Does temporary ileostomy via specimen extraction site affect the short outcomes and complications after laparoscopic low anterior resection in rectal cancer patients? A propensity score matching analysis

Dong Peng¹, Dong-Ling Yu², Xiao-Yu Liu¹, Wei Tao¹, Bing Kang³, Hua Zhang¹, Zheng-Qiang Wei¹ and Guang-Yan Ji¹*

Abstract

Purpose: The purpose of the current study was to compare the outcomes of temporary stoma through the specimen extraction site (SSES) and stoma through a new site (SNS) after laparoscopic low anterior resection.

Methods: The rectal cancer patients who underwent laparoscopic low anterior resection plus temporary ileostomy were recruited in a single clinical database from Jun 2013 to Jun 2020. The SSES group and the SNS group were compared using propensity score matching (PSM) analysis.

Results: A total of 257 rectal cancer patients were included in this study, there were 162 patients in the SSES group and 95 patients in the SNS group. After 1:1 ratio PSM, there was no difference in baseline information (p > 0.05). The SSES group had smaller intraoperative blood loss (p = 0.016 < 0.05), shorter operation time (p < 0.01) and shorter post-operative hospital stay (p = 0.021 < 0.05) than the SNS group before PSM. However, the SSES group shorter operation time (p = 0.006 < 0.05) than the SNS group after PSM, moreover, there was no significant difference in stoma-related complications (p > 0.05). In the multivariate analysis, longer operation time was an independent factor (p = 0.019 < 0.05, OR = 1.006, 95% CI = 1.001–1.011) for the stoma-related complications.

Conclusion: Based on the current evidence, the SSES group had smaller intraoperative blood loss, shorter operation time and shorter post-operative hospital stay before PSM, and shorter operation time after PSM. Therefore, SSES might be superior than SNS after laparoscopic low anterior resection for rectal cancer patients.

Keywords: Rectal cancer, Ileostomy, Laparoscopic low anterior resection, Propensity score matching, Specimen extraction

Introduction

According to the World Health Organization, cancer is the leading cause of death globally, with approximately 18.1 million new cases diagnosed each year, which is expected to increase to 24 million by 2035 [1]. Colorectal cancer (CRC) is a major public health problem worldwide which ranks the third most common cancers, with...
nearly 1.9 million new cases of CRC detected each year, and CRC is responsible for 916,000 deaths every year and is the second leading cause of cancer-related death [2–5].

CRC can be divided into rectal cancer and colon cancer. For patients with lower rectal cancer, temporary ileostomy is often performed to minimize the risk of anastomotic complications including leakage and re-operation after rectal resection [6–8]. Patients with temporary ileostomy have a lower risk of developing anastomotic leakage and peritonitis than patients without temporary ileostomy [9–12].

There were two methods in terms of the site of temporary ileostomy: temporary ileostomy through the specimen extraction site (SSES) and stoma through a new site (SNS) after laparoscopic low anterior resection. However, it remained controversial which site of temporary ileostomy was better [13–17]. Some studies reported there was no difference between SSES and SNS [17], however, other studies reported SSES was a better method [13–15]. Therefore, the purpose of the current study aims to compare the outcomes of temporary ileostomy through SSES and SNS after laparoscopic low anterior resection.

**Methods**

**Patients**
The rectal cancer patients who underwent laparoscopic low anterior resection plus temporary ileostomy were recruited in a single clinical database from Jun 2013 to Jun 2020. The study was approved by the ethics committee of local institution (The First Affiliated Hospital of Chongqing Medical University, 2021-519), and all patients signed informed consent forms. This study was conducted in accordance with the World Medical Association Declaration of Helsinki as well.

**Inclusion and exclusion criteria**
Patients who were diagnosed with CRC and underwent laparoscopic low anterior resection plus temporary ileostomy were included in this study (n = 322). The exclusion criteria were as follows: 1, Patients with incomplete clinical medical data (n = 42); and 2, Plus other organs resection (n = 23). Finally, a total of 257 patients were included in this study. (Fig. 1).

