Objective: To compare the outcomes of laparoscopic total mesorectal excision (L-TME) with Denovilliers’ fascia (DFV) preservation versus resection on urogenital function of male patients with rectal cancer.

Background: The protective effect of DFV during L-TME on pelvic autonomic nerves and postoperative urogenital function remains controversial.

Methods: Between August 26, 2015 and July 18, 2019, 253 male patients with cT1–4 (T1–2 for anterior wall) N0–2 M0 rectal cancer from 11 institutions were enrolled, and randomly assigned to L-TME with DFV preservation (Exp-group, n = 123) or resection procedures (Con-group, n = 130). Urinary function was assessed by residual urine volume, maximal flow rate, and International Prostate Symptom Score; sexual function was assessed by 5-item version of the International Index of Erectile Function (IIEF-5) and ejaculation grading.

Results: The Exp-group patients showed a lower urinary dysfunction rate (6.8% vs 25.4%, P = 0.003), higher maximal flow rate (16.25 ± 8.02 vs 12.40 ± 7.05 mL/s, P = 0.007), and lower International Prostate Symptom Score (6.55 ± 5.86 vs 8.57 ± 5.85, P = 0.026) than the Con-group patients at 2 weeks after surgery. The incidence of erectile dysfunction (IIEF-5 < 11) at 12 months after surgery was lower in the Exp-group than in the Con-group (12.5% vs 34.2%, P = 0.023). Exp-group manifested superior IIEF-5 (16.63 ± 6.28 vs 12.26 ± 6.83, P = 0.018). The incidence of ejaculation dysfunction was lower in the Exp-group than in the Con-group at 12 months after surgery (10.0% vs 29.4%, P = 0.034).

Conclusions: DFV preservation during L-TME revealed protective effects on postoperative urogenital function, and could be a better choice for male rectal cancer patients with specific staging and location.

Trial registration number: NCT02435758.

Keywords: Denovilliers’ fascia, ejaculation dysfunction, erectile dysfunction, laparoscopic total mesorectal excision, urinary dysfunction.
Given the technical progress in radiology and better understanding of the anatomy, embryology, histology, and functions of the DVF, we, together with other researchers, have proposed dissection posterior to the DVF for better preservation of the DVF and bilateral NVB and its branches.10–13 Our previous retrospective small-sample-size study revealed that TME with DVF preservation, that is, TME posterior to the DVF, was effective in protecting postoperative urogenital function in patients with early-stage rectal cancer.10 Moreover, we discovered a thickened white line located at the lowest level of peritoneal reflection, which helped to objectively identify and preserve the DVF.14 Thus, dissection posterior to the DVF with entire preservation is feasible and practical.15 However, there is a lack of randomized controlled trials (RCTs) to prove the superiority of TME with preservation of the DVF over traditional TME.

With solid evidence from our previous research, we conducted a prospective, multicenter, randomized trial (www.ClinicalTrial.gov, registration: NCT02435758) to evaluate the effects of preserving or resecting the DVF during laparoscopic TME (L-TME) on postoperative urogenital function in male patients with rectal cancer. In addition, surgical safety and oncologic outcomes were also evaluated.

METHODS

Study Design and Participants

The protocol (Supplement 1, http://links.lww.com/SLA/C701) was approved by the Ethics Committee of the Third Affiliated Hospital, Sun Yat-Sen University. The primary endpoints of this prospective, multicenter, superiority design, parallel, open-label RCT included urinary dysfunction rate at postoperative week (POW) 2 and sexual dysfunction rate at postoperative month (POM) 12. The secondary endpoints included the 1-, 3-, and 5-year overall survival (OS) and recurrence-free survival (RFS), postoperative complications, and recurrence rate. Eligibility criteria are listed in eTable 1 in Supplement 2. All candidates provided written informed consent.

Randomization and Data Monitoring

Stratified blocked randomization was used, stratification factors for DVF-resecting procedures were 44.68% and 42.55%.10

Sample Size Calculations

In our previous study, the incidence of urinary dysfunction at POW2 and sexual dysfunction at POM12 were 24.39% and 9.76%, respectively, for DVF-preserving procedure; the corresponding incidences for DVF-resecting procedures were 44.68% and 42.55%. According to the superiority study design, the sample size was determined using an alpha of 5% and 0.025 as the unilateral statistical significance level, setting the test efficiency to 90%. The final sample size takes the maximum 1 from the 2 indicators. At least 110 patients were required in each group. The sample size was calculated using the SAS 9.3 software. According to the established research plan, the preliminary functional evaluation results will be reported after enrollment is completed. The study was terminated at the end of the 5-year follow-up of the last patient enrolled.

