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Clinical efficacy of modified sacral fixation under Leonardo da Vinci robot laparoscopy for pelvic organ prolapse

W. WEI, Z.-Y. FANG, Y.-L. CHEN, Y.-Q. MA, X. WEI, H.-Y. YANG, C.-L. ZHANG, Y.-Z. ZHAI, Q. CAI, Y.-X. LU

Department of Obstetrics and Gynecology, Liuzhou Workers' Hospital, the Fourth Affiliated Hospital of Guangxi Medical University, Liuzhou, China

Wei Wei and Ziyu Fang equally contributed to this work

Abstract. – OBJECTIVE: The aim of this study was to analyze the clinical efficacy of modified sacral fixation under Leonardo da Vinci robot laparoscopy for pelvic organ prolapse (POP).

PATIENTS AND METHODS: Sixty POP patients admitted to our hospital from January 2020 to December 2021 were picked and divided into Group A (laparoscopic Y-mesh, n = 20), Group B (laparoscopic sacrovaginal fixation, n = 20), and Group C (da Vinci robotic sacral fixation, n = 20). These three groups were compared in terms of the perioperative indexes, such as operation time, intraoperative blood loss, postoperative indwelling catheter days, anal exhaust time, postoperative hospitalization days, etc. The occurrence of short-term and long-term complications in the three groups was compared. The changes of the following index values in the POP quantification system (POP -Q) staging before and 1 year after surgery were recorded and compared among the three groups. It mainly includes the midline of the anterior vaginal wall at 3 cm from the hymenal margin (Aa), the farthest point of the anterior vaginal vault from point Aa (Ba), the farthest point of the ectocervix (C), the location of the posterior vaginal vault or rectal uterine trap (D), the midline of the posterior vaginal wall at 3 cm from the hymenal margin (Ap), and the reflection of the posterior vaginal vault at the farthest point from the Ap point (Bp) values. The changes in Pelvic Floor Distress Inventory-Short Form 20 (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) were recorded and compared before and 1 year after the operation.

RESULTS: The patients in Group C had significantly lower intraoperative bleeding, postoperative indwelling catheter days, anal exhaust time, and postoperative hospitalization days compared with those in Group A and Group B ($p < 0.05$). There existed no statistical difference in the incidence of short-term and long-term complications between Group B and Group C ($p > 0.05$), but both were much lower than Group A ($p < 0.05$). The differences in POP-Q staging, PFDI-20 scale, and PISQ-12 scale were not statistically significant among the three groups before surgery ($p > 0.05$), and the POP-Q staging Aa, Ba, C, D, Ap, and Bp values, PFDI-20 scale, and PISQ-12 scale were strongly improved in three groups after the surgery ($p < 0.05$). However, the POP-Q staging, PFDI-20 scale, and PISQ-12 scale among the three groups had no obvious difference after the surgery ($p > 0.05$).

CONCLUSIONS: The efficacy of modified sacral fixation under Leonardo da Vinci robot laparoscopy for POP was comparable to that of laparoscopic Y-mesh treatment and laparoscopic sacral vaginal fixation. However, da Vinci's robotic sacral fixation had the advantages of less intraoperative bleeding and faster postoperative recovery, which helped patients recover quickly and improved their quality of life.

Key Words:
Da Vinci robot, Laparoscopy, Modified sacral fixation, Pelvic organ prolapse, Clinical efficacy.

Introduction

Pelvic organ prolapse (POP) is a gynecological disease caused by the weakness of pelvic floor supporting tissue due to various reasons, which causes the pelvic organ to move down and cause abnormal function[1-2]. POP is often manifested clinically as prolapse of vulva mass with or without abnormal urination, defecation, vulva bleeding, inflammation, and other symptoms. Previous

Corresponding Authors: Yingxin Lu, MM; e-mail: luyingxinlu@21cn.com
Wei Wei, MM; e-mail: tgzfxfo@163.com

studies[3-4] found that gender, childbirth, nerve injury, and tissue laceration can all lead to POP.

