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Original Research

Short-term efficacy of transvaginal specimen extraction for right colon cancer based on propensity score matching: A retrospective cohort study

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ABSTRACT

Background: Recently, the incidence of colorectal cancer has increased each year. Natural orifice specimen extraction surgery (NOSES) removes the specimen from a natural cavity of the human body (anal or vaginal) and completes reconstruction of the digestive tract. There are only a few trocar scars in the abdomen after surgery. Transvaginal specimen extraction for right-sided colon cancer is one of the classic NOSES surgeries. As NOSES is accepted by increasing numbers of colorectal surgeons, NOSES technology is becoming increasingly widely used in China and abroad. Studies have confirmed the feasibility and safety of NOSES. Therefore, it is necessary to conduct further clinical studies to evaluate the short-term efficacy of the NOSES procedure.

Objective: To investigate the short-term efficacy of transvaginal specimens for laparoscopic right colon cancer (NOSES).

Methods: We conducted a retrospective analysis of 90 cases of laparoscopic right colon cancer radical surgery performed continuously in the anorectal surgery of our Hospital from June 2015 to December 2018. Thirty-two patients underwent complete laparoscopic anastomosis and transvaginal specimen removal (NOSES group), and 58 patients underwent conventional abdominal wall removal specimen surgery (LAP group). The general data of the patients were matched by the propensity score matching (PSM) method 1:1. Thirty-one pairs of cases were successfully matched, and the intraoperative and postoperative data were analysed.

Results: After PSM, the baseline data were balanced between the two groups. A total of 62 patients in the two groups were successfully operated without conversion. There were no significant differences in intraoperative blood loss, lymph node dissection, sputum tumour cell positive rate, bacterial culture positive rate, postoperative follow-up and postoperative pelvic floor function evaluation ($P > 0.05$). Neither tumour cells nor bacteria were detected in the rinse solution at the start of the operation. Compared with the LAP group, the incidence of postoperative complications was lower in the NOSES group (6.4% vs. 29.0%, $P = 0.006$), and the gastrointestinal function recovery time was shorter (2.58 ± 0.92 vs. 3.42 ± 0.92, $P = 0.001$), postoperative hospital stay was shorter (6.68 ± 1.47 vs. 9.58 ± 2.22, $P < 0.001$), postoperative pain score was lower (postoperative day 1: 2.35 ± 1.52 vs. 4.87 ± 1.50; postoperative day 3: 1.81 ± 1.11 vs. 4.00 ± 1.18; postoperative day 5: 1.45 ± 1.00 vs. 2.97 ± 1.17; $P < 0.001$), additional analgesic drug use rate was lower (12.9% vs. 61.3%, $P < 0.001$), and patients were more satisfied with the appearance of the abdominal wall after surgery (100% vs. 23.6%, $P < 0.001$).

Conclusion: This study used PSM to remove confounding factors and retrospectively analysed the short-term efficacy of transvaginal specimens for laparoscopic right colon cancer radical resection. The results showed that the laparoscopic right colon cancer radical resection was satisfactory, ensuring sterility. At the same time, there is a clear advantage in reducing postoperative pain, shortening postoperative hospital stays, reducing the incidence of postoperative complications, and improving the appearance of the abdominal wall.

1. Introduction

The incidence of colorectal cancer is increasing yearly, and colon cancer is one of the most common malignant tumours of the digestive tract. The incidence and mortality of colon cancer ranks third among malignant tumours worldwide [1]. In the 21st century, with the in-

