Clinical characteristics and predictive factors of pathological lateral pelvic lymph node metastasis in patients with rectal cancer

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Abstract. In recent years, selective lateral lymph node dissection (LLND) has been performed more frequently. The present study aimed to explore the clinical characteristics and predictive factors of pathological lateral pelvic lymph node metastasis (LPLNM), which may be helpful for pre-treatment decisions. The present study included 64 patients with rectal cancer and clinically suspected LPLNM who underwent total mesorectal excision (TME) and LLND between February 2019 and April 2024. According to pathological outcomes, the patients were divided into the negative LPLN (n=40) and positive LPLN (n=24) groups. The primary endpoints were the overall pathological LPLNM positivity rate and different clinical characteristics between the two groups. The secondary endpoint was the identification of predictive factors of pathological LPLNM before surgery. Among the 64 patients, 24 (37.5%) had pathologically confirmed LPLNM, and pathological LPLNM was related to initial lymph node size. When initial LPLN size was <7 mm, the pathological LPLNM rate was 10.5%, whereas when LPLN size was between 7 and 10 mm, the rate was 34.6%, and when LPLN size was >10 mm, the rate was 68.4%. Initial LPLN size (≥7.1 mm, P=0.003) and cN stage (N1-2, P=0.005) were significantly associated with pathological LPLNM. In multivariate analysis of risk factors, initial LPN size (≥7.1 mm; hazard ratio=4.856, 95% confidence interval 1.158-20.359, P=0.031) was the only independent risk factor for pathological LPLNM. When the cut-off initial LPLN size was 7.1 mm, the sensitivity and specificity were 87.5 and 52.5%, respectively, and the area under the curve was 0.748 (P=0.0009). When both LPLN size ≥7.1 mm and cN1-2 were satisfied, the sensitivity was 66.7%, the specificity increased to 77.5%, and the positive and negative predictive values were 64.0 and 79.5%, respectively. In conclusion, initial LPLN size and cN stage were identified as significant clinical characteristics associated with pathological LPLNM. Patients with an initial LPLN size of ≥7.1 mm and with cN1-2 stage cancer could benefit from TME + LLND surgery.

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Introduction

Lateral pelvic lymph nodes (LPLNs) are a common site of metastasis in patients with middle-low rectal cancer. Previous studies have indicated that, worldwide, LPLN metastasis (LPLNM) ranges from 8.6 to 21.0% for rectal cancer (1-3). Moreover, a retrospective study in Japan showed that in patients with T3/T4 rectal cancer below the peritoneal reflection, lateral lymph node dissection (LLND) could theoretically reduce local recurrence by 50.3% and improve 5-year survival by 8% (4). However, LLND surgery is associated with a long operation time, sizable blood loss and frequent postoperative complications (5-9). Furthermore, in the past 30 years, since preoperative neoadjuvant chemoradiotherapy (CRT) + total mesorectal excision (TME) surgery has become the standard treatment strategy for locally advanced rectal cancer, local recurrence has been well controlled. Therefore, the use of preventive LLND is controversial (10).

Despite the lack of data to support this, recent treatment patterns have converged toward performing LLND in cases with clinical suspected LPLNM in both Western and Eastern countries (10,11). However, a clear consensus is required on the indications for selective LLND. It is important to determine the clinical characteristics of rectal cancer with pathological LPLNM, which can guide precise treatment with selective LLND and identify patients who may benefit from this surgical procedure.

The present study retrospectively analyzed 64 patients who underwent TME + LLND surgery, and aimed to identify the clinical characteristics of pathological LPLNM and to determine predictive factors guiding pre-treatment decisions.

Materials and methods

Patients and treatment strategies. Between February 2019 and April 2024, 64 patients received TME + LLND surgery at

the Department of Colorectal Surgery, Zhangzhou Municipal Hospital Affiliated of Fujian Medical University (Zhangzhou, China). The patients were pathologically confirmed as having rectal cancer and had suspected clinical LPLNM based on preoperative MRI. The criteria for clinically suspicious LPLNM were as follows: i) Short-axis diameter of LPLN ≥5 mm; and ii) high-risk factors detected by MRI evaluation, such as irregular shape and rough edges, heterogeneous or intense enhancement of LPLN.