Statistical Analysis

The data are expressed as mean ± standard deviation for continuous variables and number for categorical variables.

A single-blind design is adopted in this study. The participants and research assistants who participated in patient follow-up and functional evaluation were blinded, and the surgeons were informed of enrollment information before the operation. The study was inspected annually by an expert group from the Sun Yat-Sen University Clinical Medicine Research 5010 Program.

Eligibility of Surgeons

Eleven Chinese colorectal surgeons from 11 institutions satisfying the following criteria were selected: 1) the surgeons had performed at least 50 L-TME procedures, 2) their surgical technique and radical resection skills were recognized by an Academic Committee.

Postoperative Management

Postoperative prophylactic antibiotics and pain medications, fluid therapy, and nutritional support were administered in accordance with routine medical practice. Complications were diagnosed by either an image-based evaluation (magnetic resonance imaging [MRI], computed tomography, X-ray, endoscopy, or ultrasonography) or obvious clinical evidence. The Clavien-Dindo classification was used to assess the severity of postoperative complications.18 Adjuvant chemotherapy was initiated within POW4 or POM5 in the absence of contraindications.

Endpoint Measurements and Follow-up

The patients’ urinary function status was evaluated by bladder residual urine volume (RUV, mL, by ultrasonography), maximum flow rate (MFR, mL/s, by urodynamics), and International Prostate Symptom Score (IPSS). RUV > 100 mL was defined as urinary dysfunction. Erectile function and ejaculation function were evaluated by the 5-item version of the International Erectile Function Index Questionnaire (IIEF-5, addressing erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction) and ejaculation function grading (Grade I: normal ejaculation; Grade II: retrograde ejaculation; Grade III: anejaculation), respectively.19 Considering the influence of age and primary disease on erectile function, erectile dysfunction was defined as an IIEF-5 score of ≤11 points, and ejaculation dysfunction was identified as ejaculation function grade of II/III in this study.

Postoperative follow-up was performed every 3 months for 2 years after surgery, and every 6 months 3 to 5 years after surgery. Comprehensive hematology, chest and abdomen spiral computed tomography, and colonoscopy were used to evaluate the patients’ postoperative survival status, and the OS and RFS were recorded.
Quantitative data were analyzed using the t test; qualitative data, Pearson or Cochran-Mantel-Haenszel chi-square test; rank data, nonparametric test; and survival data, Kaplan–Meier analysis and Cox models. P values < 0.05 indicated statistical differences. Statistical analysis was performed using the SPSS 25.0 statistical software (IBM Corp., Armonk, NY, USA).

RESULTS

Case Recruitment and Surgery

Between August 26, 2015 and July 18, 2019, enrolled male patients with rectal cancer were randomly assigned to the Exp-group (n = 123) or Con-group (n = 130). Until August 30, 2019, based on the exclusion and withdrawal criteria, 56 patients were excluded. Finally, 100 cases in the Exp-group and 97 cases in the Con-group were included in the data analysis (Fig. 2).

There were no significant differences in the baseline data of the included patients (all P > 0.05), as shown in (eTable 2 in Supplement 2, http://links.lww.com/SLA/C702). All enrolled patients underwent the assigned procedures successfully without conversion. One case of intraoperative hypercarbia occurred in the Con-group. Postoperative complications in the Exp- and Con-groups included anastomotic leakage (6 vs 5), anastomotic stenosis (2 each), urinary infection (1 each), and incision infection (2 vs 1). Further,
there were 2 cases of intestinal obstruction, 1 case of catheter-related infection, 2 cases of anastomotic bleeding in the Exp-group, and 1 case of incisional hernia in the Con-group. There were no significant differences in incidence and Clavien-Dindo classification of postoperative complications between the 2 groups (all $P > 0.05$) (Table 1).