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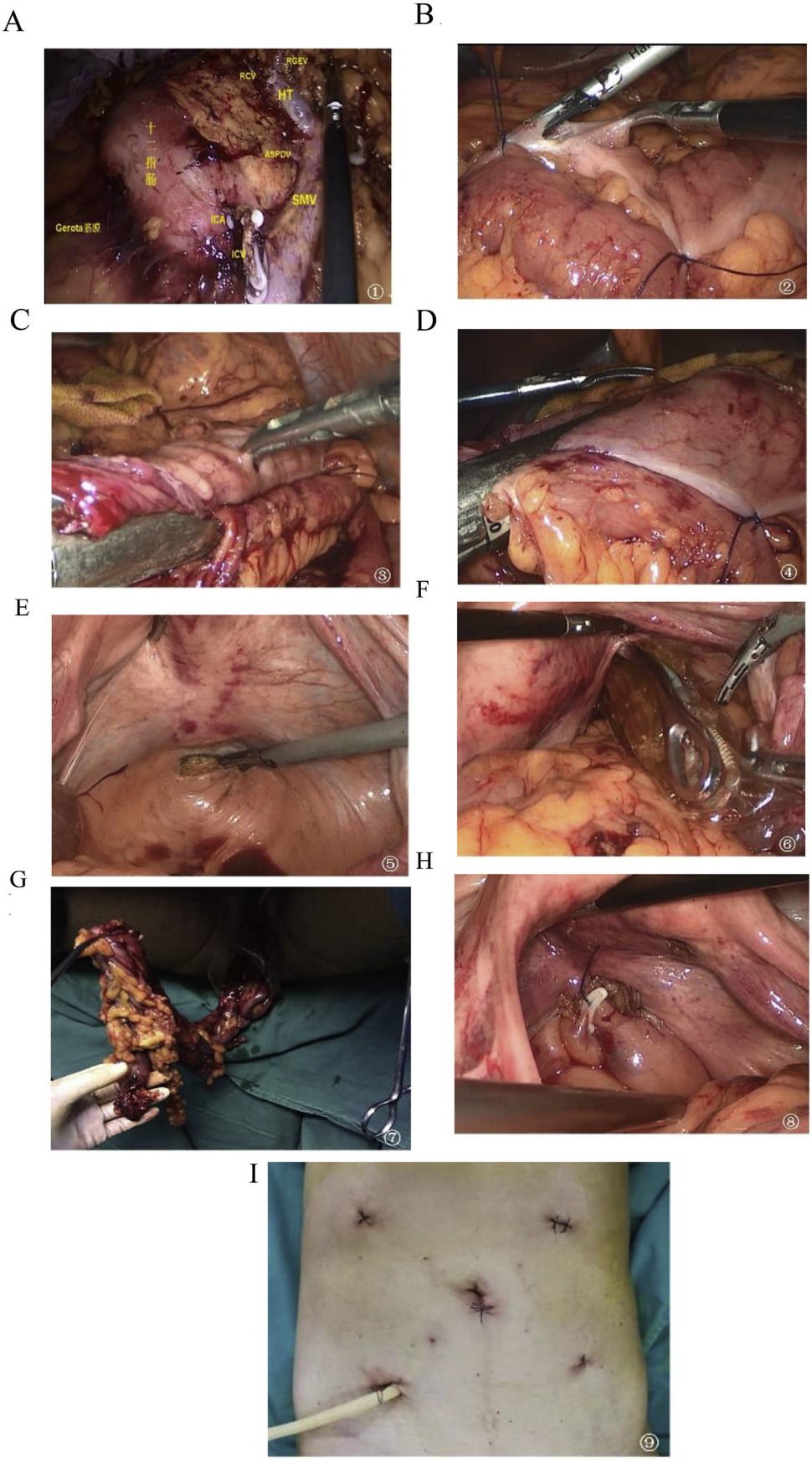

Fig. 1. NOSES surgical procedure. A Fully free perivascular lymph and adipose tissue. B At the pre-cut anastomosis, the suture is pulled to open the intestine. C cutting the occipital anastomosis. D cutting the ileum and transverse colon, completing the anastomosis to remove the specimen. E opening the vagina. F through the 12 mm Trocar into the protective sleeve, pulling the specimen. G the specimen is pulled out of the body through the protective sleeve through the vagina. H endoscopic suture closed after the incision. I postoperative abdominal wall without auxiliary incision.

depth development of minimally invasive technology, people are not satisfied with only the radical resection of oncology but also have higher aesthetic requirements for the appearance of the body. Thus, NOSES came into being. NOSES takes the specimen out of the body through a natural cavity (anal or vaginal) and reconstructs the digestive tract in the abdominal cavity. There are only a few Trocar scars in the abdomen after surgery, which perfectly describes the concept of minimally invasive surgery and functional surgery, and truly achieves the purpose of having no auxiliary incision in the abdomen. Transvaginal specimen extraction for right colon cancer is one of the NOSES [2,3], and because there is no auxiliary incision in the abdomen, postoperative pain is minimal recovery is fast, and it is gradually being applied in the clinic [4]. However, whether the NOSES procedure can solve the problem of being aseptic and tumour-free is still controversial. Operation of transvaginal specimens requires strict control of surgical indications. Ethical issues affecting fertility and sexual life quality cannot be ignored by the surgeons [5]. Pelvic floor dysfunction has been valued by surgeons. Because transvaginal natural delivery is a predisposing factor for pelvic floor dysfunction, whether transvaginal NOSES will affect the patient's postoperative pelvic floor function, and the recent efficacy have not been reported in China or abroad.

