Original Article

Neoadjuvant Chemoradiotherapy Followed by Pelvic Lymph Node Dissection in Patients with Locally Advanced Rectal Cancer: A 18-patient Case Series

Yi-Kai Kao
Hsin-Pao Chen
Kuang-Wen Liu
Ling-Chiao Song
Chih-I Chen
Division of Colon and Rectal Surgery, Department of Surgery, E-DA Hospital, Kaohsiung, Taiwan

Key Words
Locally advanced rectal cancer;
Neoadjuvant chemoradiotherapy;
Pelvic lymph node dissection

Purpose. To investigate the role and necessity of pelvic lymph node dissection in patients with locally advanced rectal cancer who underwent neoadjuvant chemoradiotherapy plus total mesorectal excision.
Methods. A total of 18 patients with locally advanced rectal cancer underwent neoadjuvant chemoradiotherapy followed by total mesorectal excision and pelvic lymph node dissection. We compared the internal iliac, obturator, and external iliac lymph node sizes and responsiveness to treatment before and after neoadjuvant chemoradiotherapy. The pathologic staging, tumor morphology, regional lymph node and pelvic lymph node were examined by a pathologist.
Results. Among the 18 patients, the short axes of 19 lymph nodes in 11 patients were ≥ 5 mm. After receiving neoadjuvant chemoradiotherapy, there were still 10 lymph nodes in 6 patients ≥ 5 mm in the post neoadjuvant chemoradiotherapy image. A total of 556 lymph nodes including 217 mesorectal and 339 pelvic lymph nodes were removed from 18 patients. Five patients with 19 lymph nodes tested positive. All pelvic lymph nodes tested negative. One right ureter was injured during surgery and was immediately repaired. There were four complete response cases, three stage I cases, six stage II cases, and five stage III cases.
Conclusions. Routine pelvic lymph node dissection is not recommended in patients with locally advanced rectal cancer receiving neoadjuvant chemoradiotherapy. Additional pelvic lymph node dissection also increased surgical time and risk.

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Since the introduction of total mesorectal excision (TME) for rectal cancer, local recurrence and overall survival have improved significantly.[1,2] TME, including the removal of sufficient circumferential margin and perirectal lymph nodes, has reduced the locoregional recurrence rate;[3] however, rectal cancer cells tend to spread to the pelvic lateral lymph nodes, including the internal iliac, obturator, and external iliac nodes, which could lead to recurrence in the lateral pelvic sidewall.[4,5]

In Western countries, neoadjuvant chemoradiotherapy (nCRT) plus TME has been standardized for treating locally advanced rectal cancer (LARC).[6,7] Although the locoregional recurrence rate is not high in

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Correspondence to: Dr. Chih-I Chen, Division of Colon and Rectal Surgery, Department of Surgery, E-DA Hospital, No. 1, Yida Rd., Yanchao Dist., Kaohsiung 824005, Taiwan. Tel: 886-910861030; E-mail: jimmyee0901@gmail.com

rectal cancer after nCRT plus TME, more than half of locoregional recurrences occur in the lateral pelvic sidewall.[8]

In Japan and some other Asian countries, TME plus pelvic lymph node dissection (PLND) is performed in LARC for local control. The Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines recommend TME plus PLND regardless of a pelvic lymph node short-axis diameter greater than 10 mm on preoperative computed tomography (CT) or magnetic resonance imaging (MRI).[9]

The role of PLND in LARC remains debatable. Japan and some Asian countries prefer TME plus PLND for local control in LARC; however, Western countries prefer nCRT plus TME. Recently, some studies have suggested TME plus PLND after nCRT for selective patients.[10-13]

Although there is no uniform definition of rectal anatomy, the rectum is conventionally divided into three parts: the upper, middle, and lower rectum, which are above the anterior peritoneal reflection, at the anterior peritoneal reflection, and below the anterior peritoneal reflection, respectively. Lymphatic drainage of the rectum is divided into three parts depending on the rectal level.