**Comparison of Urinary Function Outcomes**

Patients in both groups revealed a decrease in bladder detrusor contractility after surgery, manifesting an increase in RUV and IPSS, and a decrease in MFR. The differences between the Exp-group and Con-group at POW2, POM3, and POM6 for RUV (all $P < 0.05$), and at POW2 and POM6 for MFR (all $P < 0.05$) were statistically significant. In terms of subjective urination-related symptoms, the IPSS scores were significantly different at POW2 ($P = 0.026$), but not at POM3 or POM6 (all $P > 0.05$). Urinary dysfunction rates differed significantly at POW2 in the Exp- and Con-groups (6.8% vs 25.4%, $P = 0.003$), but not at POM3 or POM6 (all $P > 0.05$) (Table 2).

**Comparison of Erectile and Ejaculation Function**

Two self-rating scales, the IIEF-5 and ejaculation grading, were used to evaluate erectile and ejaculation functions, respectively. The results revealed that the IIEF-5 score decreased significantly after surgery in the Con-group, but not in the Exp-group. The mean IIEF-5 score in the Exp-group was significantly higher than that in the Con-group at POM3–12 (all $P < 0.05$, Table 3). At POM12, the moderate–severe erectile dysfunction (IIEF-5 score $\leq 11$) rate was 12.5% in the Exp-group and 34.2% in the Con-group, and the difference was statistically significant ($P = 0.023$).

The proportion of patients with grade II/III ejaculation function in the Exp-group gradually decreased from POM3, suggesting restoration of ejaculation function, while the recovery in the Con-group was not discernable. The difference in ejaculation dysfunction rate between the Exp- and Con-groups was significant at POM12 (10.0% vs 29.4%, $P = 0.034$).

**Hierarchical Analysis**

Stratifying patients by age, at POW2, the urinary function of patients aged 50 to 59 years in the Exp-group was significantly better than that in the Con-group, with lesser RUV ($P = 0.004$), higher MFR ($P = 0.002$), lower IPSS ($P = 0.004$), and lower urinary dysfunction rate ($P = 0.004$). The urinary function of patients aged $\geq 60$ years in the Exp-group was also better than that in the Con-group, but was not statistically significant ($P > 0.05$). At POM12, the moderate–severe erectile dysfunction rate of patients aged 50 to 59 and $\geq 60$ years in the Exp-group was lower than that in the Con-
group (0 vs 29.4%, $P = 0.059$; 22.7% vs 53.5%, $P = 0.056$, respectively), and the ejaculation dysfunction rate in patients aged ≥ 60 years in the Exp-group was lower than that in the Con-group (18.2% vs 53.8%, $P = 0.057$) (Table 4).

Comparison of Survival Status

Seventeen patients (5 in the Exp-group and 12 in the Con-group) were lost to follow-up. As of August 30, 2019, the overall follow-up rate was 94.32%, with a mean follow-up of 16.6 months. The median OS was 13.32 months in the Exp-group and 12.57 months in the Con-group (Log Rank $P = 0.337$). Two cases of liver metastasis and 4 cases of anastomotic recurrence occurred in the Exp-group. In the Con-group, 4 patients developed lung metastasis and 1 developed liver metastasis. The recurrence rates were similar, with a median RFS of 12.94 and 11.75 months in the Exp- and Con-group, respectively (Log Rank $P = 0.662$) (Fig. 3).

DISCUSSION

Intraoperative PAN injury is the most dominant etiology of urogenital dysfunction after rectal cancer surgery.5,20 The ligation of IMA and separation of the retrorectal space can accidentally damage the superior hypogastric plexus (SHP) or HN, and dissection in the lateral rectal ligament and division of the DVF can damage the inferior hypogastric plexus (IHP) and its efferent fibers.21 It is