2. Materials and methods

2.1. Normal information

Case data of 90 female patients undergoing radical resection of laparoscopic right colon cancer who fit the inclusion criteria from June 2015 to December 2018 in our Hospital were collected. All operations were performed by the same surgical team. Thirty-two patients underwent complete laparoscopic anastomosis transvaginal NOSES (NOSES group), and 58 patients underwent conventional abdominal wall removal surgery (LAP group). The patients' general data were used to match 31 pairs of cases with the propensity score matching method, and the intraoperative and postoperative data were analysed. The study was approved by the Hospital Medical Ethics Committee (ethical approval number: 2015084) and registered with the China Clinical Trial Registration Center (NO.: ChiCTR1900023101). All patients signed informed consent before surgery. The work has been reported in line with the STROCSS criteria [6].

2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) colon cancer and histopathology confirmed as right colon cancer; (2) tumour circumference less than 5 cm; (3) no history of abdominal surgery; (4) preoperative evaluation without local extensive infiltration or far transfer.

Exclusion criteria: (1) body mass index (BMI) > 35 kg/m^2; (2) patients with severe perforation, bleeding, or obstruction requiring emergency surgery; (3) combined with severe respiratory, circulatory and other organ dysfunction; (4) The patient's clinical medical record information is missing.

2.3. The surgical procedure in the NOSES group is shown in Fig. 1

2.3.1. Observation index

The main indicators included operative time, intraoperative blood loss, lymph node dissection, sputum culture tumour cell positive rate, bacterial positive rate, postoperative additional analgesic drug use rate, postoperative complication rate, gastrointestinal function recovery time, hospital stay, follow-up and patient satisfaction with the appearance of the abdominal wall after surgery. Pain scores on days 1, 3, and 5 after surgery were obtained using the visual analogue score (VAS) [7]. For tumour cell detection and bacterial culture, abdominal lavage fluid was hand-made for ultra-thin cell smear and professional cytology examination. Tumour cell characteristics of cancer cells were found to be positive. Washing liquid specimens were inoculated on blood agar plates, and the K–B method was used for drug sensitivity testing. The results were determined using the American Clinical Laboratory Committee criteria [8,9]. The pelvic floor function was evaluated by the pelvic floor distress inventory-short form 20 (PFDI-20) before and 3 months after surgery. The questionnaire involved symptoms of pelvic organ prolapse distress inventory 6 (POPDI-6), colorectal-anal distress inventory 8 (CRADI -8), and bladder urinary distress inventory 6 (UDI-6). According to the degree of impact of symptoms on quality of life, the higher the score, the greater the impact.

2.3.2. Statistical analysis

Data processing and statistical analysis were performed using SPSS 24.0, and baseline data such as age, Body Mass Index (BMI), American Society of Anaesthesiologists (ASA) classification, preoperative CEA, and preoperative T stage were entered for all 90 female patients. On the basis of multi-factor logistic analysis, SPSS 24.0 was used to calculate the propensity score. The precision was set to 0.2. Measurement data were expressed as the mean ± SD, and an independent sample *t*-test was used. Postoperative pain scores were measured by repeated measures statistical methods and related line charts were generated. Qualitative data were expressed using the $\chi 2$ test or Fisher's exact probability method, and $P < 0.05$ was considered statistically significant (two-tailed test).

3. Results

3.1. Comparison of baseline data between the two groups

Before matching, the age, BMI, and preoperative PFDI-20 scores were not evenly distributed among the baseline data of the NOSES and LAP groups ($P < 0.05$). After PSM, although no cases could achieve an exact match, there were 31 pairs of cases with fuzzy matching, and 1 case in the NOSES group failed to match. That is, all baseline data of 31 pairs of successfully matched cases were balanced among groups (all $P > 0.05$), which is comparable (Table 1).