Tumors above the peritoneal reflection drain superiorly through the superior rectal and inferior mesenteric nodes, whereas those below the peritoneal reflection drain through the internal iliac and obturator nodes.[14] Tumors below the dentate line may drain through the superficial inguinal and external iliac nodes.[13]

In a previous study, pelvic lymph node (PLN)-positive rate was found to be 8.2% in upper rectal cancer, and 15.6% for lower rectal cancer in LARC without radiotherapy.[5] One study evaluated the pathological results of PLND after nCRT plus TME for rectal cancer. The study revealed no metastatic PLN in the short axis < 5 mm on post-nCRT MRI.[15]

Most patients with LARC in Taiwan underwent nCRT plus TME without PLND. To the best of our knowledge, there is no consensus in the literature on whether to perform nCRT plus TME or TME plus PLND in LARC, or even in selective patients receiving nCRT and TME plus PLND. The purpose of this case series study was to evaluate the effect of nCRT and to determine suspected metastatic PLN by examining the short axis of the lymph node (LN) and pathologic results after nCRT in rectal cancer.

Methods

Patients

This study enrolled patients with LARC who underwent TME plus PLND at a single hospital between January 2020 and June 2023. Patients with clinical stages II and III rectal cancer were included, and those with stages I and IV were excluded. Among the 28 patients with LARC who underwent TME plus PLND, nine patients did not receive preoperative radiotherapy, and one of the remaining patients did not receive chemotherapy. Ultimately, there were 18 patients included in the case series.

Image and pathologic analyses

In this study, the patients underwent computed tomography (CT) or magnetic resonance imaging (MRI) before and after nCRT. In addition to the standard American Joint Committee on Cancer TNM staging, the short-axis node size and location of the external iliac, obturator, and internal iliac LN were assessed by the same colorectal surgeon. Shrinkage size was defined as the difference in millimeters, and disappearance was defined as the absence of a visible node after nCRT.

All patients underwent laparoscopic or Da Vin Ci robot-assisted TME plus PLND. Pathological staging was performed according to American Joint Committee on Cancer Staging guidelines. In addition to pathologic TNM staging, tumor regression grade,[16] differentiation, angiolymphatic invasion, perineural invasion, and PLN (external iliac, obturator, and internal iliac lymph node) status were also recorded.

Statistical analysis

The PLN location and short-axis sizes were assessed by CT or MRI both before and after nCRT, and

