. The thread remained uncut, and a unipolar electrical hook was then used to cut through the myoplasmic muscle layer in the middle of the tumour until the fibroid was exposed. After this operation, almost no significant bleeding or even oozing of blood on the surface of the tumour occurred. Remaining fibroids were sutured in the original way, forming a circle around the 'O' shape. The fibroids were peeled until they reached the base of the fibroids, where blood vessels could be attached. Continuous suturing was then performed at the base of the fibroid. Finally, the suture was knotted and tightened, and the fibroids were completely removed. The remainder of the uterus was sutured to further compress vessels for haemostasis and to promote wound healing. During the entire operation, no massive bleeding occurred in the endoscopic field.

Baseball suture method of uterus

The centre's other attending physician and their surgical team used traditional baseball sutures to directly treat fibroids and remainder of the uterus. In traditional surgery, uterine fibroids are removed from shallow to deep levels, and the tumour cavity is sutured closed. The surface of the sutured uterus resembles a baseball, and

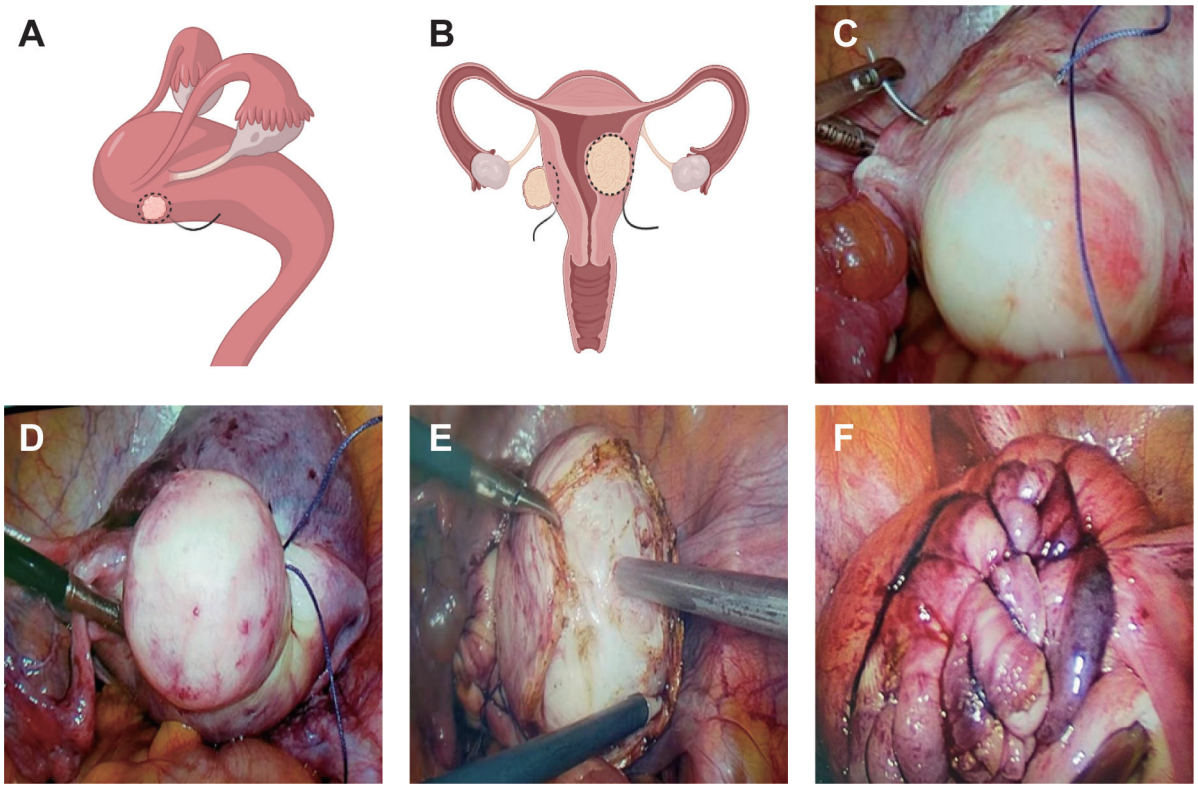

Figure 1 Schematic diagram and photos of the main surgical procedures of continuous seromuscular circumsuture for uterine fibroids myomectomy under laparoscopy. (A) Lateral view of circumsuture of uterine fibroids. (B) Schematic diagram of annular suture section during the resection of multiple uterine myomas. (C–F) Photos of the surgical process of myomectomy with circular suture. (C) Needle insertion and needle distance. (D) A C-shaped suture is formed around the uterine fibroid. (E) Carefully and integrally remove the uterine fibroids. (F) Close the wound and tie with a little tension.

the deeper the tumour, the greater the amount of blood loss. For the remaining patients at the surgical centre, the tumours were excised through this traditional method. These patients served as the control group in this study, with the approval of the centre. Although this procedure had fewer steps than the modified procedure, bleeding in the surgical field was significantly greater.