3.2. Intraoperative and postoperative observational indicators in the two groups

Compared with the LAP group, patients in the NOSES group had a lower rate of additional analgesic use (12.9% vs. 61.3%, $P < 0.001$), shorter recovery of gastrointestinal function (2.58 ± 0.92 vs. 3.42 ± 0.92, $P = 0.001$), shorter hospital stay (6.68 ± 1.47 vs. 9.58 ± 2.22, $P < 0.001$), lower postoperative pain score ($P < 0.001$), higher postoperative abdominal wall appearance satisfaction and postoperative complication rate was lower, especially in the long-term bed-related incision-related complications and venous thrombosis complications (P = 0.006). One case of postoperative pulmonary infection in the NOSES group and one case of early anastomotic haemorrhage improved after symptomatic treatment. There was 1 case of postoperative urinary retention in the LAP group, 4 cases of abdominal wall incision infection or poor healing, 1 case of anastomotic leakage, 1 case of pulmonary infection, and 1 case of venous thrombosis. All of them improved after conservative symptomatic treatment. At the beginning of the operation, the tumour cytology and bacterial culture results of the peritoneal washings were negative. At the end of the operation, the last peritoneal lavage fluid was taken for bacterial culture. Eight (25.8%) of the LAP group and nine (29.0%) of the NOSES group were cultured with bacteria, all of which were *Escherichia coli*. The difference was not statistically significant ($P = 0.776$). No tumour cells were detected in the LAP group, and 1 case was detected in the NOSES group. The difference was not statistically significant ($P = 0.313$). There was no significant difference in recurrence and metastasis ($P = 0.554$) and death ($P = 0.554$) between the two groups. There were no significant differences. The other intraoperative and

Table 1
Baseline data of patients in the LAP and NOSES groups.

	Before PSM				After PSM			
	LAP(n = 58)	NOSES(n = 32)	t/χ2	*P*	LAP(n = 31)	NOSES(n = 31)	t/χ2	*P*
Age (yr)	64.64 ± 12.97	70.31 ± 9.25	−2.185	0.032	68.90 ± 11.96	70.06 ± 9.29	−0.427	0.671
BMI (kg/m^2)	26.24 ± 4.80	23.63 ± 3.93	2.634	0.010	25.58 ± 4.70	23.77 ± 3.91	1.647	0.105
ASA grade			2.165	0.339			1.170	0.557
I	19(32.8%)	8(25%)			9(29.0%)	8(25.8%)		
II	34(58.6%)	18(56.2%)			19(61.3%)	17(54.8%)		
III	5(8.6%)	6(18.8%)			3(9.7%)	6(19.4%)		
Preoperative CEA (ng/ml)	9.55 ± 23.27	16.78 ± 66.44	−0.752	0.454	13.28 ± 30.30	17.23 ± 67.49	−0.297	0.767
Tumour location			0.236	0.889			0.683	0.711
Ileocaecal tumour	12(20.7%)	8(25%)			7(22.6%)	8(25.8%)		
Ascending colon tumour	30(51.7%)	16(50%)			13(41.9%)	15(48.4%)		
Colonic hepatic tumour	16(27.6%)	8(25%)			11 (35.5%)	8 (25.8%)		
cTNM Grade			0.037	0.982			0.000	1.000
T1	15(25.9%)	8(25%)			8(25.8%)	8(25.8%)		
T2	26(44.8%)	14(43.8%)			14(45.2%)	14(45.2%)		
T3	17(29.3%)	10(31.2%)			9(29.0%)	9(29.0%)		
Preoperative PFDI-20	9.24 ± 2.32	10.34 ± 2.07	−2.239	0.028	10.03 ± 2.24	10.23 ± 2.00	−0.359	0.721

Table 2
Intraoperative and postoperative conditions in patients with LAP and NOSES.