**Surgery management and Definitions**
The tumor stage was diagnosed according to the AJCC 8th Edition [18]. The laparoscopic low anterior resection plus in temporary ileostomy was according to the principles of oncology, the positions of the five trocars were as follows: one trocar was punctured up the umbilicus, two trocars were punctured at left side of abdomen and the other two trocars were punctured at right side of abdomen. Placing a wound protector before specimen removal. Find the end of the ileum under laparoscopy (40 cm from the left temporary ileostomy and 20 cm from the right temporary ileostomy), and use absorbable sutures to suture the bowel with the peritoneum, the anterior sheath and the skin layer intermittently, then temporary ileostomy was performed. The temporary ileostomy was divided into two groups: SSES and SNS. The SSES group was defined as the temporary ileostomy was located at the specimen extraction site and the SNS group was defined as the temporary ileostomy was located at a new site. (Fig. 2) Postoperative complications were graded by the Clavien-Dindo classification [19], and the major complications were defined as ≥ grade III, which required surgery, endoscopy or radiological intervention.

**Data collection**
The clinical characteristics were collected in the inpatient system, outpatient system and telephone interviews. The baseline information included age, sex, body mass index (BMI), smoking, drinking, hypertension, type 2 diabetes mellitus (T2DM), coronary heart disease (CHD), pre-operative hemoglobin, pre-operative albumin,
neoadjuvant chemoradiation, stoma formation (SSES and SNS) and tumor nodes metastasis (TNM) stage. The outcomes included intraoperative blood loss, operation time, post-operative hospital stay, post-operative overall complications, post-operative major complications and stoma-related complications (The time from laparoscopic low anterior resection plus in temporary ileostomy to stoma retraction).

PSM
To minimize the bias of baseline characteristics of the SSES group and the SNS group, PSM was conducted. Nearest neighbor matching was performed without replacement at a 1:1 ratio and a caliper width with a 0.2 standard deviation was specified. The matched baseline information was as follows: age, sex, BMI, drinking, smoking, T2DM, hypertension, CHD, pre-operative hemoglobin, pre-operative albumin, neoadjuvant chemoradiation and TNM stage.

Statistical analysis
Continuous variables are expressed as the mean ± SD and independent-sample t test was used. Frequency variables are expressed as n (%), and Chi-square test or Fisher's exact test was used. The univariate logistic regression was conducted to find potential predictors for stoma-related complications, the p value < 0.1 and clinical important risk factors were included in the final multivariate logistic regression for independent risk factors. Data were analyzed using SPSS (version 22.0) statistical software. A bilateral p value of < 0.05 was considered statistically significant.

Results
Patients
A total of 257 rectal cancer patients were included in this study, the rectal cancer patients who underwent laparoscopic low anterior resection plus temporary ileostomy and no conversion occurred. The average age was 61.3 ± 10.8 years old. There were 163 (63.4%) males and 94 (36.6%) females. The other clinical characteristics were summarized in Table 1.

Baseline characteristics before and after PSM
There were 162 patients in the SSES group and 95 patients in the SNS group. Baseline information including age, sex, BMI, smoking, drinking, hypertension, T2DM, CHD, pre-operative hemoglobin, pre-operative albumin and TNM stage were compared before and after 1:1 ratio PSM. The pre-operative albumin was 41.6 ± 4.7 g/L in the SSES group which was significantly higher than 40.3 ± 4.9 g/L in the SNS group (p = 0.041 < 0.05) before PSM. Therefore, PSM was conducted and there was no significant difference between the two groups (p > 0.05) in baseline information after PSM. (Table 2).

Outcomes
The outcomes including intraoperative blood loss, operation time, post-operative hospital stay, post-operative overall complications, post-operative major complications and stoma-related complications (stoma edema, stoma prolapse, stoma necrosis, stoma bleeding, stoma stenosis, parastomal hernia and skin inflammation around the stoma) were compared before and after PSM. Although stoma complications occurred, no patients underwent reestablishment of stoma.