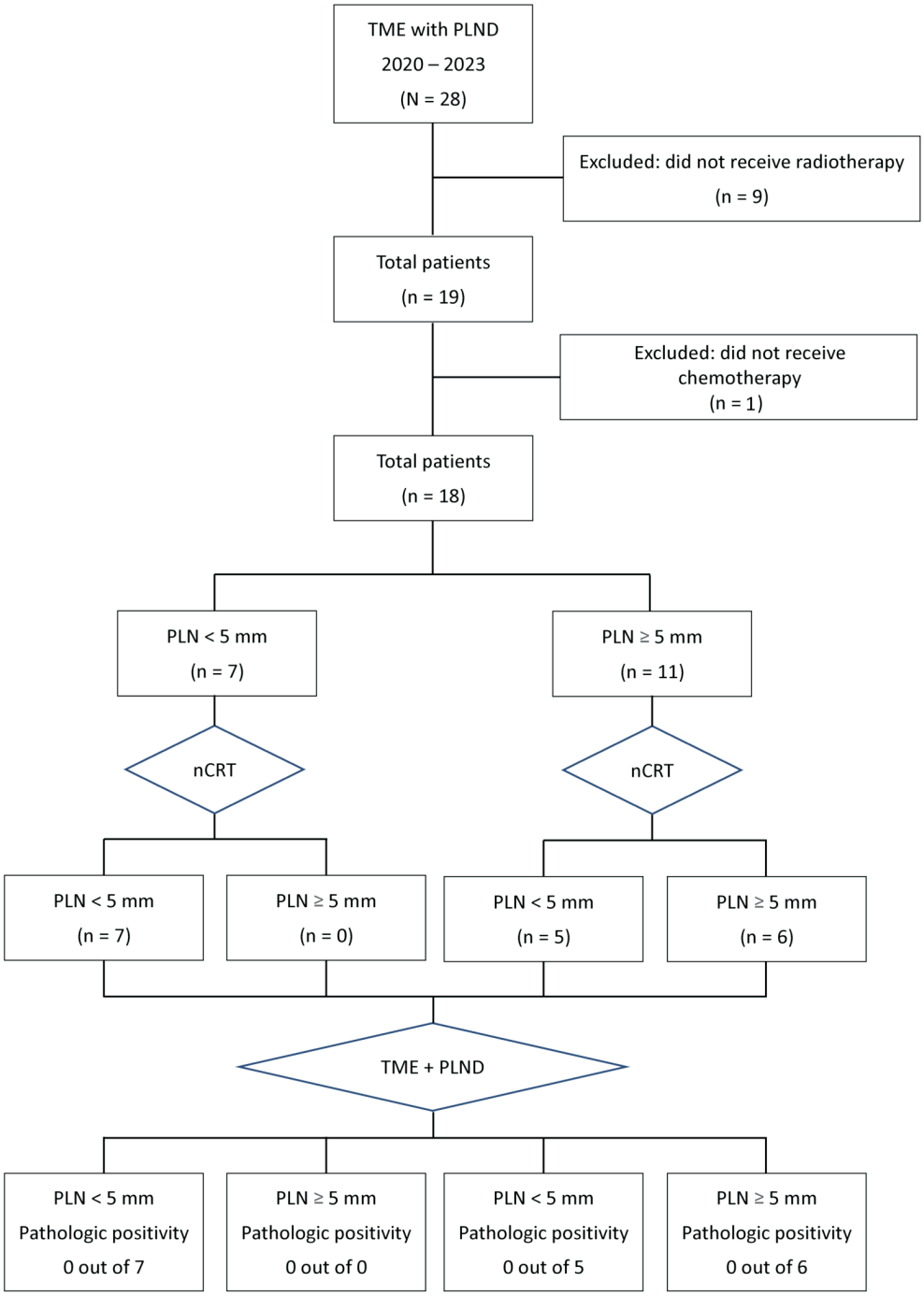

Fig. 1. Flow chart demonstrating the proportion of pathologic PLN-positive patients pre- and post-nCRT by PLN size. PLN, pelvic lymph node; PLND, pelvic lymph node dissection; nCRT, neoadjuvant chemoradiotherapy; TME, total mesorectal excision.

the associations between PLN size, post-nCRT response, and pathologic PLN positivity were evaluated.

Data were summarized using descriptive statistics. Data analyses were performed using SPSS Statistics software (v.22, IBM Corp, Armonk, NY).

Results

Patients

Eighteen patients were enrolled in the study and

treated. All patients received chemoradiotherapy before radical surgery; 8 of 18 patients received total neoadjuvant therapy, and the other 10 received preoperative chemoradiotherapy. After nCRT, 16 patients underwent laparoscopic TME plus PLND, and the other two underwent Da Vinci robotic TME plus PLND. Six tumors were in the upper rectum which were located above the anterior peritoneal reflection, and 12 were located in the lower rectum which were at the level or below the anterior peritoneal reflection. The median age of all the enrolled patients was 63.5 years (range, 45 to 82), and 22.22% were females. Of the 18 patients, 14 had clinical stage III disease, and 4 had clinical stage II disease (Tables 1 and 2).

Tumor and lymph node characteristics

The median tumor size on the CT image was 48.5 mm (range, 15-100 mm). Among the 18 patients, 11 patients had a total of 19 PLN greater than 5 mm (range, 5-10 mm). After receiving nCRT, 6 patients had 10 PLN greater than 5 mm, and 6 PLN remained the same size.

The median tumor size of the pathological speci-

Table 1. Demographic and disease characteristics of the patients at baseline.