	LAP Group (n = 31)	NOSES Group (n = 31)	t/χ2	*p*
Operative time (min)	182.39 ± 23.64	185.81 ± 24.48	−0.559	0.578
Intraoperative blood loss (ml)	68.39 ± 45.61	62.26 ± 46.88	0.522	0.604
Number of dissected lymph nodes (pieces)	14.58 ± 2.01	14.74 ± 2.71	−0.266	0.791
Usage rate of additional analgesics	19(61.3%)	4(12.9%)	15.55	< 0.001
Postoperative complication rate	9(29.0%)	2(6.4%)	7.631	0.006
Anastomotic fistula	1(3.2%)	0		
Anastomotic bleeding	0	1(3.2%)		
Urinary retention	1(3.2%)	0		
Intestinal obstruction	1(3.2%)	0		
Pulmonary infection	1(3.2%)	1(3.2%)		
Venous thrombosis	1(3.2%)	0		
Incision-related complications	4(12.9%)	0		
Gastrointestinal function recovery time (d)	3.42 ± 0.92	2.58 ± 0.92	3.578	0.001
Postoperative hospital stay (d)	9.58 ± 2.22	6.68 ± 1.47	6.076	< 0.001
VAS score			94.496	< 0.001[a]
Day 1 postoperatively	4.87 ± 1.50	2.35 ± 1.52		
Day 3 postoperatively	4.00 ± 1.18	1.81 ± 1.11		
Day 5 postoperatively	2.97 ± 1.17	1.45 ± 1.00		
Postoperative PFDI-20 score	11.61 ± 2.28	10.90 ± 2.34	1.210	0.231
Rinse liquid bacterial culture positive rate	8(25.8%)	9(29.0%)	0.081	0.776
Cancer cell detection positive rate	0	1(3.2%)	1.016	0.313
Abdominal wall appearance satisfaction	7(22.6%)	31(100%)	39.158	< 0.001
Follow-up				
Recurrence	2(6.5%)	1(3.2%)	0.350	0.554
Death	1(3.2%)	2(6.5%)	0.350	0.554

[a] The *P*-value was calculated by repeated measures statistical analysis.

postoperative data of transvaginal specimen extraction for right-sided colon cancer (NOSES group) and traditional laparoscopic surgery (LAP group) were compared, see Table 2.

3.3. Evaluation of pelvic floor function before and after operation in the NOSES group

There was no statistically significant difference in pelvic floor function between the NOSES group and PFDI-20 before operation. $P > 0.05$. See Table 3.

3.4. Comparison of postoperative VAS pain scores

The pain scores on days 1, 3, and 5 after NOSES were significantly lower than those in the traditional LAP group (postoperative day 1: 2.35 ± 1.52 vs. 4.87 ± 1.50; postoperative day 3: 1.81 ± 1.11 vs. 4.00 ± 1.18; postoperative day 5: 1.45 ± 1.00 vs. 2.97 ± 1.17; $P < 0.001$), see Fig. 2.

Table 3
Preoperative and postoperative PFDI-20 scores in the NOSES group.

	Preoperative	Postoperative	t	*P*
POPDI-6	3.13 ± 1.54	2.84 ± 1.29	0.803	0.227
CRADI-8	4.71 ± 1.44	5.16 ± 1.59	−1.17	0.288
UDI-6	2.42 ± 1.46	2.87 ± 1.65	−1.144	0.881
PFDI-20	10.23 ± 2.00	10.90 ± 2.34	−1.226	0.135

3.5. Follow-up

3.5.1. Disease-free survival

There was no significant difference in DFS between the LAP and NOSES groups, as shown in Fig. 3.

3.5.2. Overall survival

There was no significant difference in OS between the LAP and NOSES groups, as shown in Fig. 4.

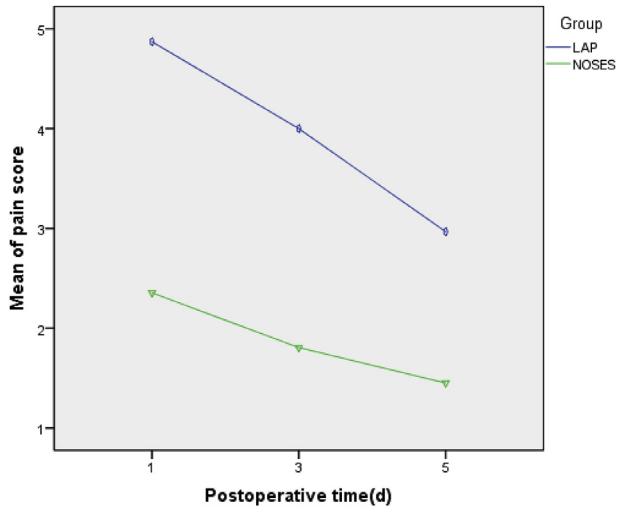

Fig. 2. Postoperative pain scores in the LAP and NOSES groups.

