Research Square

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The prognostic role of lateral pelvic lymph nodes in patients with low and mid rectal cancer

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Abstract

Purpose

Lateral pelvic lymph nodes (LPLNs) represent a potential route of locoregional dissemination in locally advanced rectal cancer (LARC). LPLN management remains controversial, with routine LPLN dissection advocated in some Eastern centres, whereas Western strategies rely primarily on neoadjuvant treatment followed by total mesorectal excision (TME) without systematic lateral pelvic lymph node dissection (LPLND). As a result, the prognostic significance of magnetic resonance imaging (MRI)-suspected LPLNs in patients treated with contemporary neoadjuvant approaches remains uncertain, particularly in Western cohorts where pathological confirmation is rare. This study aimed to determine the incidence of MRI-suspected LPLN involvement and to evaluate its prognostic impact on overall survival (OS) and disease-free survival (DFS).

Methods

This was a retrospective study at the Institut Jules Bordet that included patients treated for LARC between January 1, 2007 and December 31, 2021. Pre-treatment MRI was used to identify suspected LPLN involvement. The prognostic impact of MRI-suspected LPLNs on OS and DFS was assessed.

Results

A total of 115 patients with LARC were included. Twenty-one patients (18.3%) had MRI-suspected LPLNs at diagnosis. Despite a higher risk of LPLN recurrence in the group with MRI-suspected LPLN (9.5% vs 1.1%), no statistically significant association was observed between pre-treatment LPLN status and OS or DFS (P = 0.88 and P = 0.73, respectively).

Conclusion

In this cohort, MRI-suspected LPLN involvement was not associated with impaired survival outcomes. Prospective studies using standardised radiological criteria and treatment strategies are warranted to better define the prognostic role of LPLNs in LARC.

1. Introduction

Colorectal cancer is the third most common malignancy worldwide and a leading cause of cancer-related mortality [1]. Approximately 40%–50% of rectal cancers are diagnosed at a locally advanced stage, corresponding to American Joint Committee on Cancer (AJCC) stages II and III [2]. Lateral pelvic lymph nodes (LPLNs), including obturator and internal iliac nodes, represent a potential route of locoregional dissemination in locally advanced rectal cancer (LARC). The reported incidence of

pathological LPLN metastasis ranges from 15% to 30%, depending on tumour location and staging criteria [3–6]. The presence of LPLN metastasis has historically been associated with increased local recurrence and impaired survival, with reported 5-year overall survival (OS) rates of approximately 40% in surgical series [3–5].

The management of LPLNs remains controversial and reflects differing treatment philosophies. In Japan, LPLN metastases are considered locoregional disease, and standard treatment for advanced low- and mid-rectal cancer includes total mesorectal excision (TME) combined with systematic lateral pelvic lymph node dissection (LPLND) [7]. Several retrospective studies from Eastern centres have reported improved local control and, in selected cohorts, improved survival outcomes with the addition of LPLND [8, 9].

In contrast, Western guidelines, including those from the European Society for Medical Oncology (ESMO) and the National Comprehensive Cancer Network (NCCN), do not recommend routine LPLND [10, 11]. Instead, patients with LARC are treated with neoadjuvant treatment—either chemoradiotherapy (CRT) or, increasingly, total neoadjuvant therapy (TNT)—followed by TME. Large, randomised trials such as RAPIDO and PRODIGE 23 have demonstrated improved disease-related outcomes with intensified neoadjuvant strategies [12, 13]. In this approach, lateral pelvic lymph nodes are included within the radiation field, and surgical dissection is generally reserved for highly selected cases.

Despite increasing use of modern multimodal therapy, the prognostic significance of magnetic resonance imaging (MRI)-suspected LPLNs in Western populations remains insufficiently defined. Most available data originate from Eastern series incorporating routine LPLND, whereas MRI-based studies in patients treated without systematic LPLND are comparatively limited. Moreover, the impact of baseline LPLN suspicion in the era of TNT remains unclear.