In the present study, patients with cT3-4 stage, cN2 stage, a short-axis diameter of LPLN ≥1.0 cm or mesorectal fascia involvement were subjected to neoadjuvant therapy (chemotherapy or CRT). The choice of neoadjuvant treatment, such as chemotherapy or CRT, was determined by the wishes of the patient and through multidisciplinary team meetings, including radiologists, and medical and surgical oncologists. Surgery was performed 6-8 weeks after the completion of CRT. Patients with pathological stage III/IV, or with high-risk stage II (pT4, tumor perforation, lymphatic invasion, perineural invasion) underwent adjuvant chemotherapy after surgery (CAPE-OX or mFOLFOX6, 6 months).

In the present study, the LPLN was defined as the lymph node located in the lateral pelvic area, including three regions: The obturator nodes (283N), internal iliac nodes (263N) and external iliac nodes (293N). Briefly, the scope of LLND surgery was ureterohypogastric nerve fascia as the inner boundary, vesicohypogastric fascia as the caudal boundary, pelvic wall fascia as the lateral boundary, and iliac vessel bifurcation as the cephalic boundary. All patients underwent a laparoscopic procedure.

The Ethics Committee of Zhangzhou Hospital Affiliated of Fujian Medical University (Zhangzhou, China) approved this retrospective study (approval no. 2023LWB289), and it conformed to the ethical standards of the World Medical Association Declaration of Helsinki.

Data collection. Information regarding patient demographics, tumor characteristics and clinical outcomes was obtained. In addition, body mass index (BMI), LPLN size, tumor distance from the anal verge and neoadjuvant therapy data were collected. All data were obtained from the medical records of the patients.

The present study used MRI to detect and evaluate LPLNM. The short-axis diameter of the largest LPLN assessed by MRI was measured and set as a representative value. Tumor staging was performed using the American Joint Committee on Cancer staging system (8th edition) (12), based on the available information after surgery (pTNM).

Statistical analysis. Categorical and continuous variables were compared using the χ^2 test and unpaired Student's t-test respectively. Univariate and multivariate logistic regression analyses were used to analyze risk factors of pathological LPLNM. Multivariate analysis was performed on factors with a significant effect (P<0.1) in the univariate analysis, and the effect of each variable was assessed using the hazard ratio (HR) and 95% confidence interval (95% CI). Receiver operating characteristic (ROC) curve analysis was performed for the initial LPLN size. SPSS (version 20.0; IBM Corp.) was used to perform all analyses and GraphPad Prism (version 10.0; Dotmatics) was used to draw diagrams. P<0.05 was considered to indicate a statistically significant difference.

Results

Baseline characteristics of patients. Patient details are shown in Table I. A total of 64 patients (average age, 58.9±11.1 years; age range, 35-83 years; 37 men and 27 women) were included. The distance of the tumor from the anal verge was 5.5±1.9 cm (range, 1-11 cm). Of the 64 patients, 28 (43.8%) received neoadjuvant therapy, of which 16 received chemotherapy and 11 received CRT. The average initial LPLN size was 9.7±4.9 mm (range, 4.5-27.0 mm), and the average number of LPLNs harvested was 7.9±5.2 (range, 0-30). Of the 64 patients with suspected LPLNM under clinical criteria, 50 (78.1%) had a short-axis LPLN diameter of ≥5 mm); 38 (59.4%) had high-risk factors, such as irregular shape and rough edges, and heterogeneous or intense enhancement. Finally, 24 cases of LPLNM were confirmed by pathology (37.5%).