Before PSM, the intraoperative blood loss was 71.6 ± 67.9 mL in the SSES group which was smaller than 100.0 ± 119.2 mL in the SNS group (p = 0.016 < 0.05). The operation time was 235.5 ± 76.2 min in the SSES which was shorter than 274.7 ± 77.0 min in the SNS group (p < 0.01). The post-operative hospital stay was 8.0 ± 4.0 days in the SSES which was shorter than 9.5 ± 6.0 days in the SNS group (p = 0.021 < 0.05). There was no significant difference in stoma-related complications (p > 0.05).

Table 1 Clinical characteristics of rectal cancer patients

| Characteristics                  | No. 257 |
|----------------------------------|---------|
| Age (mean ± SD), year            | 61.3 ± 10.8 |
| Sex                              |         |
| Male                             | 163 (63.4%) |
| Female                           | 94 (36.6%) |
| BMI (mean ± SD), kg/m²           |         |
| Smoking                          | 110 (42.8%) |
| Drinking                         | 88 (32.4%) |
| Hypertension                     | 64 (24.9%) |
| T2DM                             | 25 (9.7%) |
| CHD                              | 7 (2.7%) |
| Pre-operative hemoglobin, g/L    |         |
| Pre-operative albumin, g/L       |         |
| Neoadjuvant chemoradiation       |         |
| Stoma formation                  |         |
| SSES                             | 162 (63.0%) |
| SNS                              | 95 (37.0%) |
| TNM stage                        |         |
| I                                | 94 (36.6%) |
| II                               | 74 (28.8%) |
| III                              | 81 (31.5%) |
| IV                               | 8 (3.1%) |

Variables are expressed as the mean ± SD, n (%), *P-value < 0.05

T2DM type 2 diabetes mellitus, BMI body mass index, CHD coronary heart disease, SSES stoma through the specimen extraction site, SNS stoma through a new site; TNM tumor nodes metastasis.
After PSM, the SSES group had shorter operation time ($p = 0.006 < 0.05$) than the SNS group. There was no significant difference in stoma-related complications ($p > 0.05$). (Table 3).

Table 2  Baseline characteristics before and after PSM

| Characteristics       | Before PSM   | SNS (95) | P value | After PSM   | SNS (95) | P value |
|-----------------------|--------------|----------|---------|-------------|----------|---------|
|                       | SSES (162)  | SNS (95) |         | SSES (95)  | SNS (95) |         |
| Age, year             | 62.0±10.3    | 60.3±11.5| 0.225   | 61.8±10.2   | 60.3±11.5| 0.322   |
| Sex                   |              |          | 0.639   |             |          | 0.759   |
| Male                  | 101 (62.3%)  | 62 (65.3%)|         | 64 (67.4%)  | 62 (65.3%)|         |
| Female                | 61 (37.7%)   | 33 (34.7%)|         | 31 (32.6%)  | 33 (34.7%)|         |
| BMI, kg/m$^2$         | 22.9±2.9     | 22.9±3.1 | 0.915   | 23.1±2.8    | 22.9±3.1 | 0.708   |
| Smoking               | 70 (43.2%)   | 40 (42.1%)| 0.863   | 44 (46.3%)  | 40 (42.1%)| 0.559   |
| Drinking              | 55 (34.0%)   | 33 (34.7%)| 0.898   | 37 (38.9%)  | 33 (34.7%)| 0.547   |
| Hypertension          | 39 (24.1%)   | 25 (26.3%)| 0.688   | 23 (24.2%)  | 25 (26.3%)| 0.738   |
| T2DM                  | 15 (9.3%)    | 10 (10.5%)| 0.741   | 9 (9.5%)    | 10 (10.5%)| 0.809   |
| CHD                   | 6 (3.7%)     | 1 (1.1%)  | 0.265   | 1 (1.1%)    | 1 (1.1%)  | 1.000   |
| Pre-operative hemoglobin, g/L | 125.7±19.4  | 128.4±20.4| 0.302   | 128.0±19.6  | 128.4±20.4| 0.908   |
| Pre-operative albumin, g/L    | 40.3±4.9    | 41.6±4.7 | 0.041*  | 40.5±4.8    | 41.6±4.7 | 0.099   |
| Neoadjuvant chemoradiation | 48 (29.6%)  | 25 (26.3%)| 0.668   | 28 (29.5%)  | 25 (26.3%)| 0.627   |
| TNM stage             |              |          | 0.100   |             |          | 0.053   |
| I                     | 55 (34.0%)   | 39 (41.0%)|         | 33 (34.7%)  | 39 (41.0%)|         |
| II                    | 54 (33.3%)   | 20 (21.1%)|         | 35 (36.8%)  | 20 (21.1%)|         |
| III                   | 50 (30.9%)   | 31 (32.6%)|         | 26 (27.4%)  | 31 (32.6%)|         |
| IV                    | 3 (1.8%)     | 5 (5.3%)  |         | 1 (1.1%)    | 5 (5.3%)  |         |