TABLE 1. Surgical Complications

| Parameter                  | Exp-Group (n = 100) | Con-Group (n = 97) | Chi-square Test Value | $P$ Value |
|----------------------------|---------------------|--------------------|-----------------------|-----------|
| Intraoperative complication| 0 (0%)              | 1 (1.0%)           | 1.036                 | 0.492     |
| Carbon dioxide retention   | 2 (2.0%)            | 2 (2.1%)           | 0.001                 | 1.000     |
| Postoperative complication |                     |                    |                       |           |
| Anastomotic stenosis       | 6 (6.0%)            | 5 (5.2%)           | 0.067                 | 0.791     |
| Anastomotic leakage        | 2 (2.0%)            | 0 (0%)             | 1.960                 | 0.498     |
| Anastomotic bleeding       | 0 (0%)              | 0 (0%)             | 0.975                 | 1.000     |
| Intestinal obstruction     | 1 (1.0%)            | 0 (0%)             | 0.975                 | 1.000     |
| Urinary infection          | 1 (1.0%)            | 0 (0%)             | 1.000                 | 0.000     |
| Incisional infection       | 2 (2.0%)            | 1 (1.0%)           | 0.308                 | 1.000     |
| Incisional hernia          | 0 (0%)              | 1 (1.0%)           | 0.975                 | 1.000     |
| Clavien-Dindo classification|                     |                    | 1.036                 | 0.492     |
| I                          | 13 (13.0%)          | 8 (8.2%)           | 1.168                 | 0.280     |
| II                         | 0                   | 0                  | 0                     | 1         |
| III                        | 0                   | 0                  | 0                     | 1         |
| IV                         | 0                   | 0                  | 0                     | 1         |
| Incidence of perioperative complications | 14 (14.0%) | 10 (10.3%) | 0.627                 | 0.428     |

*aQualitative data using Pearson or Cochran-Mantel-Haenszel chi-square test.

TABLE 2. Comparison of Urinary Function Between the Two Groups

| Parameter | Exp-Group | Con-Group | $P$ Value |
|-----------|-----------|-----------|-----------|
| RUV (mL)* | n (%)     | Mean (SD) | n (%)     | Mean (SD) | |
| Preoperative | 63 | 12.36 (14.04) | 65 | 16.92 (19.10) | 0.079 |
| POW2      | 73 | 35.07 (56.55) | 67 | 75.22 (85.85) | 0.002 |
| POM3      | 47 | 20.90 (24.77) | 52 | 37.26 (28.18) | 0.003 |
| POM6      | 44 | 11.97 (11.45) | 37 | 37.65 (36.13) | 0.001 |
| POM9      | 37 | 18.15 (7.05)  | 45 | 14.99 (7.45)  | 0.054 |
| POM6      | 36 | 19.06 (7.48)  | 32 | 19.06 (14.15) | 0.008 |
| Max-UFR†  | n (%)     | Mean (SD) | n (%)     | Mean (SD) | |
| Preoperative | 63 | 18.35 (8.65) | 65 | 17.81 (7.83) | 0.711 |
| POW2      | 57 | 16.25 (8.02) | 59 | 12.40 (7.50) | 0.007 |
| POM3      | 37 | 18.15 (7.05) | 45 | 14.99 (7.45) | 0.054 |
| POM6      | 36 | 19.06 (7.48) | 32 | 19.06 (14.15) | 0.008 |
| IPSS‡      | n (%)     | Mean (SD) | n (%)     | Mean (SD) | |
| Preoperative | 93 | 3.52 (2.83)  | 90 | 4.33 (4.34)  | 0.132 |
| POW2      | 85 | 6.55 (5.86)  | 84 | 8.57 (5.85)  | 0.026 |
| POM3      | 70 | 5.36 (4.87)  | 70 | 7.04 (5.64)  | 0.060 |
| POM6      | 60 | 5.25 (4.56)  | 48 | 6.46 (6.01)  | 0.238 |

*Quantitative data were calculated by t test.
†Qualitative data using Pearson or Cochran-Mantel-Haenszel chi-square test.
‡Qualitative data using Pearson or Cochran-Mantel-Haenszel chi-square test.
SD indicates standard deviation.
noncontroversial that IMA should be ligated 1.5 cm distal to its origin to preserve the SHP, and that the bilateral HN and IHP should be preserved by sharp dissection in the retrorectal plane and lateral rectal ligament, respectively. In this study, mandatory intraoperative photographs of these fields had been reviewed to ensure that no injury to the PAN occurred in these areas. Unlike agreement on careful dissection of the above-mentioned areas for PAN preservation, that is, the posterior and bilateral mesorectum, dissection of the anterior plane of rectum still remains highly controversial. The key dispute is whether TME should be performed anterior or posterior to the DVF; in other words, should the DVF be partly resected or entirely preserved?9,13,15,22