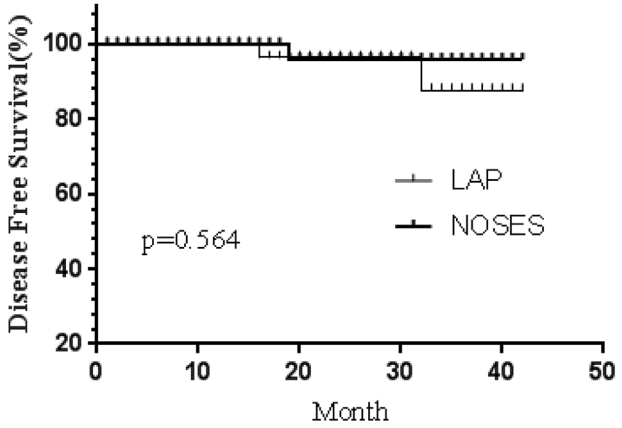

Fig. 3. Kaplan-Meier curves of DFS in LAP and NOES groups after PSM.

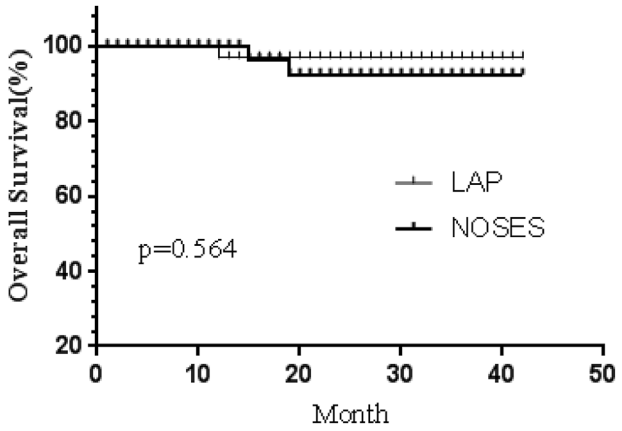

Fig. 4. Kaplan-Meier curves of OS in LAP and NOSES groups after PSM.

4. Discussion

This study used PSM to retrospectively analyse the clinical records of patients with NOSES and LAP surgery and to explore the short-term efficacy of transvaginal specimen extraction for right colon cancer (NOSES). It can be seen from Table 1 that before PSM, the age, BMI, and preoperative PFDI-20 scores were not evenly distributed between the LAP and NOSES groups ($P < 0.05$), and there was a baseline data imbalance. The results are not comparable. After PSM, all baseline data of 31 matched cases were balanced between groups ($P > 0.05$).

The emergence of laparoscopic technology opened the door to minimally invasive technological innovation. In 1991, Professor Jacobs [10] performed the first laparoscopic right colon cancer radical surgery, that marked the entry of laparoscopic technology into the field of gastrointestinal surgery. Laparoscopic surgery has gained popularity because of its improved surgical field of view, more accurate anatomical identification, less intraoperative bleeding, faster postoperative recovery, etc. A large number of clinical studies have been carried out worldwide to validate the tumour resection effect of laparoscopic surgery. Nelson [11] followed patients who underwent laparoscopic colectomy for 3 years. Jayne [12] conducted a 5-year long-term follow-up of laparoscopic radical mastectomy, and the results of the study confirmed the oncological safety of laparoscopic colon cancer surgery. McCombie [13] recently published a prospective randomized controlled trial in Diseases of the Colon & Rectum in which the quality of life after laparoscopic and open colon cancer 2 months after operation and the 5-year survival rate after surgery were evaluated. The results showed that laparoscopic colon cancer radical surgery can achieve the same postoperative survival as open surgery, and patients with laparoscopic surgery have higher quality of life scores 2 months after operation. Laparoscopic colon cancer surgery has higher safety and is more advantageous than open surgery. This view has been recognized by most scholars [14–17].