Surgery is the preferred treatment for POP. With the rapid development of laparoscopic technology in recent years, laparoscopic sacropexy (LSC) has become the main method of treatment of POP due to its advantages of minimally invasive operation, small wound, and rapid postoperative recovery. However, for obese patients or patients with vascular anatomical variation, the surgical operation is more difficult, and the probability of complications such as vascular injury, urinary system injury, and defecation difficulty is higher. Therefore, the popularization of LSC in these patients is limited[5]. The Food and Drug Administration (FDA) approved the Da Vinci robotic surgical system in 2000, and in 2005 it started to be used in the gynecology field. At present, the system is widely used in the treatment of cervical cancer, endometrial cancer, and other radical operations, which can help achieve more ideal results[6]. Studies in literature have reported that Leonardo da Vinci robot-assisted laparoscopic modified sacral fixation has a good effect in the treatment of POP, but there are few related studies in China[7].

In this study, 60 POP patients admitted to our hospital from January 2020 to December 2021 were picked as the subjects with the aim to analyze the clinical efficacy of modified sacral fixation under Leonardo da Vinci robot laparoscopy for POP and lay a foundation for clinical boost.

Patients and Methods

General Materials

Sixty POP patients admitted to our hospital from January 2020 to December 2021 were picked according to the selection process shown in Figure 1. Inclusion criteria: (1) patients with stage II or above according to the quantitative system of POP (POP-Q) developed by the International Association for Urology Control[8]; (2) patients with recurrent stump after operation (symptomatic and POP-Q grade II or above); (3) the newly treated patients with POP-Q III degree and above mainly with pelvic cavity defects; (4) patients with no obvious contraindication for operation. Exclusion criteria: (1) patients with future fertility requirements; (2) acute vaginitis; (3) important organs' serious dysfunction; (4) body mass index (BMI) $\geq$ 35.0 kg/m^2; (5) patients with coagulation dysfunction; (6) lactating or pregnant women. Subjects were distinguished as Group A (laparoscopic Y-mesh, n = 20), Group B (laparoscopic sacrovaginal fixation, n = 20), and Group C (da Vinci robotic sacral fixation, n = 20). The subjects of the three groups were women. The average age, average prolapse time, and average deliveries were (63.16 ± 11.85) years old, (4.56 ± 1.28) years, and (2.56 ± 1.85) times in Group A, respectively, (62.89 ± 10.74) years old, (4.39 ± 1.18) years and (2.46 ± 1.74) times in Group B, and (62.78 ± 12.06) years old, (4.45 ± 1.12) years, (2.39 ± 1.12) times in Group C. There existed no significant difference in age, prolapse time, and delivery times among groups ($p > 0.05$). This study was carried out with the approval of the Ethics Committee of the Fourth Affiliated Hospital of Guangxi Medical University. All patients signed the informed consent before enrolling in the study.

Methods

Patients in Group A were treated with laparoscopic Y-shaped mesh (brand: Johnson & Johnson, purchased in Henan Zeyuan Medical Equipment Sales Co., Ltd., Mancun Town, Changyuan City, Xinxiang City, Henan Province, China): separating the right uterosacral ligament and sacrum, and separating the vesicovaginal and rectovaginal spaces. The posterior peritoneum was opened longitudinally between the right ureters and between the bowels, exposing the right paracolonic sulcus and opening the lateral peritoneum along the medial side of the uterosacral ligament. Laparoscopically suture the Y-shaped mesh onto the pericervical ring where the uterosacral ligament attached to the cervix, wrap the mesh around the anterior lip of the cervix, and extend down to the pubic cervical ligament if necessary. Both sides were interrupted sutured on the main sacral ligament complex, and the other end of the mesh was interrupted suture fixed to the anterior sacral longitudinal ligament in front of the S1 vertebral body by using the non-absorbable suture of Aixibang MB66 (MB66G, Johnson & Johnson, Shanghai Xingxin Medical Equipment Co., Ltd., Tinglin Town, Jinshan District, Shanghai, China), and the peritoneum was closed with suture. The patients in Group B were treated with modified mesh sacral fixation: Laparoscopic ultrasound separated the bladder-vaginal and rectovaginal spaces. The length of the anterior and posterior vaginal walls was separated according to the degree of prolapse of the anterior and posterior vaginal walls, the presacral space was opened, the anterior longitudinal ligament of the sacral