Characteristic	Value
Patients enrolled — no. (%)	18 (100%)
Females — no. (%)	4 (22.22)
Median age (range) — yr	63.5 (45-82)
Clinical tumor stage — no. (%)	
T1 or T2	2 (11.11)
T3	10 (55.56)
T4	6 (33.33)
Clinical nodal stage — no. (%)	
Positive	14 (77.78)
Negative	4 (22.22)
Tumor location — no. (%)	
Upper rectum	6 (33.33)
Lower rectum	12 (66.67)
Radiotherapy type — no. (%)	
Short course	10 (55.56)
Long course	8 (44.44)
Surgical complication — no. (%)	
Major complication	1 (5.55)
Minor complication	0 (0)

Table 2. Individual patient data

Patient No. (sex, age)	Clinical tumor stage; Nodal stage	Tumor location	Image tumor size (mm)	PLN location	Pre-RT PLN short axis (mm)	Pre-operative RT	Pre-operative chemotherapy	Post-RT PLN short axis (mm)	Surgical approach	Complication
1 (F, 56 yr)	T3; N1b	Low	30	R't I	7	Long	UFUR	5	Laparoscopic	Nil
2 (M, 57 yr)	T4a; N2a	Low	70	R't I; R't I	8; 10	Long	5-FU + UFUR	4; 0	Laparoscopic	Nil
3 (M, 51 yr)	T4a: N2a	Low	90	L't O	5	Long	UFUR	3	Laparoscopic	Nil
4 (M, 69 yr)	T3; N1a	Low	40	R't I	5	Short	5-FU	0	Laparoscopic	Nil
5 (M, 82 yr)	T3; N1b	Low	45	Nil	Nil	Long	UFUR	Nil	Laparoscopic	Nil
6 (M, 68 yr)	T4a; N0	Low	50	Nil	Nil	Long	UFUR	Nil	Laparoscopic	Nil
7 (F, 60 yr)	T3; N1b	Upper	23	R't E; L't E; R't I	6; 7; 9	Long	5-FU	6; 5; 5	Laparoscopic	Nil
8 (M, 48 yr)	T2; N1b	Upper	15	Nil	Nil	Short	FOLFOX	Nil	Laparoscopic	Nil
9 (M, 64 yr)	T3; N1b	Low	35	R't E; L't E	5; 5	Short	FOLFOX	5; 5	Laparoscopic	Nil
10 (M, 45 yr)	T3; N2b	Low	100	R't I; L't E	8; 10	Long	5-FU	8; 7	Laparoscopic	Nil
11 (F, 54 yr)	T4a; N1b	Upper	80	Nil	Nil	Short	Xeloda + Oxaliplatin	Nil	Da Vinci Robotic	Right ureter injury
12 (F, 63 yr)	T2; N1b	Low	20	R't E; L't E	5; 7	Long	FOLFOX	5; 3	Laparoscopic	Nil
13 (M, 67 yr)	T3; N1b	Upper	65	R't I; L't I	6; 6	Short	FOLFOX	6; 0	Laparoscopic	Nil
14 (M, 64 yr)	T3; N0	Low	55	Nil	Nil	Short	FOLFOX	Nil	Laparoscopic	Nil
15 (M, 81 yr)	T3; N0	Low	65	Nil	Nil	Short	Xeloda	Nil	Laparoscopic	Nil
16 (M, 53 yr)	T4a; N1b	Upper	64	R't E; L't I	5; 5	Short	FOLFOX	4; 4	Laparoscopic	Nil
17 (M, 74 yr)	T4a; N0	Upper	47	Nil	Nil	Short	FOLFOX	Nil	Da Vinci Robotic	Nil
18 (M, 66 yr)	T3; N1a	Low	43	R't I	6	Short	FOLFOX	4	Laparoscopic	Nil

PLN, pelvic lymph node; RT, radiotherapy; R't I, right internal; R't O, right obturator; R't E, right external; L't I, left internal; L't O, left obturator; L't E, left external; UFUR = Tegafur 100 mg + Uracil 224 mg; 5-FU = 5-Fluorouracil; FOLFOX = Folinic acid + Fluorouracil + Oxaliplatin; M, male; F, female.

mens was 25 mm (range, 0-56 mm). Among the 18 patients, 4 had a complete response (ypT0N0), 3 had pathologic stage I disease, 6 had pathologic stage II disease, and 5 had pathologic stage III disease.

Except for the four complete response cases, there were 13 moderately differentiated and one poorly differentiated cases, four patients were positive for angiolymphatic invasion, and eight patients were positive for perineural invasion.