In the 21st century, with the in-depth development of minimally invasive techniques in various clinical disciplines, new technologies and new concepts such as 3D and 4K have been changing with each passing day. At this time, NOSES has gradually entered the view of colorectal surgeons. The results of Park [18] and Kim [19] showed that transvaginal specimen extraction surgery for colon cancer (NOSES) has the advantage of reducing trauma and has a better prognosis. Izquierdo [20] summarized that patients with BMI < 30, ASA grade no more than 3, specimen diameter < 6.5 cm and no severe underlying disease were safe to choose NOSES. Such arguments coincide with those by Wang Xishan [5]. After the NOSES was put forward, it was continuously improved, and is gradually improving in theory, surgical operation methods and quality control. Currently, China has established a NOSES case information management platform to provide data support for better development of NOSES. Additionally, the international NOSES expert consensus has been published [21].

The most important and controversial part of NOSES is whether it can guarantee an aseptic and tumour-free operation, especially transvaginal specimen extraction surgery for right colon cancer. Before the specimen is taken out from the vagina, a series of operations such as specimen removal and intestinal anastomosis need to be performed in the abdominal cavity. The process of opening the intestines requires an operator who has a wealth of experience and tacit teamwork. It is necessary to perform adequate preoperative bowel preparation for NOSES operation. In addition, we used the method of placing the protective sleeve through the 12-mm main puncture hole, and then the specimen was placed in the protective sleeve and pulled out of the body through the vagina, which prevented the tumour from planting and transferring with the other tissues such as the abdominal wall and vagina. For patients in the NOSES group, the vagina needs to be opened, and then, the specimen is removed, and the incision is sutured. In theory, NOSES group's operation time should be longer, but there is no significant difference in the operation time between the two groups. The reason may be that females have thicker abdominal wall fat. Patients in the LAP group needed to have the abdominal wall opened, and it took longer to cut and suture the abdominal wall. The NOSES group only needed to suture several Trocar puncture holes, which ultimately resulted in no difference in the operation time between the two groups. Furthermore, in terms of postoperative complications, in the LAP group, there was 1 case of venous thrombosis, 1 case of pulmonary infection, and 4 cases of abdominal wall incision complications, including 2 cases of wound infection and 2 cases of poor wound healing.

All of these may be related to less activity after surgery. In the NOSES group, there was no auxiliary incision in the abdominal wall, the VAS score was low, and the appearance of the abdominal wall was satisfactory, which promoted early postoperative activities. Early out-of-bed activities promote postoperative gastrointestinal function recovery, and the time for oral feeding is also significantly shortened, hospitalization time is shortened, and medical costs are reduced.

Limitations: The study method is a retrospective cohort study. Although the PSM treatment balances the confounding factors and improves the credibility of the research evidence level, it is still inconsistent with the prospective RCT study. In addition, the study sample size was only 90 cases. Only 31 pairs of 62 samples were included in the study after PSM 1:1 matching. The sample size was small and the follow-up time was short, which affected the persuasiveness of the research conclusion.

Overall, transvaginal specimen extraction surgery for right colon cancer meets the principles of aseptic and tumour-free operation. And there are many other benefits for patients. For example,it can ease postoperative pain, accelerate recovery, drop the incidence of postoperative complications, reduce medical costs, and improve the postoperative abdominal wall aesthetics. Simultaneously, NOSES is more minimally invasive than traditional laparoscopic surgery, and do not affect the pelvic floor function of female patients. The development of NOSES requires strict understanding of surgical indications, its long-term efficacy and extensive clinical promotion still need to be validated by high-quality randomized controlled trials.

Ethical approval

Ethics Committee of Huaihe Hospital Affiliated with Henan University (NO. 2015084).

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Author contribution

Xing-Wang Li: conception and design of the study, literature search, acquisition of data, data analysis, interpretation of data, drafting the article, final approval of the article, agreement to be accountable for all aspects of the work.

Chen-Yu Wang: literature search, acquisition of data, data analysis, drafting the article, final approval of the article, agreement to be accountable for all aspects of the work.

Jun-Jie Zhang and Zheng Ge: acquisition of data, data analysis, drafting the article, final approval of the article, agreement to be accountable for all aspects of the work.

Jun-Hong Hu: conception and design of the study, interpretation of data, article revision, final approval of the article, agreement to be accountable for all aspects of the work.

Conflicts of interest

The authors declare no conflict of interest.

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Guarantor

Jun-Hong Hu.

Declarations of interest

None.

Data statement

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

CRediT authorship contribution statement

Xing-Wang Li: Writing - original draft.

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Appendix A. Supplementary data

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