Pathological LPLNM is related to initial lymph node size. Pathological LPLNM was revealed to be related to initial lymph node size (Fig. 1A). When the initial LPLN size was <7 mm, the pathological LPLNM rate was 10.5%, whereas when the LPLN was between 7 and 10 mm, the rate was 34.6%, and when the LPLN size was >10 mm, the rate was 68.4%. Furthermore, ROC curve analysis was performed for the initial LPLN size. The area under the curve was 0.748 (P=0.0009; Fig. 1B). When the cut-off initial LPLN size was 7.1 mm, the sensitivity and specificity were 87.5 and 52.5%, respectively.

Clinical characteristics of pathological LPLNM. The clinical characteristics of the patients in the positive and negative LPLN groups are shown in Table II. After analyzing sex, age, BMI, tumor distance from the anal verge, neoadjuvant therapy, average initial LPLN size, cT/N stage and numbers of LPLNs, it was revealed that initial LPLN size and cN stage were statistically different between the positive and negative LPLN groups. The average initial LPLN size in the positive LPLN group was bigger than that in the negative LPLN group (12.1±5.6 mm vs. 8.3±4.0 mm; P<0.05). In addition, the rates of cN1-2 in the positive LPN group were higher than those in the negative LPLN group (P<0.05).

Univariate and multivariate logistic regression analyses of preoperative factors associated with pathological LPLNM. In the univariate analysis of risk factors, initial LPLN size (≥7.1 mm; HR=7.737, 95%CI 1.987-30.132, P=0.003) and cN stage (N1-2; HR=4.667, 95% CI 1.577-13.813, P=0.005) were significantly associated with pathological LPLNM (Table III). Notably, male sex may also represent a potential risk factor for pathological LPLNM; however, this was not significant (P=0.072). In the multivariate analysis of risk factors, initial LPLN size (≥7.1 mm; HR=4.856, 95% CI 1.158-20.359, P=0.031) was the only independent risk factor for pathological LPLNM.

Association of pathological LPLNM rate with LPLN size and cN. Table IV shows the sensitivity, specificity, and positive and negative predictive values for diagnosing LPLNM based on

Table I. Baseline characteristics of patients.

Characteristic	Values
Sex, n (%)	
Male	37 (57.8%)
Female	27 (42.2%)
Mean ± SD age, years (range)	58.9±11.1 (35-83)
Mean ± SD BMI, kg/m^2 (range)	23.0±2.3 (18.2-28.1)
Mean ± SD distance of tumor from the AV, cm (range)	5.5±1.9 (1-11)
Rectal tumor location, n (%)	
>5 cm from AV	25 (39.1%)
≤5 cm from AV	39 (60.9%)
Mean ± SD initial LPLN size[a], mm (range)	9.7±4.9 (4.5-27.0)
Diagnostic criteria for clinical LPLNM, n (%)	
≥5 mm	50 (78.1%)
Imaging risk factors	38 (59.4%)
Mean ± SD CEA, ng/ml (range)	7.4±8.3 (1.3-56.0)
cT stage, n (%)	
cT1-2	15 (23.4%)
cT3-4	49 (76.6%)
cN stage, n (%)	
cN0	36 (56.3%)
cN1-2	28 (43.7%)
Neoadjuvant therapy, n (%)	
None	37 (57.8%)
Chemotherapy	16 (25.0%)
Chemoradiotherapy	11 (17.2%)
Mean ± SD LPLN harvested (range)	7.9±5.2 (0-30)
Positive LPLN, n (%)	24 (37.5%)

[a]Initial LPLN size refers to the short-axis diameter of the largest LPLN assessed by MRI. BMI, body mass index; AV, anal verge; LPLN, lateral pelvic lymph nodes; CEA, carcinoembryonic antigen.

different diagnostic criteria. Regarding the initial LPLN size, with a cut-off value of ≥7.1 mm, the sensitivity for LPLNM was 87.5%, but the specificity was only 52.5%. When both LPLN size ≥7.1 mm and cN1-2 criteria were met, the sensitivity was 66.7%, the specificity increased to 77.5%, and the positive and negative predictive values were 64.0 and 79.5%, respectively.