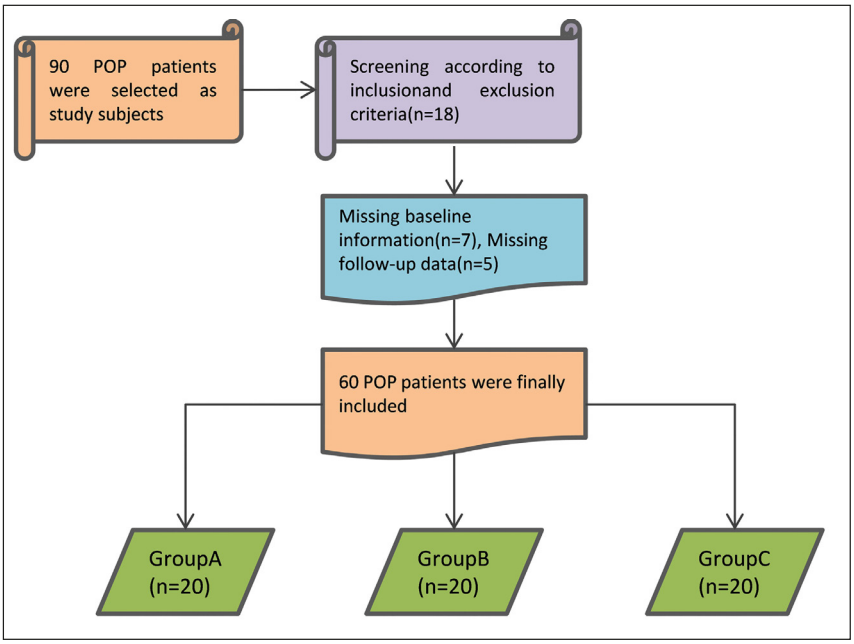

Figure 1. The selection process of general data in 60 subjects.

was fully exposed, and the lateral extraperitoneal tunnel was made to the parasacral ligament after the right ureter. Take two boot-shaped mesh (Johnson & Johnson, purchased in Henan Zeyuan Medical Equipment Sales Co., Ltd., Mancun Town, Changyuan City, Xinxiang City, Henan Province, China) pieces 15 cm long, 3 cm wide and 3 cm wide and place them in the abdominal cavity. The boot end of a boot-shaped mesh was laid on the lower part of the anterior uterine wall and the anterior vaginal wall, and three stitches were fixed with two or three rows of intermittent sutures with a 3-0 absorbable thread, and the long arm of the mesh was led out of the left round ligament space, so that the mesh was embedded in the round ligament space. The other posterior boot-shaped mesh was laid flat on the posterior vaginal wall, and unlike group A, the mesh was tiled with the posterior vaginal wall and sutured with the sacral main ligament for 2-3 stitches was more conducive to the reinforcement of the vaginal vault position. The long arm mesh was then fixed on the anterior sacral longitudinal ligament in front of the S1 vertebral body through the lateral peritoneal tunnel and closed peritoneum. Anti-infection and anti-thrombotic treatment were given after the operation according to the doctor's advice. The patients in Group C received the treatment of laparoscopic sacrovaginal fixation assisted by the Da Vinci robot. The robot was the fourth generation of Da Vinci robot Si system of Intuitive Surgical (Sunnyvale, California, USA). Anti-infection and anti-thrombotic treatment were given after the operation according to the doctor's advice.

Outcome Measures

Perioperative indexes

The perioperative indexes of the three groups, such as operation time, intraoperative bleeding, postoperative indwelling catheter days, anal exhaust time, postoperative hospitalization days, etc., were observed and compared.

Complications

The patient's condition was closely observed. The occurrence of short-term complications, such as bleeding, infection, deep vein thrombosis, etc., in three groups were compared. The patients were followed up for 1 year, and the occurrence of long-term complications, such as mesh exposure and recurrence, were recorded and compared.

Operative effect

The changes of each indicator in POP-Q stage before and 1 year after the operation were compared among the three groups to assess the improvement of POP-Q. The indicators included the midline of the anterior vaginal wall at 3 cm from the hymenal margin (Aa), the farthest point of the anterior vaginal vault from point Aa (Ba), the far-

Table I. Baseline demographic, clinical, electrocardiographic, and echocardiographic variables of patients.