A total of 556 dissected LN from 18 patients were examined by a pathologist; 217 were dissected from the mesorectum and 339 were dissected by PLND. The median number of mesorectal LN was 13 (range, 3-23), with 19 positive LNs in five patients. The median number of PLN was 18 (range, 6-33), and none of the examined PLN were positive (Tables 3 and 4).

Complications by PLND

There was one major complication among 18 patients (5.56%), and no minor complications were noted. Major complications were defined as grade > 3 according to the Clavien-Dindo classification. A right ureter injury occurred during one Da Vinci robotic-assisted surgery. In every TME plus PLND, bilateral double-J stents were routinely placed at the beginning of surgery. Thus, the injured right ureter could be re-

Table 3. Tumor and pelvic lymph node status of the patients

Characteristic	Value
Patients enrolled — no. (%)	18 (100%)
Pre-nCRT PLN ≥ 5 mm — no. (%)	
Positive	11 (61.11)
Negative	7 (38.89)
Post-nCRT PLN ≥ 5 mm — no. (%)	
Positive	6 (33.33)
Negative	12 (66.67)
Tumor regression grade after nCRT — no. (%)	
Grade 1	4 (22.22)
Grade 2	5 (27.78)
Grade 3	5 (27.78)
Grade 4	4 (22.22)
Pathological LN — no. (%)	
Positive	0 (0)
Negative	18 (100)

nCRT, neoadjuvant chemoradiotherapy; PLN, pelvic lymph node; LN, lymph node.

Table 4. Individual pathological data

Patient No. (sex, age)	Pathological tumor stage; Nodal stage	Pathological tumor size (mm)	Tumor regression grade	Differentiation	Angiolymphatic invasion	Perineural invasion	Regional LN (positive/total)	Right PLN (positive/total)			Left PLN (positive/total)		
								R't E	R't O	R't I	L't E	L't O	L't I
1 (F, 56 yr)	T3; N2b	45	Grade 1	Poorly	Negative	Positive	8/18	0/3	0/3	0/0	0/2	0/1	0/4
2 (M, 57 yr)	T2; N0	56	Grade 2	Moderately	Negative	Positive	0/19	0/2	0/7	0/2	0/4	0/8	0/0
3 (M, 51 yr)	T3; N1a	40	Grade 2	Moderately	Negative	Positive	1/21	0/2	0/5	0/5	0/2	0/8	0/4
4 (M, 69 yr)	T1; N0	25	Grade 1	Moderately	Negative	Negative	0/3	0/1	0/4	0/2	0/2	0/1	0/3
5 (M, 82 yr)	T0; N1b	Total regression	Grade 3	Moderately	Negative	Positive	2/5	0/5	0/3	0/0	0/0	0/0	0/0
6 (M, 68 yr)	T3; N0	15	Grade 3	Moderately	Negative	Positive	0/13	0/5	0/5	0/1	0/4	0/6	0/1
7 (F, 60 yr)	T4a; N0	30	Grade 2	Moderately	Negative	Negative	0/5	0/5	0/1	0/6	0/1	0/3	0/4
8 (M, 48 yr)	T0; N0	Total regression	Grade 4	Nil	Nil	Nil	0/13	0/5	0/7	0/3	0/0	0/13	0/5
9 (M, 64 yr)	T0; N0	Total regression	Grade 4	Nil	Nil	Nil	0/5	0/1	0/7	0/9	0/4	0/4	0/0
10 (M, 45 yr)	T3; N0	40	Grade 2	Moderately	Negative	Negative	0/12	0/0	0/4	0/6	0/0	0/2	0/3
11 (F, 54 yr)	T3; N2b	30	Grade 1	Moderately	Positive	Negative	7/16	0/2	0/10	0/2	0/6	0/7	0/1
12 (F, 63 yr)	T2; N0	1	Grade 3	Moderately	Negative	Negative	0/5	0/0	0/12	0/1	0/2	0/11	0/2
13 (M, 67 yr)	T3; N0	32	Grade 1	Moderately	Negative	Positive	0/19	0/0	0/4	0/0	0/3	0/5	0/1
14 (M, 64 yr)	T0; N0	Total regression	Grade 4	Nil	Nil	Nil	0/5	0/5	0/0	0/0	0/3	0/0	0/3
15 (M, 81 yr)	T3; N1a	35	Grade 2	Moderately	Positive	Negative	1/13	0/5	0/5	0/2	0/1	0/2	0/1
16 (M, 53 yr)	T3; N0	25	Grade 3	Moderately	Positive	Positive	0/7	0/0	0/2	0/0	0/0	0/4	0/0
17 (M, 74 yr)	T3; N0	20	Grade 3	Moderately	Positive	Positive	0/15	0/7			0/6		
18 (M, 66 yr)	T0; N0	Total regression	Grade 4	Nil	Nil	Nil	0/23	0/4	0/9	0/1	0/4	0/8	0/0