Table 3  Outcomes before and after PSM

| Characteristics              | Before PSM     | SNS (95) | P value | After PSM     | SNS (95) | P value |
|------------------------------|----------------|----------|---------|---------------|----------|---------|
|                             | SSES (162)    | SNS (95) |         | SSES (95)    | SNS (95) |         |
| Intraoperative blood loss, mL| 71.6±67.9      | 100.0±119.2 | 0.016* | 76.0±63.5    | 100.0±119.2 | 0.085   |
| Operation time, min          | 235.5±76.2     | 274.7±77.0 | <0.01**| 243.1±78.5   | 274.7±77.0 | 0.006**|
| Post-operative hospital stay, day| 8.0±4.0 | 9.5±6.0 | 0.021* | 8.4±4.7 | 9.5±6.0 | 0.182   |
| Post-operative overall complications | 34 (21.0%) | 26 (27.4%) | 0.243  | 22 (23.2%) | 26 (27.4%) | 0.504   |
| Post-operative major complications | 1 (0.6%) | 4 (4.2%) | 0.064  | 0 (0.0%) | 4 (4.2%) | 0.121   |
| Stoma-related complications  | 25 (0.6%)      | 11 (11.6%)| 0.390  | 17 (17.9%)   | 11 (11.6%)| 0.219   |
| Stoma edema                 | 0 (0.0%)       | 2 (2.1%)  | 0.136 | 0 (0.0%)     | 2 (2.1%)  | 0.497   |
| Stoma prolapse              | 1 (0.6%)       | 0 (0.0%)  | 1.000  | 0 (0.0%)     | 0 (0.0%)  | –       |
| Stoma necrosis              | 0 (0.0%)       | 1 (1.1%)  | 0.370  | 0 (0.0%)     | 1 (1.1%)  | 1.000   |
| Stoma bleeding              | 2 (1.2%)       | 0 (0.0%)  | 0.532  | 1 (1.1%)     | 0 (0.0%)  | 1.000   |
| Stoma stenosis              | 2 (1.2%)       | 0 (0.0%)  | 0.532  | 2 (2.1%)     | 0 (0.0%)  | 0.497   |
| Skin inflammation around the stoma | 16 (9.9%) | 6 (6.3%) | 0.325 | 11 (11.6%) | 6 (6.3%) | 0.204 |
| Parastomal necrosis         | 4 (2.5%)       | 2 (2.1%)  | 1.000  | 3 (3.2%)     | 2 (2.1%)  | 1.000   |

PSM propensity score matching, SSES stoma through the specimen extraction site, SNS stoma through a new site

Variables are expressed as the mean ± SD, n (%), *P-value < 0.05, **P-value < 0.01
(\(p = 0.038 < 0.05, \text{ OR} = 1.005, \text{ 95\% CI} = 1.000–1.010\)) for the stoma-related complications. Furthermore, in the multivariate analysis, longer operation time was an independent factor (\(p = 0.019 < 0.05, \text{ OR} = 1.006, \text{ 95\% CI} = 1.001–1.011\)). (Table 4).

**Discussion**

A total of 257 rectal cancer patients were included in this study, there were 162 patients in the SSES group and 95 patients in the SNS group. After 1:1 ratio PSM, there was no difference in baseline information. The SSES group had smaller intraoperative blood loss, shorter operation time and shorter post-operative hospital stay than the SNS group before PSM, and shorter operation time after PSM. However, there was no significant difference in stoma-related complications. In the multivariate analysis, longer operation time was an independent factor for stoma-related complications.