Perioperative indexes	Group A (n = 20)	Group B (n = 20)	Group C (n = 20)	F	p
Operation time (min)	162.26 ± 23.15	158.96 ± 25.86	152.04±30.14	0.770	0.467
Intraoperative bleeding (ml)	63.85 ± 4.46	62.15 ± 5.59	64.81 ± 5.45	0.880	0.420
Postoperative indwelling catheter days (d)	1.92±0.35	1.98±0.44	1.55±0.53[ab]	5.450	0.007
Anal exhaust time (d)	1.45±0.76	1.50±0.54	1.01±0.33[ab]	4.460	0.016
Postoperative hospitalization days (d)	4.85 ± 0.96	4.78 ± 0.84	4.01 ± 0.63[ab]	6.440	0.003

F represented the statistical test value of ANOVA for the measurement data of group A, group B and group C. [a]$p < 0.05$ *vs*. Group A; [b]$p < 0.05$ *vs*. Group B.

thest point of the ectocervix (C), the location of the posterior vaginal vault or rectal, uterine trap (D), the midline of the posterior vaginal wall at 3 cm from the hymenal margin (Ap), and the reflection of the posterior vaginal vault at the farthest point from the Ap point (Bp).

Quality of life-related scale

The changes in Pelvic Floor Distress Inventory-Short Form 20 (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) were recorded and compared before and 1 year after the operation. PFDI-20 reflects the condition of pelvic floor dysfunction. The lower the score was, the better the quality of life and pelvic floor function of patients were. PISQ-12 could be used to evaluate the quality of patients' sexual life. A higher score indicated that the patient had a better sexual life.

Statistical Analysis

SPSS 20.0 (SPSS Corp., Armonk, NY, USA) software was adopted to analyze the experimental data. The measurement data, such as age, operation time, intraoperative bleeding, postoperative indwelling catheter days, etc., were expressed in (). The analysis of variance (F test) was used for the comparison between multiple samples. When the conditions of the analysis of variance could not be met, the non-parametric test (Kruskal-Wallis) could be used for data analysis, and the SNK-q test was used for the comparison between the two samples. Enumeration data such as gender and complications were expressed in (%) and were compared using the χ^2 test. The statistical results were statistically significant if $p < 0.05$.

Results

Comparison of Perioperative Indexes

The patients in Group C had lower intraoperative bleeding, postoperative indwelling catheter days, anal exhaust time, and postoperative hospitalization days compared with those in Group A and Group B ($p < 0.05$). There existed no significant difference in these above indexes between Group B and Group A ($p > 0.05$, Table I and Figure 2).

Comparison of the Incidence Rate of Complications

There existed no statistical difference in the incidence of short-term and long-term complications between Group B and Group C ($p > 0.05$), but both were much lower than Group A ($p < 0.05$, Table II).

Comparison of POP-Q Staging Indicators

The differences in POP-Q staging were not statistically significant among the three groups before surgery ($p > 0.05$), and the POP-Q staging Aa, Ba, C, D, Ap, and Bp values were all strongly improved in the three groups after the surgery ($p < 0.05$). However, the POP-Q staging among the three groups had no obvious difference after the surgery ($p > 0.05$, Table III).

Comparison of Indicators Related to Quality of Life

The differences in PFDI-20 scale, and PISQ-12 scale were not statistically significant among the three groups before surgery ($p > 0.05$). PFDI-20 scale and PISQ-12 scale were all significantly improved in the groups after surgery ($p < 0.05$). However, PFDI-20 scale and PISQ-12 scale among the three groups had no obvious difference after the surgery ($p > 0.05$, Table IV and Figure 3).

Discussion

POP is currently a relatively common gynecological disease worldwide, mostly seen in middle-aged and elderly women. POP is often manifested as dysuria, urinary incontinence, sexual