LN, lymph node; PLN, pelvic lymph node; R't I, right internal; R't O, right obturator; R't E, right external; L't I, left internal; L't O, left obturator; L't E, left external; M, male; F, female.

paired easily and immediately. A urinoma was noted one week after surgery and was managed with CT-guided drainage.

Discussion

According to the 8th edition of the American Joint Committee on Cancer (AJCC) tumor-node-metastasis classification of rectal cancer, regional LNs include mesorectal, perirectal, superior rectal, inferior mesenteric, internal iliac, and inferior rectal LNs. The obturator LN was not mentioned but was generally regarded as a regional LN. The external iliac and inguinal LNs are regarded as non-regional LNs.[17-19]

Pelvic LN included internal, obturator, and external LN. Under the omission of PLND, the PLN could not be examined, and the risk of pelvic wall recurrence increased. Kim et al. reported locoregional recurrence rate of 7.9% in patients with LARC receiving nCRT plus TME, and 82.7% of local recurrences were lateral pelvic wall recurrences.[8] PLND could help obtain a more accurate N stage for LARC.

In our case series, 18 patients with LARC received nCRT, followed by TME plus PLND. Among the 18 patients, there was no LNs' short axis greater than 10 mm. Eleven patients had LNs' short axis greater than 5 mm before nCRT. In six patients with 10 LNs, the size remained greater than 5 mm, and in the other 5 (45.5%) patients with 9 LNs, the sizes were smaller than 5 mm after nCRT. However, none of the LNs were pathologically positive in our study.

Ishibe et al. reported that the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy values were 43.8, 98.5, 87.5, 88.1, and 88.1%, respectively in the LN cut-off value of 10 mm in low rectal cancer without preoperative treatment.[20]

Malakorn et al. evaluated 64 patients' LNs after nCRT and reported that 13 (20.3%) patients had no LN greater than 5 mm, and none were pathologically positive. Among the remaining 51 (79.7%) patients who had LNs greater than 5 mm, 33 (64.7%) patients were pathologically positive, and no patients with positive PLN developed pelvic wall recurrence after PLND.[15]

Ogura et al. investigated 741 patients and reported the importance of LN size reduction. The LNs sizes were 7 mm or greater and remained greater than 4 mm after chemoradiotherapy or radiotherapy. Subsequently, it showed a 5-year lateral local recurrence rate of 52.3% and 9.5% in the internal iliac and obturator compartment respectively. In patients with shrinkage of PLN short axis from ≥ 7 mm to ≤ 4 mm after treatment, PLND can be avoided.[11] Ogura et al. also demonstrated a significantly lower 5-year lateral local recurrence rate between additional PLND (5.7%) and nCRT plus PLND alone (19.5%) in patients with PLN ≥7 mm.

The importance of MRI in rectal cancer staging has increased in recent years. However, accessibility, waiting time, and allocation of medical resources have caused dilemmas in using MRI in rectal staging. To our knowledge, MRI has better performance in the T stage and perirectal tissue invasion than CT. Some studies have reported no difference in sensitivity, specificity, or accuracy between MRI and CT in the rectal cancer N stage.[21,22] However, with the evolution of imaging, some studies have reported better signals in high-resolution MRI on metastatic LNs[23] or the application of Positron Emission Tomography (PET)/CT or PET/MRI for LN staging in rectal cancer.[18]