Furthermore, the pathological positivity rate of different conditions was analyzed in 64 patients. Those with LPLN ≥7.1 mm and cN1-2 had a pathological positivity rate of 69.6% (16/23). Those with LPLN <7.1 mm and cN1-2 had a pathological positivity rate of 0% (0/5), while those with LPLN ≥7.1 mm and cN0 had a pathological positivity rate of 29.4% (5/17).

Discussion

In recent years, with the increase in evidence, and the results of multi-center studies in Asia, Europe and the United States (13-16), TME + selective LLND surgery has been a mainstream strategy for the treatment of rectal cancer with suspected LPLNM based on MRI or CT. Although selective LLND can effectively enhance the detection rate of LPLNM, the consideration of surgical trauma and associated risks has necessitated a discussion on accurately selecting the appropriate patient population for this treatment. The present study conducted a retrospective analysis of 64 patients who underwent selective LLND, aiming to characterize the clinical features of pathological LPLNM for guiding pre-treatment decisions.

The strongest predictor of LPLNM known to date is LPLN size; however the size criteria vary between 5 and 10 mm, and the pathological positivity rate between 7.3 and 34.3% (17-20). Notably, the results vary widely and are controversial. In the present study, patients with a LPLN size of ≥5 mm or with imaging risk factors identified by preoperative MRI evaluation were suspected of having clinical metastasis. Overall, the pathological positivity rate of LPLNM by surgery was 37.5%. Moreover, pathological LPLNM was related to initial LPLN size. When the initial LPLN size was <7 mm, the pathological LPLNM rate was 10.5%, whereas when the LPLN size was 7-10 mm, the rate was 34.6%, and when the LPLN size was >10 mm, the rate was 68.4%. The results of the ROC curve analysis of initial LPLN sizes revealed that the sensitivity and specificity were 87.5 and 52.5%, respectively, when the cut-off initial LPLN size was 7.1 mm. Furthermore, the multivariate analysis identified initial LPLN size (≥7.1 mm) as the only independent risk factor for pathological LPLNM (HR=4.856, 95% CI 1.158-20.359, P=0.031). The current study revealed that an initial LPLN size of ≥7.1 mm may be a better indicator for selective LLND than 5 mm. A study from Korea found that an initial LPLN of 8 mm had the best sensitivity and specificity (21). The sensitivity for LPN metastasis was 100% with a cut-off value of 6 mm for the initial LPN size, but the specificity was only 24.6%, whereas the sensitivity and specificity were 94.4 and 47.8%, respectively, with a cut-off value of 8 mm for the initial LPN size. Numerous studies have revealed similar results, indicating that an initial LPLN of 5 mm may not be a good indicator for selective LLND (13,22-25).

It remains unclear as to whether initial LPLN size or size post-treatment (chemotherapy or CRT) should be used as the criterion. A previous report (17) showed that LPLN size after CRT was a significant predictive factor of LPLNM, but initial LPLN size was not. Another study (20) demonstrated that a LPLN size of ≥5 mm after CRT could be a cut-off value for selective LLND surgery. The purpose of the present study was to accurately identify pathological LPLNM when suspicious LPLNs were detected by MRI, and then to arrange treatment strategies (surgery or CRT). The findings revealed that the pathological positivity rate of initial LPLN size (≥7 mm) was >30%, regardless of whether CRT was administered. Considering such a high pathological positivity rate, it may be acceptable to perform LLND surgery based on initial LPLN size. Secondly, it was revealed that neoadjuvant therapy could not completely kill tumor cells; 2/64 patients in the current study were pathologically confirmed as having LPLNM, even though LPLN size was 4 mm after neoadjuvant treatment. A similar finding was also reported in a survey from Korea (26).

Table II. Clinical characteristics of positive and negative LPLN groups.