Postoperative care

A pelvic drainage tube was placed intraoperatively in all patients undergoing surgery to monitor postoperative bleeding and pelvic infection. In addition, uterine hormone was also postoperatively administered to promote uterine contraction and prevent bleeding. Anti-infective therapy is administered according to the standard of antibiotic use. Patients were encouraged to resume ambulation as soon as possible after the removal of indwelling catheters to promote rapid recovery.

Histopathology

All removed fibroids were pathologically examined to confirm the diagnosis. Each tissue was embedded in paraffin, and at least five sections of each tissue were examined by at least three pathologists (attending physician or of higher rank) to confirm the diagnosis of fibroids. Patients in whom the findings were inconsistent with the preoperative diagnosis were excluded.

Follow-up and outcome measures

Standardised follow-up protocols include clinical examination and CT or MRI within 6 months after surgery. The patients were then asked to undergo at least one ultrasound examination or other imaging test every 6 months to assess for relapse. Because this haemostatic procedure is a new, short-term follow-up, comprised observing short-term recurrence of uterine fibroids within 2 years; the long-term follow-up (3–5 years) has not been established. Reproductive health information and accompanying screening for malignant tumours are routinely included in follow-up data.

Statistical analyses and construction of nomograms

All consecutive patients who fulfilled the inclusion criteria were included in the study cohort to ensure adequate sample size and avoid bias. The Pearson χ^2 test was used to analyse the significance of differences among categorical variables. Where appropriate, the Mann-Whitney U test or Kruskal-Wallis test was used to assess the significance of continuous variables. To plot the distributions of recurrence-free survival (RFS), we used the Kaplan-Meier method, and significance was assessed with the log-rank (Mantel-Cox test). To perform univariate and multivariate analyses, we used the Cox proportional hazards regression model. P values of 0.05 were considered

statistically significant. Clinically important variables for which p value was <0.1 were included in the single-factor analysis to construct the following model.

Baseline clinical parameters were compared between the experimental and control groups, and linear hypothesis testing was performed using splines for all independent predictors of continuous variables. To improve the predictive power of the model, only independent predictors from multivariate analyses were used to construct a prognostic nomogram using linear predictors. Variables that had the greatest predictive effects were scored a maximum of 100 points, and other variables were scored according to a lower maximum in proportion to their effect sizes. All statistical tests were performed and their results plotted in SPSS (V.23.0) and R software (V.4.1.2).

Patient and public involvement

A patient representative from the Jiangsu Surgical Association of China evaluated the research. In addition, a patient representative from the uterine fibroid specialist clinic contributed by commenting on patient information.

RESULTS

Comparison of clinical characteristics

Uterine fibroids were radiographically confirmed with in 672 patients between February 2018 and December 2020 at the Jianhu Obstetrics and Gynecology Center, Jiangsu, China (online supplemental figure 1). Of these patients, 216 were scheduled to undergo laparoscopic myomectomy; they provided full patient informed consent and after undergoing fibroids evaluation. We excluded 31 patients who underwent laparoscopic conversion to open surgery and 8 patients who were lost to follow-up; the remaining 177 patients who underwent laparoscopic myomectomy were enrolled in this retrospective study.

The clinical baseline characteristics of the patients used in the analysis and mean and SD of the data are presented in table 1. The mean age of patients was 42.3 years, the mean body mass index was 24.5 kg/m^2 and ≥45% patients wished to preserve their fertility. The mean numbers of pregnancies and births per patient were 2.8 and 1.3 times, respectively. More than 75% of patients were diagnosed with fibroids using MRI, and the vast pathological location of fibroids was intermuscular (over 70%). The longest diameter of fibroids in all patients undergoing surgery was 7.3 cm, with an average number of 1.4 and a maximum tumour volume of 405 mm^3. Of the patients, 15.8% had a history of abdominal surgery, and 38.4% had received contraceptive or hormonal treatments to control symptoms. The baseline characteristics of the patients who underwent circumsuturing did not differ