DVF is a lamella-like dense fascial structure located between the rectum and the genitourinary system, first identified by the French anatomist Charles-Pierre-Denonvilliers in 1836.23 Theories on embryonic formation of the DVF are still controversial.24,25 Currently, DVF is widely recognized as being formed between the mesorectum and the seminal vesicle, prostate, or vagina under

| TABLE 3. Comparison of Erectile and Ejaculation Functions Between the Two Groups |
|-----------------------------------------------|---------------------|---------------------|---------------------|
| Parameter                              | Exp-Group       | Con-Group       |
|                                      | n | n (%) or Mean (SD) | n | n (%) or Mean (SD) | P Value |
| IIEF<sup>5</sup>                      |   |                    |   |                    |         |
| Preoperative                          | 92 | 17.38 (6.76) | 87 | 16.87 (7.38) | 0.632  |
| POM1                                  | 83 | 15.94 (6.51) | 81 | 12.95 (12.90) | 0.060  |
| POM3                                  | 66 | 15.41 (6.92) | 68 | 12.53 (6.51) | 0.014  |
| POM6                                  | 56 | 15.68 (6.80) | 49 | 11.88 (6.21) | 0.004  |
| POM12                                 | 40 | 16.63 (6.28) | 38 | 12.26 (6.83) | 0.018  |
| POM12 erectile dysfunction rate (≤11 score)<sup>1</sup> | 40 | 5 (12.5%) | 38 | 13 (34.2%) | 0.023  |
| Ejaculation dysfunction rate<sup>1</sup> |   |                    |   |                    |         |
| POM1                                 | 71 | 10 (14.1%) | 66 | 20 (30.3%) | 0.022  |
| POM3                                 | 63 | 9 (14.3%) | 62 | 18 (29.0%) | 0.045  |
| POM6                                 | 47 | 6 (12.8%) | 41 | 13 (31.7%) | 0.031  |
| POM12                                | 40 | 4 (10.0%) | 34 | 10 (29.4%) | 0.034  |

<sup>1</sup>Quantitative data were calculated by t test.
<sup>1</sup>Qualitative data using Pearson or Cochran-Mantel-Haenszel chi-square test.

| TABLE 4. Age Stratification Analysis of Functional Indicators |
|-------------------------------------------------------------|
| Parameter                                      | Exp-group       | Con-group       |
|                                              | n | n (%) or Mean (SD) | n | n (%) or Mean (SD) | P Value |
| POW2 RUV (mL)<sup>2</sup>                      |   |                    |   |                    |         |
| ≤49 yrs                                       | 13 | 36.69 (56.30) | 9  | 31.33 (16.77) | 0.786  |
| 50–59 yrs                                     | 23 | 17.97 (18.73) | 19 | 11.84 (5.82) | 0.002  |
| >60 yrs                                       | 37 | 45.14 (69.52) | 35 | 69.80 (58.01) | 0.108  |
| POW2 MFR<sup>2</sup>                           |   |                    |   |                    |         |
| ≤49 yrs                                       | 10 | 18.33 (7.90) | 8  | 15.18 (4.63) | 0.333  |
| 50–59 yrs                                     | 17 | 19.32 (7.48) | 19 | 11.84 (5.82) | 0.002  |
| >60 yrs                                       | 30 | 13.81 (7.80) | 32 | 12.40 (8.13) | 0.385  |
| POW2 IPSS<sup>2</sup>                          |   |                    |   |                    |         |
| ≤49 yrs                                       | 16 | 4.81 (3.15)  | 16 | 5.75 (4.45)  | 0.497  |
| 50–59 yrs                                     | 25 | 4.24 (4.11)  | 32 | 7.94 (5.27)  | 0.004  |
| >60 yrs                                       | 44 | 8.50 (6.79)  | 36 | 10.39 (6.38) | 0.207  |
| POW2 urinary dysfunction rate<sup>2</sup>      |   |                    |   |                    |         |
| ≤49 yrs                                       | 13 | 1 (7.7%)    | 9  | 0 (0%)        | 1.000  |
| 50–59 yrs                                     | 23 | 0 (0%)      | 23 | 8 (34.6%)    | 0.004  |
| >60 yrs                                       | 37 | 4 (10.8%)   | 35 | 9 (25.7%)    | 0.100  |
| POM12 IIEF-5<sup>2</sup>                      |   |                    |   |                    |         |
| ≤49 yrs                                       | 6  | 19.33 (4.68) | 6  | 19.50 (2.43) | 0.940  |
| 50–59 yrs                                     | 12 | 19.67 (3.75) | 17 | 13.76 (5.72) | 0.004  |
| >60 yrs                                       | 22 | 14.23 (6.88) | 15 | 9.73 (6.85)  | 0.059  |
| POM12 erectile dysfunction rate (≤11 score)<sup>1</sup> |   |                    |   |                    |         |
| ≤49 yrs                                       | 6  | 0 (0%)      | 6  | 0 (0%)       | 1.000  |
| 50–59 yrs                                     | 12 | 0 (0%)      | 17 | 5 (29.4%)    | 0.059  |
| >60 yrs                                       | 22 | 5 (22.7%)   | 15 | 8 (33.3%)    | 0.056  |
| POM12 ejaculation dysfunction rate<sup>1</sup> |   |                    |   |                    |         |
| ≤49 yrs                                       | 6  | 0 (0%)      | 5  | 1 (20.0%)    | 0.455  |
| 50–59 yrs                                     | 12 | 0 (0%)      | 16 | 2 (12.5%)    | 0.492  |
| >60 yrs                                       | 22 | 4 (18.2%)   | 13 | 7 (53.8%)    | 0.057  |