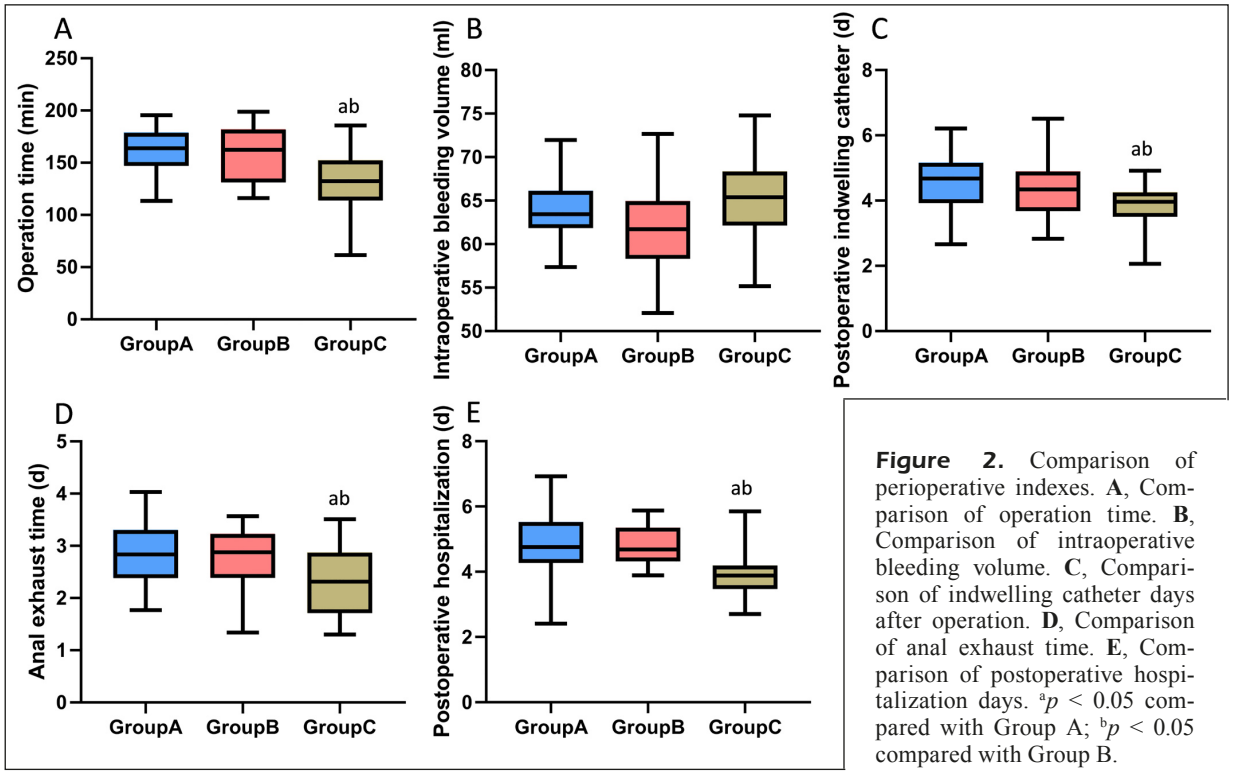

Figure 2. Comparison of perioperative indexes. **A**, Comparison of operation time. **B**, Comparison of intraoperative bleeding volume. **C**, Comparison of indwelling catheter days after operation. **D**, Comparison of anal exhaust time. **E**, Comparison of postoperative hospitalization days. [a]$p < 0.05$ compared with Group A; [b]$p < 0.05$ compared with Group B.

Table II. Comparison of the incidence rate of complications (cases, %).

Groups	Short-term complications			Total incidence	Long-term complications		Total incidence
	Hemorrhagic	Infection	Deep vein thrombosis		Mesh exposure	Recurrence	
Group A (n = 20)	3 (15.00%)	2 (10.00%)	1 (5.00%)	6 (30.00%)	3 (15.00%)	2 (10.00%)	5 (25.00%)
Group B (n = 20)	1 (5.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)[a]	1 (5.00%)	0 (0.00%)	1 (5.00%)[a]
Group C (n = 20)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)[a]	0 (5.00%)	0 (0.00%)	0 (0.00%)[a]
χ^2				10.027			7.778
p				0.007			0.020

[a]$p < 0.05$ *vs.* Group A.

Table III. Comparison of POP-Q staging indicators ($\bar{x} \pm s$).

Group		Aa (cm)	Ba (cm)	C (cm)	D (cm)	Ap (cm)	Bp (cm)
Before operation	Group A (n = 20)	2.16 ± 1.05	2.56±2.15	4.18±1.59	2.19±0.50	1.43±1.33	2.56 ± 2.15
	Group B (n = 20)	2.18 ± 1.24	2.44±1.36	4.05±0.96	2.26±0.45	1.46±1.25	2.61±2.05
	Group C (n = 20)	2.26 ± 1.45	2.48±0.96	4.27±1.46	2.33±0.47	1.53±1.47	2.59±1.89
	F	0.040	0.030	0.130	0.440	0.030	0.000
	p	0.965	0.970	0.877	0.648	0.972	0.997
After operation	Group A (n = 20)	-2.33 ± 0.46[a]	-6.58±1.45[a]	-2.65±0.45[a]	-4.85±0.96[a]	-2.78±1.84[a]	-2.78±0.59[a]
	Group B (n = 20)	-2.58 ± 0.36[a]	-7.12±1.23[a]	-2.86±0.56[a]	-4.71±0.37[a]	-2.82±1.64[a]	-2.69±0.48[a]
	Group C (n = 20)	-2.45 ± 0.29[a]	-6.79±1.25[a]	-2.78±0.49[a]	-4.94±0.55[a]	-2.76±1.28[a]	-2.74±0.36[a]
	F	2.210	0.890	0.860	0.590	0.010	0.170
	p	0.120	0.416	0.429	0.557	0.993	0.842