Table 1 Clinical characteristics of the patients underwent laparoscopic myomectomy in the whole cohort

Variable	No. (%) Cohort (n=177)	Circumsuture (n=102)	Baseball suture (n=75)	P value
Demographic characteristics and pregnancy history				
Age—year (IQR)	42.3 (38.0–46.0)	41.1 (38.0–46.0)	43.5 (37.0–49.0)	0.062
Body mass index	24.5±3.1	24.1±2.9	24.9±3.3	0.194
Desire for pregnancy	83 (46.9)	47 (46.1)	36 (48.0)	0.077
Parity	1.3±0.5	1.2±0.6	1.4±0.5	0.110
Gravidity	2.8±1.5	2.8±1.5	2.8±1.5	0.828
Fibroid assessment				
Imaging used to diagnose fibroid				
MRI	134 (75.7)	75 (73.5)	59 (78.7)	0.497
Ultrasonography	42 (23.7)	26 (25.5)	16 (21.3)	
Location of largest fibroid				
Submucosa	6 (3.4)	4 (3.9)	2 (2.7)	0.879
Subserosa	46 (26.0)	27 (26.5)	19 (25.3)	
Muscle wall	125 (70.6)	71 (69.6)	54 (72)	
Longest dimension of largest fibroid—mm	7.3±1.3			
No. of fibroids	1.4±0.7	1.4±0.7	1.4±0.7	0.837
Largest fibroid volume—mm^3	405±524	354±442	413±369	0.152
Surgical and medication history				
Previous abdominal surgery	28 (15.8)	15 (14.7)	13 (17.3)	0.705
Contraceptive or hormonal treatments to control symptoms	68 (38.4)	41 (40.2)	27 (36)	0.571

from those of patients who underwent traditional suturing between the two groups because patients in both groups were continuously enrolled in the study and the surgical indications were the same.

Comparison of perioperative and surgical outcomes

Online supplemental table 1 lists the main outcomes of the patients, which are divided mainly into surgery-related outcomes, perioperative complications and long-term postoperative outcomes. The patients who underwent traditional laparoscopic myomectomy were monitored with regular examinations and questionnaires for a median of 19 months. As shown in online supplemental table 1, the operation time with the circumsuture method (79.2 min), which had additional surgical steps, was not statistically longer than that of the traditional method (83.4 min), possibly because the traditional method entailed more time to deal with unexpected bleeding. However, the total amount of blood lost during surgery varied significantly (37.6 vs 99.5 mL; p<0.001). The differences in postoperative drainage volume and intestinal exhaust time, which reflected surgical recovery speed, were also statistically significant (p<0.001); patients who underwent circumsuturing recovered faster. Because of routine antibiotic use and close monitoring, the incidence of serious postoperative complications was controlled to within 3%.

Routine and biochemical blood tests were performed according to standard routine before and after surgery. Figure 2 illustrates the changes in haemoglobin and leucocyte levels, as well as oestradiol levels, 1 week after surgery, among which the changes in haemoglobin were statistically significant (p<0.05). These differences may be related to differences in surgical trauma and postoperative recovery speed. Online supplemental figure 2 illustrates the recurrence of uterine fibroids in patients during follow-up, as well as the RFS ratio and follow-up time. The two different suturing techniques did not have different effects on the recurrence of uterine fibroids (p=0.809). These results suggest that laparoscopic circumsuturing is no more dangerous than the traditional method for myomectomy in terms of associated complications or long-term adverse reactions.