Characteristic	Positive LPLN (n=24)	Negative LPLN (n=40)	P-value
Sex, n (%)			0.069
Male	10 (41.7%)	26 (65.0%)	
Female	14 (58.3%)	14 (35.0%)	
Mean ± SD age, years (range)	58.3±12.0 (38-83)	59.2±10.7 (35-78)	0.759
Mean ± SD BMI, kg/m^2 (range)	22.9±2.1 (18.2-26.2)	23.1±2.4 (18.9-28.1)	0.857
Mean ± SD distance of tumor from the AV, cm (range)	5.4±1.8 (1-10)	5.6±1.0 (1-11)	0.731
Rectal tumor location, n (%)			0.074
>5 cm from AV	6 (25.0%)	19 (47.5%)	
≤5 cm from AV	18 (75.0%)	21 (52.5%)	
Mean ± SD initial LPLN size[a], mm (range)	12.1±5.6 (5.0-27.0)	8.3±4.0 (4.5-25.0)	0.003
Imaging risk factors, n (%)			0.693
No	9 (37.5%)	17 (42.5%)	
Yes	15 (62.5%)	23 (57.5%)	
Mean ± SD CEA, ng/ml (range)	8.5±12.0 (1.3-56.0)	6.7±4.9 (1.7-24.6)	0.411
cT stage, n (%)			0.819
cT1-2	6 (25.0%)	9 (22.5%)	
cT3-4	18 (75.0%)	31 (77.5%)	
cN stage, n (%)			0.004
cN0	8 (33.3%)	28 (70.0%)	
cN1-2	16 (66.7%)	12 (30.0%)	
Neoadjuvant therapy, n (%)			0.835
No	13 (54.2%)	24 (60.0%)	
Chemotherapy	7 (29.2%)	9 (22.5%)	
Chemoradiotherapy	4 (16.7%)	7 (17.5%)	
Mean ± SD LPLN harvested (range)	8.6±6.4 (1-30)	7.6±4.4 (0-20)	0.517

[a]Initial LPLN size refers to the short-axis diameter of the largest LPLN assessed by MRI. BMI, body mass index; AV, anal verge; LPLN, lateral pelvic lymph nodes; CEA, carcinoembryonic antigen.