For local recurrent control of LARC, the application of nCRT plus TME or TME plus PLND remains debatable. In addition to these two treatment options, some studies have discussed nCRT followed by TME plus PLND. An early randomized controlled trial reported by Nagawa et al. showed no difference in overall survival, disease-free survival, or recurrence rates to introduce additional PLND after preoperative radiotherapy, with higher rates of urinary and sexual dysfunction.[24] A meta-analysis and systematic review demonstrated a significantly lower local lateral recurrence rate with additional PLND after nCRT using the TME. PLND has been suggested despite increasing operative time and risk of urinary dysfunction.[25] Another meta-analysis and systematic review reported that nCRT followed by additional PLND during TME reduced the local recurrence rate. However, there was no difference in disease-free survival and overall survival.[26]

In our study, there was one (5.56%) major complication of right ureteral injury during the operation. A previous study reported similar major complication rates for PLND plus TME (9.3%) and TME alone (5.5%).[27] The authors of the JCOG0212 trial also demonstrated no significant differences in urinary dysfunction[28] and sexual dysfunction[29] between PLND plus TME and TME alone.

In our study, eight patients received total neoadjuvant therapy (TNT) with short- or long-course radiotherapy following six cycles of chemotherapy (FOLFOX). Among the 18 patients, a pathologically complete response (ypT0N0) was observed in four patients, all of whom received TNT. The other four patients who received TNT were all negative for regional LN. Among the remaining 10 patients who received nCRT before surgery, five were positive for regional LN. Recently, the use of TNT for LARC has gradually increased. Although a few studies have discussed TNT plus PLND, they have shown a lower risk of PLN metastasis after TNT than after conventional nCRT.[13,30]

Limitation

This study had several limitations. First, this was a single-hospital study involving only a small sample size. We look forward to enrolling more cases in the future. Furthermore, rectal cancer LN staging could be more precise by using PET/CT or high-resolution MRI. Moreover, overall survival, disease-free survival, and lateral pelvic wall recurrence should be monitored over the long term. Despite the small sample size in this study, the pathological outcomes were remarkable in patients who received TNT. Therefore, future studies should separate TNT from conventional nCRT.

Conclusions

Based on this study, we thought the routinely PLND is not recommended for patients with LARC receiving nCRT plus TME. Additional PLND also increase the operative time and risk of urinary dysfunction. The role of additional PLND in TNT plus TME remains unclear compared with conventional nCRT plus TME, and more studies are needed to clarify its benefits.

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原　著

局部侵襲性直腸癌病患接受術前化學及放射治療後，進行骨盆腔淋巴清除手術：18 位病患系列病例

高翊凱　陳興保　劉廣文　宋翎巧　陳致一

義大財團法人義大醫院　大腸直腸外科

目的　局部侵襲性直腸癌病患接受手術前化學及放射治療後，除了進行全直腸繫膜切除，探討骨盆腔淋巴清除手術的角色及必要性。

方法　總共 18 位局部侵襲性直腸癌病人於化學及放射治療後，接受全直腸繫膜切除及骨盆腔淋巴結清除手術。比較化學及放射治療前後之影像，觀察內髂、閉孔、外髂淋巴結的大小以及對化放療的反應。術後由病理科檢查腫瘤型態及期別、局部淋巴結及骨盆腔淋巴結是否有轉移。

結果　在 18 位病人的影像中，有 11 位病人共 19 顆淋巴結大於等於 5 mm，在接受化放療後的影像中，仍有 6 位病人共 10 顆淋巴結大於等於 5 mm。手術檢體共有 556 顆淋巴結，包括 217 顆直腸繫膜淋巴結和 339 骨盆腔淋巴結，其中 5 位病人共 19 顆直腸繫膜淋巴結有轉移，所有病人的骨盆腔淋巴結皆無轉移。於 18 位病人中，有一位右側輸尿管損傷，術中立即進行修補。病理分期有 4 個完全反應、3 個第一期、6 個第二期、5 個第三期。

結論　對於接受手術前化學及放射治療的局部侵襲性直腸癌病患，並不建議常規進行骨盆腔淋巴清除手術。且額外的骨盆腔淋巴清除手術會增加手術時間及風險。

關鍵詞　局部侵襲性直腸癌、手術前化學及放射治療、骨盆腔淋巴結清除手術。