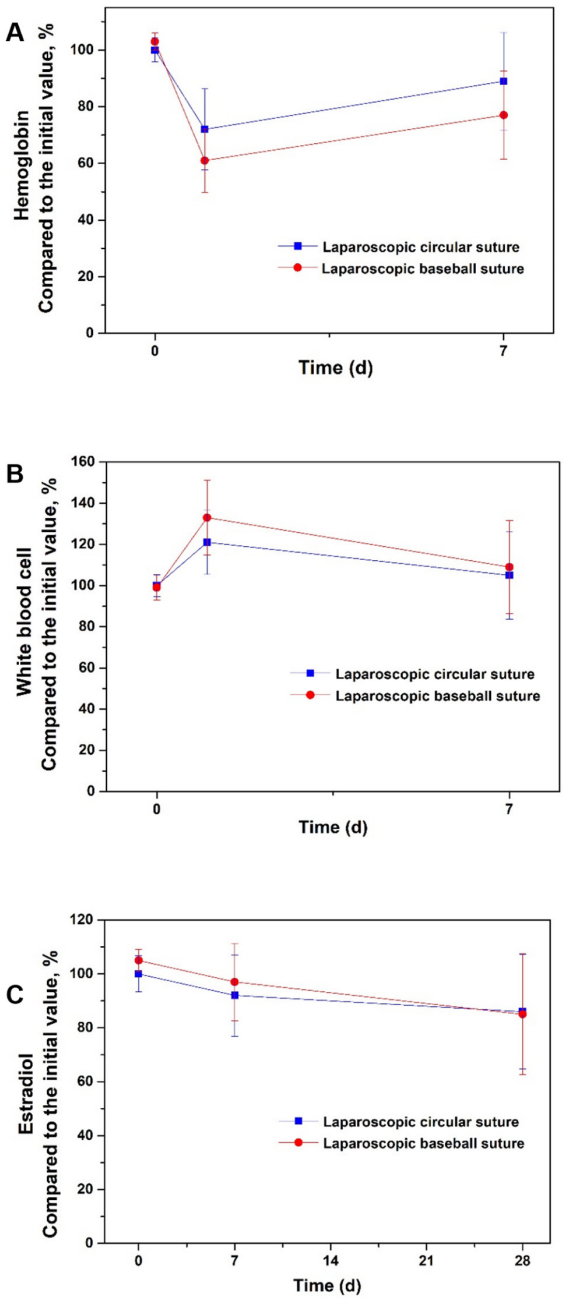

Figure 2 Major blood and biochemical indexes changed before and after surgery.

Cox regression analysis and the related nomograms of RFS

The results of the univariate and multivariate Cox proportional hazard regression analyses of RFS after laparoscopic myomectomy for uterine fibroids are listed in table 2. We found that independent risk factors for uterine fibroid recurrence after myomectomy were patient age of ≥40 years (HR 2.222; 95% CI 1.376 to 3.977), intramural location of fibroids (HR 3.625; 95% CI 1.526 to 6.985), the presence of multiple fibroids (HR 3.139; 95% CI 1.651 to 5.968) and large diameter of fibroids (HR 2.328; 95% CI 0.869 to 3.244).

The formula for the nomogram prediction model was based on the results of the Cox regression analysis (figure 3). After we determined the correspondence between the patients' information and the prognostic factors, the total score was calculated to reveal the expected probabilities of 1-year and 2-year RFS. In this way, the recurrence of uterine fibroids could be predicted more intuitively by inputting the independent risk factors of the Cox regression model.

DISCUSSION

Summary of main results

In the continuous retrospective database, 672 patients were included for follow-up analysis, and 177 patients who underwent laparoscopic myomectomy, we found no difference in baseline characteristics between those

Table 2 Univariate and multivariate Cox regression analysis of recurrence-free survival in the total cohort of uterine fibroids

Variables	Comparisons	UV HR (95% CI)	UV P value	MV HR (95% CI)	MV P value
Age—year	≥40 vs <40	2.222 (1.376 to 3.977)	**0.039**	0.783 (0.225 to 2.722)	0.700
Body mass index	≥24 vs <24	0.993 (0.993 to 0.837)	0.940		
Parity	Yes vs no	0.894 (0.702 to 1.409)	0.775		
Gravidity	Yes vs no	1.922 (0.713 to 5.128)	0.197		
Position	Intramural myoma vs others	3.625 (1.526 to 6.985)	**0.003**	2.135 (1.253 to 4.289)	**0.043**
No. of fibroids	Multiple vs singles	3.139 (1.651 to 5.968)	**<0.001**	3.443 (1.700 to 6.976)	**0.001**
Largest fibroid volume—mm^3	≥50 vs <50	2.328 (0.869 to 3.244)	**0.040**	1.200 (0.741 to 1.943)	0.458
Operation time—min	≥80 vs <80	1.039 (0.988 to 1.078)	0.052		
Peroperative bleeding—mL	≥60 vs <60	1.006 (1.001 to 1.011)	0.070		
Blood transfusion	Yes vs no	1.219 (0.919 to 1.931)	0.370		
Postoperative drainage—mL	≥50 vs <50	1.035 (0.856 to 1.523)	0.526		
Postoperative intestinal exhaust time—hour	≥30 vs <30	1.014 (0.979 to 1.051)	0.439		

P values less than 0.05 are shown in bold.
MV, multivariable; UV, univariable.