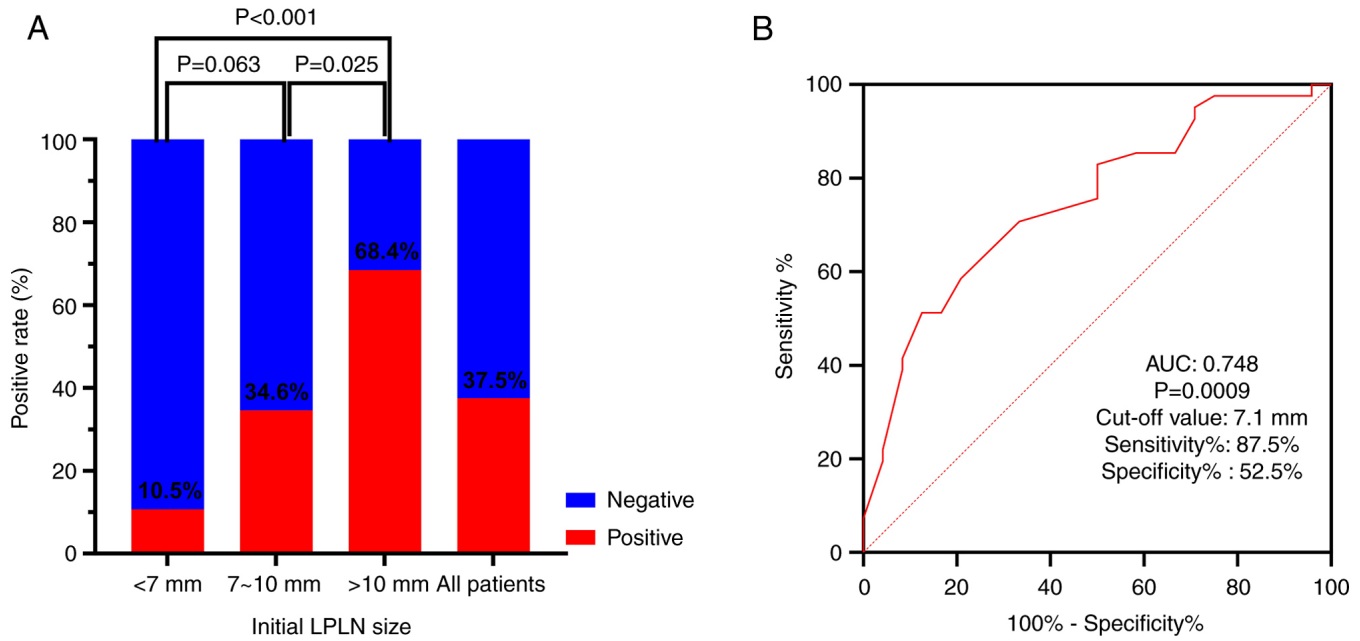

Figure 1. Pathological positivity rate and ROC curve analysis of LPLN metastasis. (A) Pathological positivity rates according to different LPLN initial sizes. (B) ROC curve analysis of initial LPLN size (mm). LPLN, lateral pelvic lymph node; ROC, receiver operative characteristic.

Table III. Univariate and multivariate analyses of preoperative factors associated with pathological LPLN metastasis.

	Univariate analysis		Multivariate analysis	
Variable	HR (95% CI)	P-value	HR (95% CI)	P-value
Sex (male/female)	2.600 (0.919-7.353)	0.072	2.288 (0.707-7.412)	0.167
Age, (<60/≥60 years)	0.944 (0.415-2.834)	0.919		
Rectal tumor distance from AV (>5/≤5 cm)	2.714 (0.892-8.261)	0.079		
BMI (<23/≥23 kg/m^2)	1.353 (0.490-3.739)	0.560		
Imaging risk factors (No/Yes)	1.232 (0.437-3.476)	0.694		
Initial LPLN size[a], (<7.1/≥7.1 mm)	7.737 (1.987-30.132)	0.003	4.856 (1.158-20.359)	0.031
CEA (≤5/>5 ng/ml)	0.443 (0.157-1.251)	0.124		
cT stage (T1-2/T3-4)	0.871 (0.266-2.849)	0.819		
cN stage (N0/N1-2)	4.667 (1.577-13.813)	0.005	3.185 (0.960-10.569)	0.058
Neoadjuvant therapy (No/Yes)	1.269 (0.457-3.528)	0.648		
MRF (-/+)	1.491 (0.401-5.543)	0.551		
EMVI (-/+)	2.000 (0.634-6.311)	0.237		

[a]Initial LPLN size refers to the short-axis diameter of the largest LPLN assessed by MRI BMI, body mass index; AV, anal verge; LPLN, lateral pelvic lymph node; MFR, mesorectal fascia; EMVI, extramural venous invasion; CEA, carcinoembryonic antigen.

Table IV. Diagnosis of LPLN metastasis according to the initial LPLN size and cN stage in all patients (n=64).

Value	Sensitivity[a]	Specificity[b]	Positive predictive value[c]	Negative predictive value[d]	Pathological positivity rate[e]
LPLN size ≥7.1 mm	87.5% (21/24)	52.5% (21/40)	52.5% (21/40)	87.5% (21/24)	52.5% (21/40)
cN1-2	66.7% (16/24)	70.0% (28/40)	57.1% (16/28)	77.8% (28/36)	57.1% (16/28)
LPLN size ≥7.1 mm and cN1-2	66.7% (16/24)	77.5% (31/40)	64.0% (16/25)	79.5% (31/39)	69.6% (16/23)

[a]Number of patients who met the criteria among the patients with positive LPLN/number of patients with positive LPLN. [b]Number of patients who did not meet the criteria among the patients with negative LPLN/number of patients with negative LPLN. [c]Number of patients with positive LPLN among the patients who met the criteria/number of patients who met the criteria. [d]Number of patients with negative LPLN among the patients who did not meet the criteria/number of patients who did not meet the criteria. LPLN, lateral pelvic lymph node. [e]Number of patients with positive LPLN/number of patients who met the criteria.