F represented the statistical test value of ANOVA for the measurement data of group A, group B and group C. [a]$p < 0.05$ *vs.* before operation.

Table IV. Comparison of indicators related to quality of life ($\bar{x} \pm s$).

Group			PFDI-20 (score)	PISQ-12 (score)
Before operation		Group A (n = 20)	91.25 ± 26.53	20.59 ± 6.35
		Group B (n = 20)	90.85 ± 26.45	20.45 ± 6.45
		Group C (n = 20)	91.28 ± 23.45	20.96 ± 8.49
	F		0.000	0.030
	p		0.998	0.973
After operation		Group A (n = 20)	42.16 ± 8.49[a]	35.82 ± 5.12[a]
		Group B (n = 20)	45.12 ± 6.32[a]	34.69 ± 4.96[a]
		Group C (n = 20)	44.96 ± 2.85[a]	37.41 ± 5.12[a]
	F		1.190	1450
	p		0.312	0.242

F represented the statistical test value of ANOVA for the measurement data of group A, group B and group C. [a]$p < 0.05$ *vs.* the same group before operation.

discomfort and dysdefecation, which seriously affects the normal life and work of patients[9,10]. With the aggravation of the aging of the population and the increase in the number of pregnant women in recent years, the number of POP patients has increased year by year, which not only brings great pain to patients but also brings a heavy economic burden to families and society[11]. Therefore, how to effectively treat POP and improve the quality of life of POP patients has become the focus of current medical scholars.

LSC is, at present, the main clinical treatment of POP, and has significant advantages in beauty, reducing pain, and shortening recovery time. However, the exposure of the presacral region (S1, S2) and the flat suture of the mesh on the posterior wall of the vagina are still the difficulties of the operation[12,13]. Da Vinci robot surgery system is a technological revolution in the development history of minimally invasive surgery. The presacral region and blood vessels can be more clearly and stably observed through three-dimensional surgical vision, which can reduce bleeding and other conditions[14,15]. At the same time, the Da Vinci robot can rotate at 540° and operate flexibly in narrow areas such as the pelvic cavity, which can reduce errors and injuries during the operation and increase the accuracy and precision of the operation. The operator can also control the lens independently, which conforms to ergonomics and can effectively shorten the operation time, being more advantageous than conventional surgery[16,17]. In this study, the patients in Group C had significantly lower intraoperative bleeding, postoperative indwelling catheter days, anal exhaust time, and postoperative hospitalization days compared

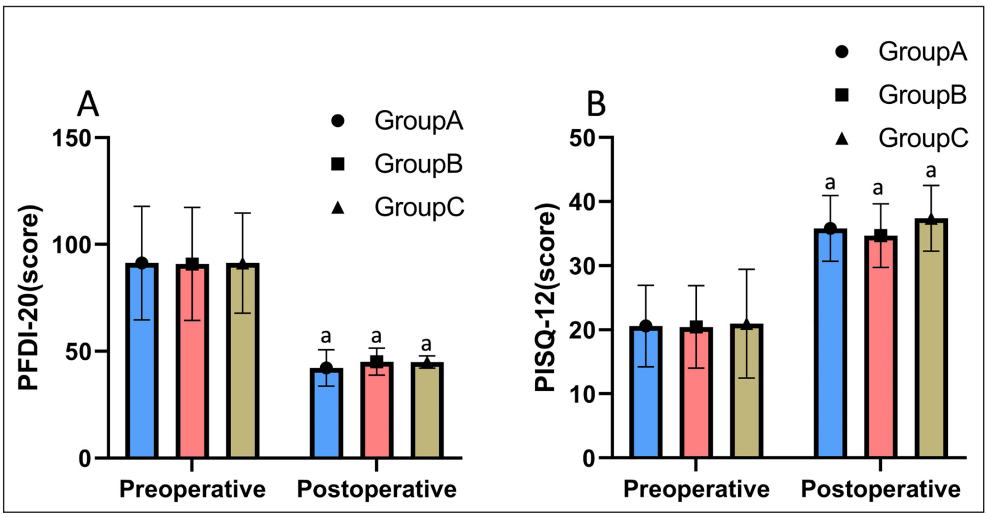

Figure 3. Comparison of indicators related to quality of life. [a]$p < 0.05$ compared with the same group before the operation.