undergoing laparoscopic circumsuturing and those undergoing traditional suturing. Patients undergoing circumsuturing lost significantly less blood during surgery than did those undergoing traditional suturing (p<0.001). Patients undergoing circumsuturing also had significantly less postoperative drainage volume and intestinal exhaust time (p<0.001) and thus recovered from surgery faster. The changes in haemoglobin levels 1 week after surgery were statistically significant (p<0.05). Univariate analyses revealed that age of ≥40 years,

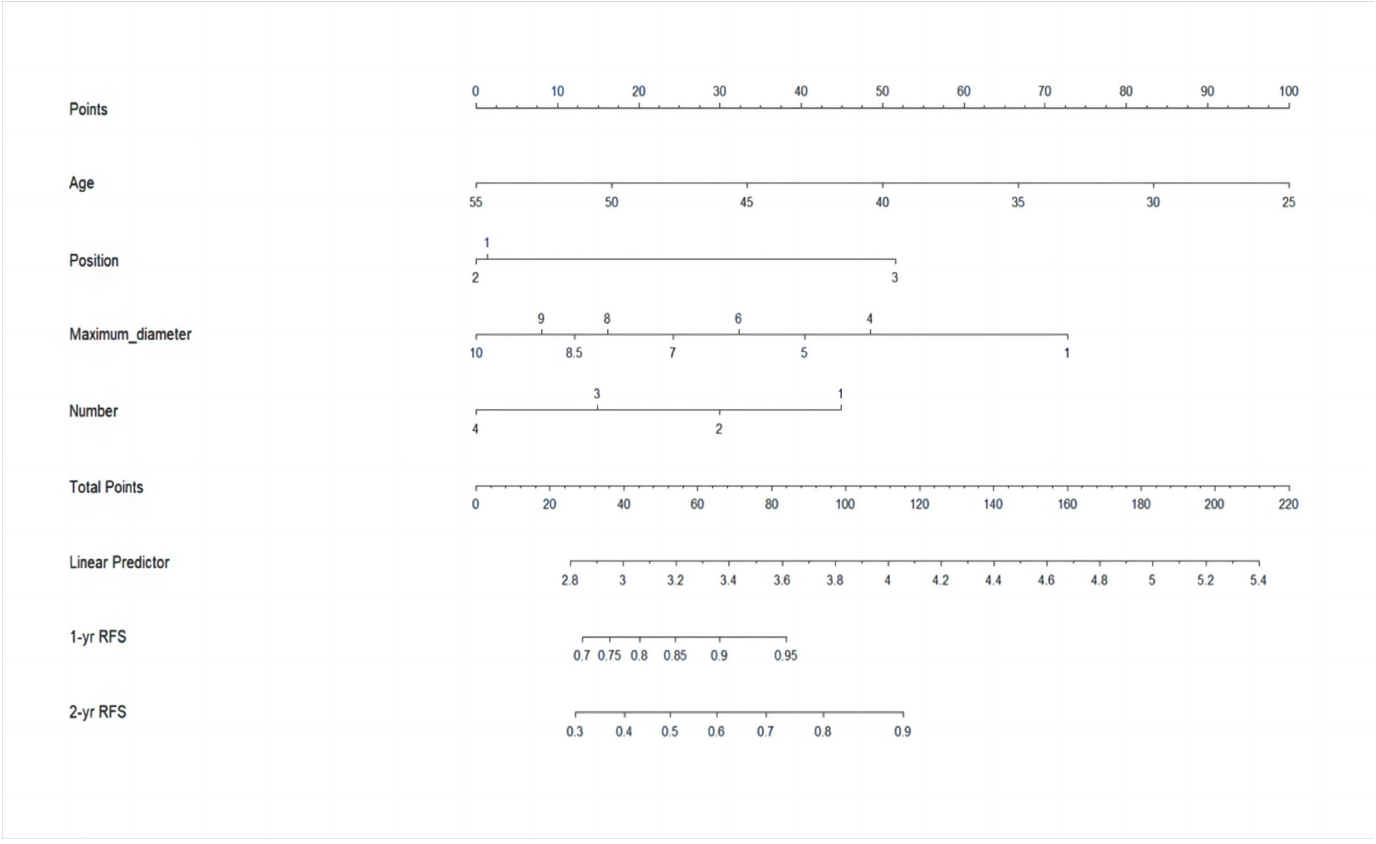

Figure 3 Nomograms for the uterine fibroids recurrence after laparoscopic surgery probability estimate.

intramural location of fibroids, the presence of multiple fibroids and a maximum fibroid volume of ≥50 mm^3 (HR 2.222, 95% CI 1.376 to 3.977, p=0.039; HR 3.625, 95% CI 1.526 to 6.985, p=0.003; HR 3.139, 95% CI 1.651 to 5.968, p<0.001; HR 2.328, 95% CI 0.869 to 3.244, p=0.040, respectively) are independent risk factors for uterine fibroid recurrence. Multivariate analyses confirmed that the intramural location of fibroids and the presence of multiple fibroids are important independent risk factors for fibroid recurrence (p<0.05).