Anastomotic leakage remains a major problem after laparoscopic anterior resection, with an incidence of 1.4%–15.2% [20–23]. In some cases, anastomotic leakage could lead to devastating consequences including peritonitis, pelvic abscess, and rectovaginal fistula [24, 25]. Prophylactic stoma was often required after laparoscopic low rectal cancer surgery [7]. During the laparoscopic low rectal cancer surgery, a small incision was often required to remove the specimen and prophylactic stoma was made through the specimen extraction site or through a new site. Prophylactic stoma could reduce the occurrence of anastomotic leakage and reoperation [6–8].

We summarize the detailed viewpoints in Table 5 concerning the difference between SSES and SNS. Some studies reported that there was no statistically significant difference between the SSES group and SNS group in all stoma related complications [13, 14, 17]. However, Li W et al. [15] reported the SSES had group had a lower parastomal hernia rate. Karakayali FY et al. [16] reported the SNS group had lower parastomal hernia rate than the SSES group. As for other surgical outcomes including operation time, post-operative hospital stay, it remained controversial as well [13–17]. Therefore, it is important to analyze the surgical outcomes and stoma related complications elaborately. Furthermore, PSM was conducted to reduce the selection bias, which could benefit precise results when there was no difference in baseline information [26, 27].

In this study, we found that the SSES group had smaller intraoperative blood loss, shorter operation time and shorter post-operative hospital stay than the SNS group before PSM, and the SSES group had shorter operation time after PSM. These results were similar with previous studies [13–16], the possible reason was that the SSES group omitted the step of suturing the incision, which greatly reduced the operation time.

As for stoma-related complications, there was no significant difference between the SSES group and SNS group. Previous studies had controversial outcomes

| Risk factors                        | Univariate analysis | P value | Multivariate analysis | P value |
|-------------------------------------|---------------------|---------|-----------------------|---------|
|                                     | OR (95% CI)         |         | OR (95% CI)           |         |
| Age, year                           | 1.008 (0.971–1.046) | 0.673   | 1.006 (1.001–1.011)   | 0.019*  |
| Sex (male/female)                   | 0.757 (0.314–1.828) | 0.536   |                       |         |
| BMI, Kg/m²                          | 1.013 (0.884–1.160) | 0.858   |                       |         |
| Hypertension (yes/no)               | 1.220 (0.499–2.984) | 0.663   |                       |         |
| T2DM (yes/no)                       | 1.095 (0.297–4.034) | 0.892   |                       |         |
| TNM stage (IV/III/II/I)             | 0.921 (0.587–1.447) | 0.722   |                       |         |
| Smoking (yes/no)                    | 1.314 (0.589–2.935) | 0.505   |                       |         |
| Drinking (yes/no)                   | 1.130 (0.496–2.573) | 0.772   |                       |         |
| CHD (yes/no)                        | 5.963 (0.362–98.217)| 0.212   |                       |         |
| Pre-operative hemoglobin, g/L       | 1.002 (0.982–1.022) | 0.866   |                       |         |
| Pre-operative albumin, g/L          | 0.996 (0.915–1.084) | 0.925   |                       |         |
| Operation time, min                 | 1.005 (1.000–1.010) | 0.038*  | 1.006 (1.001–1.011)   | 0.019*  |
| Intraoperative blood loss, mL       | 1.001 (0.997–1.005) | 0.565   |                       |         |
| Neoadjuvant chemoradiation          | 1.040 (0.427–2.530) | 0.931   |                       |         |
| Stoma formation (SSES/ SNS)         | 1.664 (0.734–3.774) | 0.223   | 2.023 (0.864–4.736)   | 0.105   |

OR Odds ratio, CI confidence interval, BMI body mass index, T2DM type 2 diabetes mellitus, CHD coronary heart disease, SSES stoma through the specimen extraction site, SNS stoma through a new site, TNM tumor nodes metastasis

*\(P\)-value < 0.05, **\(P\)-value < 0.01
of parastomal hernia between the two groups [15, 16]. Our study indicated that the SSES group and SNS group had similar stoma-related complications.