Furthermore, there were a number of cases in which neoadjuvant CRT was not performed for various reasons, such as patient refusal, old age or comorbidity in clinical practice. Therefore, it could be hypothesized that it is more appropriate to utilize initial LPLN size as the criteria for LPLND, rather than LPLN size after CRT.

Another preoperative risk factor for pathological LPLNM was cN stage. In the univariate analysis of risk factors, cN1-2 stage was significantly associated with pathological LPLNM (HR=4.667, 95% CI 1.577-13.813, P=0.005); those with N1-2 had a higher pathological positivity rate of LPLNM. However, there is a clinical difficulty in estimating neoplasm staging accurately. Some previous studies have reported that high-resolution MRI has a high sensitivity (88%) and specificity (85%) in diagnosing LPLNM (27,28). The combination of diffusion-weighted imaging and thin-layer imaging has been suggested to further improve the sensitivity and specificity of diagnosis (29). The consensus of Chinese experts recommend that high-resolution MRI is the preferred diagnostic method for LPLNM (30). Therefore, the current study balanced the complexity of patient selection with the likelihood of benefit from treatment using MRI evaluation as the selection criteria.

In the present study, initial LPLN size was the only independent risk factor for pathological LPLNM, while cN was not. However, the specificity was only 52.5% when a cut-off initial LPLN size of 7.1 mm was set. Therefore, it is worth considering how to judge positive LPLN more accurately in clinical decision-making. When both LPLN size ≥7.1 mm and cN1-2 criteria were met, the specificity increased to 77.5%. These findings indicated that patients with an initial LPLN size of ≥7.1 mm and also with cN1-2 stage cancer, may benefit from TME + LLND surgery. Notably, patients with LPLN size <7.1 mm and cN1-2 had a pathological positivity rate of 0% (0/5), whereas those with LPLN size ≥7.1 mm and cN0 had a pathological positivity rate of 29.6% (5/19). These findings indicated that cN1-2 alone, without LPLN size or imaging risk factors, is not enough to be the standard of diagnosis and to decide on the treatment for LPLNM. These findings

coincide with those of the JCOG0212 trial, which showed that in patients with advanced rectal cancer and a LPLN size of ≤10 mm, the rate of pathological LPLNM was 7%; however, for those with a LPLN size <5 mm, the pathological metastasis rate was only 5.2% (10).

The present study had several limitations. Firstly, as the study was retrospective, inherent and unintentional selection biases cannot be dismissed. Secondly, the study population was too small to set the indications for LLND after chemotherapy and CRT. In the future, individualized treatment based on LPLN response after neoadjuvant therapy may be more precise. Finally, pathological LPLNM is the most important factor in formulating treatment strategies.

In conclusion, initial LPLN size and cN stage were identified as significant clinical risk factors of pathological LPLNM. Patients with an initial LPLN size of ≥7.1 mm and with cN1-2 stage cancer could benefit from TME + LLND surgery.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

XiajX, HS and MC contributed to the study conception and design. YY and XiaozX acquired materials, and collected and analyzed data. All authors substantially contributed to critically reviewing the manuscript for important intellectual content. XiajX and HS confirm the authenticity of all the raw data. YY prepared the first draft of the manuscript and all authors commented on previous versions of the manuscript. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

All procedures performed in studies involving human participants adhered to the ethical standards of the institutional and national research committee, and to The 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study was approved by the Institutional Research Ethics Committee of Zhangzhou Hospital Affiliated with Fujian Medical University (approval no. 2023LWB289). As a retrospective study, the requirement for informed consent was waived by the ethics committee.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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