with those in Group A and Group B. The POP-Q staging Aa, Ba, C, D, Ap, and Bp values, PFDI-20 scale, and PISQ-12 scale were all strongly improved in three groups after the surgery. However, the POP-Q staging, PFDI-20 scale, and PISQ-12 scale among the three groups had no significant difference after the surgery. These results suggested that these three surgical methods had good effects on POP and could effectively improve the quality of life and sexual life of patients. Among them, the Da Vinci robot-assisted LSC treatment could greatly reduce the operation time and was conducive to the postoperative recovery of patients. Related reasons[18] may be that the instruments in the Da Vinci robot system operate more flexibly and precisely in narrow spaces, ensure free vaginal wall and rectal lateral space, reduce damage, and provide maximum support for the mesh. Besides, the rotatable needle holder makes the mesh suture site more accurate. The anatomical structure of sacral promontory vessels is complex, and the three-dimensional surgical field makes the display of the presacral region and vessels clearer and more stable to reduce bleeding. The operator can control the lens independently to avoid a run-in with the assistant, thus shortening the operation time. The system is easy to master and facilitates learning and promotion. The setting conforms to ergonomics and reduces the fatigue of the neck, shoulder, and back of the operator, thus shortening the operation time. Therefore, in laparoscopic sacral fixation surgery, Leonardo da Vinci robot surgery has more advantages than traditional laparoscopic surgery in facing the complex presacral region.

In addition to anatomical reduction, the postoperative complications of patients with POP are more concerning for clinical practice. Traditional surgery will distort and damage the anatomical structure. If not treated effectively, vaginal constriction and recurrence often occur, which will have a certain impact on the life of patients[19]. Laparoscopic Y-mesh treatment of POP has a high postoperative recurrence rate. Modified sacral fixation shuttles through the round ligament on the basis of traditional Y net. The posterior wall mesh is fixed in the rectovaginal space and sutured with the main ligament for reinforcement, so the fixation effect is relatively good. The operation process of the Da Vinci robot surgery system is more accurate and precise. It can adjust the size of the mesh implanted in the vesicovaginal space and rectovaginal space according to the individual condition of the patient. In addition, it can reinforce the anterior and posterior walls of the vagina on the premise of reducing the damage to the anatomical structure, so the postoperative complications are significantly reduced[20,21]. In this experiment, the incidence of short-term and long-term complications of patients in Group B and Group C was sharply lower than that in Group A, indicating that the incidence of short-term and long-term complications after Da Vinci-assisted LSC treatment was lower, and the safety was higher.

Conclusions

In general, the efficacy of modified sacral fixation under Leonardo da Vinci robot laparoscopy for POP was comparable to that of laparoscopic Y-mesh treatment and modified sacral fixation. However, da Vinci robotic sacral fixation had the advantages of less intraoperative bleeding and faster postoperative recovery, which helped patients recover quickly and improved their quality of life. However, because this present experiment was a retrospective study, there might be information and confusion bias. At the same time, the follow-up time was only one year, which was relatively short. Thus, multi-center studies with larger sample sizes will be carried out in our following study.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Funding

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Ethics Approval

This study was carried out with the approval of the Ethics Committee of the Fourth Affiliated Hospital of Guangxi Medical University (Approval acceptance number: KY2021039).

Informed Consent

All patients involved in the study signed the informed consent.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contribution

W. Wei and Y.-X. Lu conceived and designed the project. W. Wei, Z.-Y. Fang, Y.-L. Chen and Y.-Q. Ma performed the experiments. X. Wei, H.-Y. Yang, C.-L. Zhang, Y.-Z. Zhai and Q. Cai analyzed the data. W. Wei drafted the manuscript, W. Wei and Y.-X. Lu edited and revised the manuscript. All authors have read and approved the final manuscript.

ORCID ID

Yingxin Lu: 0009-0004-1875-8626.
Wei Wei: 0009-0004-6408-3762.

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