The primary objective of this study was to determine the incidence of MRI-suspected LPLN involvement in patients with LARC treated with neoadjuvant treatment followed by TME. The secondary objective was to evaluate the prognostic impact of baseline MRI-suspected LPLNs on OS, disease-free survival (DFS), and recurrence patterns.

2. Materials and Methods

2.1 Study design and population

This retrospective single-centre study included consecutive patients with LARC treated at the Institut Jules Bordet between January 1, 2007 and December 31, 2021. The study was approved by the institutional ethics committee (approval number OM011; internal reference CE3807; March 21, 2024).

2.2 Data collection

Clinical, radiological, surgical, and pathological data were extracted from the institutional electronic medical record system (Oribase). The following variables were collected: age, sex, American Society of

Anesthesiologists (ASA) score, clinical stage before neoadjuvant treatment (cTNM), carcinoembryonic antigen (CEA) levels (at diagnosis, after neoadjuvant treatment, and at first follow-up), MRI-suspected mesorectal and lateral pelvic lymph node involvement before and after neoadjuvant treatment, pathological stage after neoadjuvant treatment (ypTNM), Dworak tumour regression grade (TRG), type of surgery, conversion to laparotomy, number of retrieved and positive mesorectal lymph nodes, tumour differentiation, lymphovascular invasion (LVI), perineural invasion (PNI), resection margin status, microsatellite status (microsatellite stable, MSS, or microsatellite instability, MSI), and administration of adjuvant chemotherapy. Dates and patterns of recurrence (locoregional, lateral pelvic, or distant) and date of death were recorded.

2.3 Inclusion and exclusion criteria

Staging (cTNM and ypTNM) was determined according to the 7th edition of the AJCC classification. Eligible patients had stage II–III LARC of the low or mid rectum treated with neoadjuvant treatment followed by low anterior resection (LAR) or abdominoperineal resection (APR) with TME. A high-quality pre-treatment MRI was required for inclusion. Patients with stage I or stage IV disease and those with synchronous malignancies were excluded.

2.4 Preoperative staging and radiological assessment

Clinical staging was based on pelvic MRI performed before and after neoadjuvant treatment. Thoraco-abdomino-pelvic computed tomography (CT) was routinely performed. Endorectal ultrasound (EUS) was used mainly during the earlier study period (2007–2013). Positron emission tomography (PET-CT) was performed when metastatic disease was suspected. Radiological reports considered incomplete were reviewed by an experienced radiologist (A.V.). MRI-suspected LPLNs were defined as nodes with a short-axis diameter ≥ 7 mm before neoadjuvant treatment and ≥ 5 mm after neoadjuvant treatment [14].

2.5 Neoadjuvant treatment

Patients received neoadjuvant treatment according to institutional protocols and multidisciplinary discussion. Long-course neoadjuvant CRT consisted of 45–50 Gy delivered in 25 fractions to the pelvis, with concurrent fluoropyrimidine-based chemotherapy (continuous intravenous 5-fluorouracil). A simultaneous integrated boost was administered based on macroscopic tumour volume when indicated. Short-course radiotherapy was administered in selected patients, particularly those considered unfit for long-course treatment or those who did not require tumour downstaging. In the later years of the study period, TNT incorporating systemic chemotherapy before surgery was introduced in selected patients.

2.6 Surgery

All patients underwent laparoscopic resection, consisting of LAR or APR with TME, according to tumour location and standard oncological principles. Conversion to open surgery was performed when necessary. Resection margins were considered negative (R0) when ≥ 1 mm and positive (R1) when < 1 mm [15].

2.7 Follow-up

Patients were followed every 3 months during the first year, every 4 months during the second year, every 6 months for the subsequent 3 years, and annually thereafter. Follow-up included clinical evaluation, serum CEA measurement, and thoraco-abdomino-pelvic CT imaging.