<sup>1</sup>Quantitative data were calculated by t test.
<sup>2</sup>Qualitative data using Pearson or Cochran-Mantel-Haenszel chi-square test.
tension and mechanical stress as the peritoneal reflex migrates upward in the 8th week of embryogenesis. Meanwhile, the NVB, covered by the DVF from the anterolateral side, travels inward and downward, and branches out to dominate seminal vesicles and the prostate.\textsuperscript{23,25} Anatomical and histological studies have confirmed that the DVF is thick and rigid in the central region and relaxed on bilateral sides, forming irregular bilateral "Y-shaped" structures that merge with the parietal pelvic fascia and wrap around the branches of the IHP to the seminal vesicle and prostate.\textsuperscript{25} Our immunohistochemical staining of the excised DVF tissue also revealed that it contains many nerve fibers, including erectile function related nitric oxide synthase (NOS)-positive nerve fibers, with a wider distribution not limited to the previously recognized NVB region.\textsuperscript{17} Therefore, even in the "inverted U-shaped" excision of the DVF, protection of the NVB is futile as there could be likely damage to the efferent branches of the IHP with effects on postoperative urinary and sexual functions, especially erectile function. In previous studies, we applied intraoperative nerve stimulation to identify PAN, and revealed that after resection of the DVF, intraoperative nerve stimulation failed to induce active bladder contractions, thus objectively confirming the close relationship between the DVF and PAN.\textsuperscript{10,26}

Nevertheless, most surgeons still perform TME with an "inverted U-shaped" cut of the DVF because they believe that there is no surgical plane posterior to the DVF.\textsuperscript{9} In our previous surgery, we dissected 1 to 1.5 cm above the peritoneal reflection as most surgeons did, and found that it was difficult to find a surgical plane posterior to the DVF. Therefore, we performed an additional cadaveric study, and carefully reviewed the surgical video, and found a thickened white line located in the lowest level of the peritoneal reflection. Regardless of mobilizing the peritoneal reflection, dissecting above this marker line led to an entrance anterior to the DVF. Conversely, dissecting below this marker line led to entrance posterior to the DVF.\textsuperscript{14,27} The discovery of this surgical line has helped not only us but also all the other surgeons in this study to easily find the correct surgical plane posterior to the DVF and thus preserve the entire DVF. In this study, intraoperative videos and photographs of all cases in the Exp-group revealed successful preservation of the entire DVF with no cases of inappropriate TME, proving the significance of the surgical marker line, as well as the feasibility and practicality of this innovative form of TME. Although there had been solid evidence proving the significance of DVF in both PAN and postoperative urogenital function preservation, there was a lack of RCTs to confirm the superiority of TME with preservation of the DVF over the traditional TME. Herein, we explored the effects of partial excision or preservation of the DVF on protection of postoperative urogenital function. With respect to urinary function, the urinary dysfunction rate of the Exp-group at POW2 was significantly lower than that of the Con-group, indicating that DVF preservation was beneficial for urinary function protection. However, 3 to 6 months after surgery, the relevant indicators did not differ significantly between the 2 groups, which could be due to the gradual compensatory recovery of bladder function.