Results in the context of published literature

In recent years, laparoscopic myomectomy for the treatment of uterine fibroids has been investigated extensivel.[6 26] Numerous studies have shown that laparoscopic myomectomy is a minimally invasive and effective treatment for uterine fibroids. Laparoscopic myomectomy results in less blood loss, shorter hospitalisations and faster recovery times than does traditional open surgery.[27 28] However, because of the limited speed of instrument operation and the fact that the uterine blood supply itself is relatively rich, bleeding has always been one of the major complications of hysterectomy. Other minimally invasive techniques, such as hysteroscopic myomectomy or uterine artery embolisation, have also been widely used and discussed.[29 30] The results of these studies have been mixed: some have shown laparoscopic myomectomy to be more effective, whereas others have demonstrated that different procedures produce similar outcomes. Local thrombosis and tissue necrosis are the main safety issues to be considered in the seromuscular circumsuturing technique for uterine fibroids.[31 32] Fortunately, no more serious complications of this modified procedure occurred in our cohort, and the perioperative complication rate was similar to that of traditional baseball sutures. The choice of treatment should be based on an individual patient's specific circumstances and preferences. Similarly, the application of the circumsuture method introduced in this study should be considered in reasonable scenarios; for example, if the patient's fibroids are extremely large or if the attachments are very strong, this method is not applicable. Nonetheless, this surgical method can be an important supplement to and a source of information about laparoscopic myomectomy.

Strengths and weaknesses

This study focused on the introduction of both a haemostatic method that has proved to be effective in obstetrics and gynaecology and an auxiliary operative technique for myomectomy. Our real-world data about patients' health status, diagnosis and treatment, and healthcare were collected from the patients' daily life. In addition, we monitored patients after surgery, analysed the important factors affecting the recurrence of uterine fibroids and established a nomogram model for the prediction of recurrence in clinical practice.

This study had several limitations. First, it included only patients who underwent laparoscopic myomectomy at a single institution; therefore, the results may not be generalisable to other surgical settings or patient populations. In addition, this retrospective study did not allow for randomisation, patients were not evaluated anonymously, and the treatment method was subjectively determined by the attending physician. We will design more rigorous clinical trials to confirm the findings of this study. Finally, although the short-term outcomes were favourable in terms of decreased blood loss and shortened hospitalisation, the long-term (>3 year) effects of circumsuturing on uterine function and fertility remain unknown. We will continue monitoring patients in this cohort and hope to draw more reliable conclusions.

Implications for practice and future research

The modified procedure used in this study can effectively reduce the amount of blood loss, accelerate perioperative recovery and improve the management of patients in the hospital. In the future, such a method can be used to prevent massive bleeding in patients at high risk for haemorrhage, and it can serve as a surgical haemostatic method in grassroots units where other haemostatic measures are relatively lacking. This approach could be extended to a larger scale when laparoscopic resection of uterine fibroids is necessary for the prevention of bleeding.

CONCLUSION

Laparoscopic continuous seromuscular circumsuture for myomectomy is a safe surgical method that can effectively reduce the amount of surgical bleeding and accelerate perioperative recovery. Cox regression analysis showed that the main factors affecting the recurrence of uterine fibroids are patients' age of ≥40 years, intramural location of uterine fibroids, the presence of multiple fibroids and large volume of fibroids. The nomogram that we devised can more intuitively assist clinicians in determining the risk of fibroid recurrence after laparoscopic resection of fibroids.

Contributors Guarantor: XS. Contribute equally: XS, HW. Study concept and design: XS, HW, JZ and LZ. Acquisition, analysis or interpretation of data: HW, LZ and JL. Drafting of the manuscript: HW, XS and LZ. Critical revision of the manuscript for important intellectual content: XS, JL and JZ. Statistical analysis: HW and LZ.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and this study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the Jianhu Hospital affiliated to Yangzhou University (No. JY-LL-202305-L002). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request.

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