Moreover, In this study, multivariate logistic regression was used for analyzing independent risk factors of stoma-related complications and we found that longer operation time was an independent predictor of stoma-related complications. The reason was unclear, but it might be related to the difficulty of surgery and the difficulty of stoma formation. We hypothesized that the stoma-related complications were mainly based on the difficulty of stoma formation, however the baseline characteristics or stoma formation did not affect the outcomes. Therefore, cautious and skilled operative procedures were necessary for surgeons.

To our knowledge, this is the first study analyzing the difference between the SSES group and the SNS group using PSM. Furthermore, we conducted the multivariate logistic analysis to find independent predictive factors of stoma-related complications for the first time.

Our study had some limitations. First, this was a single retrospective study which might cause selection bias (SSES and SNS might not be randomly selected), therefore, we conducted PSM to minimize the difference of baseline information; Second, long-term survival outcomes were lacking; Third, the sample size in this study was relatively small, some parameters such as renal function and blood electrolytes after stoma formation were not analyzed; Fourth, the operation time of stoma formation was missing as well, and the site of the temporary ileostomy was not marked before surgery which might result in non-standardized stoma formation. Therefore, larger sample size with detailed information and long-term follow-up should be conducted in the following experiments.

In conclusion, based on the current evidence, the SSES group had smaller intraoperative blood loss, shorter operation time and shorter post-operative hospital stay before PSM, and shorter operation time after PSM. Therefore, SSES might be superior than SNS after laparoscopic low anterior resection for rectal cancer patients.

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Author contributions
All authors contributed to data collection and analysis, drafting or revising the manuscript, have agreed on the journal to which the manuscript will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work. All authors read and approved the final manuscript.

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Data availability
The datasets generated and/or analysed during the current study are not publicly available due [The database from our clinical center were relatively private] but are available from the corresponding author on reasonable request.

Declarations
Ethics approval and consent to participate
The study was approved by the ethics committee of local institution (The First Affiliated Hospital of Chongqing Medical University, 2021-S19), and all patients signed informed consent. This study was conducted in accordance with the World Medical Association Declaration of Helsinki as well.

Consent for publication
Not applicable.

Table 5 Previous studies reporting the difference between the SSES group and the SNS group

| Author          | Year | Country | Sample size | SSES | SNS | Outcomes                                                      |
|-----------------|------|---------|-------------|------|-----|----------------------------------------------------------------|
| Lee KY et al.   | 2019 | Korea   | 198         | 141  | 57  | The SSES group had a shorter operation time and was associated with fewer cases of wound infection than the SNS group. There was no statistically significant difference between the SSES group and SNS group in all-stoma complications. |
| Wang P et al.   | 2018 | China   | 331         | 155  | 176 | The SSES group had a shorter operation time, less estimated blood and wound infections than the SNS group. The estimated 5-year disease-free survival and overall survival rate were similar between the two groups. There was no statistically significant difference between the SSES group and SNS group in all-stoma complications. |
| Li W et al.     | 2017 | China   | 738         | 139  | 599 | The SSES had lower parastomal hernia rate, a shorter operation time, less estimated blood and all-stoma complications than the SNS group. |
| Karakayali FY et al. | 2015 | Turkey  | 46          | 21   | 25  | The SNS group had shorter hospital stay, shorter time to resumption of regular diet and lower parastomal hernia rate than the SSES group. |
| Yoo SB et al.   | 2013 | Korea   | 105         | 56   | 49  | No significant difference was found between the SSES group and SNS group in terms of all-stoma complications. |

SSES stoma through the specimen extraction site, SNS stoma through a new site
Competing interests
The authors declare no conflicts of interest.

Author details
1 Department of Gastrointestinal Surgery, The First Affiliated Hospital of Chongqing Medical University, Chongqing 400016, China. 2 Department of General Surgery, Qijiang District People’s Hospital, Chongqing 401420, China. 3 Department of Clinical Nutrition, The First Affiliated Hospital of Chongqing Medical University, Chongqing 400016, China.

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