Pelvic plexus injury is the main cause of postoperative erectile dysfunction, mostly due to injury to the parasympathetic components at the pelvic floor fascia and the pudendal nerve.\textsuperscript{17,22} Pelvic parasympathetic nerves are involved in penile erection and should be preserved to protect erectile function.\textsuperscript{28} Herein, the IIEF-5 score was significantly higher in the Exp-group than in the Con-group, which was consistent with our anatomical findings and results of neurofibillary immunohistochemical staining of DVF.\textsuperscript{17} Correspondingly, serious injury of the IMP, SHP, or HN leads to postoperative ejaculation dysfunction. This study revealed that the ejaculation function of the Exp-group was graded better than that of the Con-group, as nerve fibers in the DVF contain branches of the HN. Overall, the incidence of sexual dysfunction in the Exp-group was lower than that in the Con-group.

Nevertheless, due to the cultural background in China, implementation of objective detection of penile erection is difficult, which may lead to uncontrolled biases and have influenced outcomes. In addition, patients with rectal cancer may have lack of self-esteem, emotional depression, pessimism or irritability, interpersonal changes, and even self-abasement caused by stoma, which may impair sexual function.\textsuperscript{29,30} Based on this, we adopted a unified functional evaluation criterion and strict controls in the enrollment process to avoid the shortcomings of previous studies in this field. Additionally, patients with emotional anxiety, psychological disorders, and poor cultural background were excluded. Moreover, there were 23 cases of abdominoperineal resection (APR) who were intraoperatively found unsuitable for low anterior resection due to obesity, narrow pelvic cavity, or low exact tumor location. APR is more traumatic, wherein perineal injury, anus loss, and artificial stoma may cause physical and psychological trauma to patients, and may have a certain influence on patients’ postoperative sexual life and sexual function. Therefore, to avoid confounding factors and obtain more consistent and credible results, we eliminated patients with APR. In future, we expect that clinical data of patients from Europe and America will help to verify our results.

Previous studies considered age as an important factor of urinary and erectile function recovery after pelvic surgeries.\textsuperscript{31,32} The hierarchical analysis in this study also revealed that older patients presented greater differences in postoperative urogenital function between the Exp- and Con-groups. This could be because younger patients may have better postoperative urogenital function recovery. Thus, the influence of the different surgical procedures was less obvious in younger patients. This result suggests that L-TME with DVF preservation to protect postoperative urogenital function may be more important in patients aged ≥50 years.

Neoadjuvant chemoradiotherapy has become the standard treatment for specific stage rectal cancer. However, the latest research demonstrated that compared with fluorouracil with radiotherapy, neoadjuvant mFOLFOX6 chemotherapy without radiotherapy revealed similar oncologic outcomes and less adverse reactions for patients with locally advanced rectal cancer.\textsuperscript{33} Considering adverse effects of radiotherapy on urogenital function,\textsuperscript{14–38} patients with neoadjuvant radiotherapy were excluded in this study.
Our study also focused on whether preservation of the DVF affected the oncologic outcome. Patients with tumors invading beyond the anterior rectal muscular layer should not undergo DVF preservation surgery. Thus, patients with tumors exceeding T2 staging in the anterior wall were excluded. Pelvic MRI was applied to evaluate the preoperative staging of rectal cancer, and the results revealed that the overall accuracy of T-staging according to MRI was 93.5%. Our short-term results revealed no significant difference in median OS, RFS, and recurrence rates between the two groups. However, assessment of the difference in long-term survival between the two surgical methods still requires further follow-up.

In addition to preoperative T-staging, tumor location should also be considered as an important inclusion criterion. We set the standard of tumor location such that there was a distance of 6 to 12 cm from the lower edge of the tumor to the anal edge. For patients with tumor located less than 6 cm from the anal edge, APR will probably be needed, which may create a bias for evaluation of postoperative sexual function. Correspondingly, for patients with tumor located more than 12 cm from the anal edge, the distal rectum may probably be severed above the peritoneal reflection, sparing the dissection of the DVF.

In conclusion, for selected rectal cancer male patients with cT2−4 (T1−3 for anterior wall) N0−2M0, DVF preserving surgery during l-TME revealed protective effects on postoperative urgenital function and thus may be a better choice. However, comparison of the oncologic outcomes between the 2 surgical methods still needs to be assessed with long-term follow-up.

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