2.8 Statistical analysis

Categorical variables are presented as number (percentage), and continuous variables as mean (range) or mean, as appropriate. Percentages were calculated on the total number of patients in each group, with unknown values reported as a separate category; statistical comparisons were performed on patients with available data. Comparisons between patients with and without MRI-suspected LPLN involvement were performed using Fisher's exact test or the Cochran–Armitage trend test for categorical variables, and the Wilcoxon rank-sum test for continuous variables. OS was defined as the interval between the date of surgery and death from any cause. DFS was defined as the interval between the date of surgery and recurrence or death. Survival curves were estimated using the Kaplan–Meier method and compared using the log-rank test.

3. Results

3.1 Patient selection and baseline characteristics

Between January 1, 2007 and December 31, 2021, 164 patients underwent LAR or APR with TME at our institution. After applying exclusion criteria, 115 patients were included in the analysis (Fig. 1). Baseline clinicopathological characteristics of the included patients are summarised in Table 1. The cohort included 64 men (55.7%) and 51 women (44.3%). The mean age at surgery was 63.1 years (median 63 years). According to pre-treatment MRI staging, most patients had stage III disease, with stage IIIb being the most frequent category. Surgical resection consisted of laparoscopic LAR in 97 patients (84.3%) including 5 conversions to open surgery and APR in 18 patients (15.7%) (Table 1). Resection margins were negative (R0) in 105 patients (91.3%) and positive (R1) in 10 (8.7%). Pathological mesorectal lymph node metastasis was identified in 24 patients (20.9%). A pathological complete response (ypT0N0) was achieved in 21 patients (18.3%). Adjuvant chemotherapy was administered to 56 patients (48.7%).

Table 1
Baseline clinicopathological characteristics of patients with locally advanced low and mid rectal cancer (N = 115)

Characteristic	Patients (N = 115)
Patient characteristics	
Age, y, mean (range)	63.1 (33–87)
Sex, n (%)	
Male	64 (55.7)
Female	51 (44.3)
ASA physical status, n (%)	
I	9 (7.8)
II	87 (75.7)
III	19 (16.5)
Baseline tumour characteristics	
Clinical stage (cTNM, AJCC 7th edition), n (%)	
IIa	21 (18.3)
IIIa	6 (5.2)
IIIb	74 (64.3)
IIIc	14 (12.2)
MRI-suspected mesorectal nodes before neoadjuvant treatment, n (%)	
Present	91 (79.1)
Absent	24 (20.9)
Treatment	
Neoadjuvant treatment, n (%)	
Long-course chemoradiotherapy	99 (86.1)
Short-course radiotherapy	6 (5.2)
Total neoadjuvant therapy	10 (8.7)
Surgical procedure, n (%)	
LAR with TME	97 (84.3)

Characteristic	Patients (N = 115)
Patient characteristics	
APR with TME	18 (15.7)
Conversion to open surgery, n (%)	5 (4.3)
Adjuvant chemotherapy, n (%)	
Yes	56 (48.7)
No	59 (51.3)
Restaging and pathological findings	
MRI-suspected mesorectal nodes after neoadjuvant treatment, n (%)	
Present	30 (26.1)
Absent	69 (60.0)
Unknown	16 (13.9)
Pathological stage (ypTNM, AJCC 7th edition), n (%)	
Stage 0	21 (18.3)
Stage I	38 (33.0)
Stage II	29 (25.2)
Stage III	27 (23.5)
Tumour regression grade (Dworak TRG), n (%)	
TRG 0	4 (3.5)
TRG 1	14 (12.2)
TRG 2	26 (22.6)
TRG 3	44 (38.3)
TRG 4	23 (20.0)
Unknown	4 (3.5)
Tumour differentiation (WHO classification), n (%)	
Undifferentiated	3 (2.6)
Poorly differentiated	10 (8.7)
Moderately differentiated	72 (62.6)

Characteristic	Patients (N = 115)
Patient characteristics	
Well differentiated	23 (20.0)
Unknown	7 (6.1)
Pathological mesorectal lymph node metastasis, n (%)	
Present	24 (20.9)
Absent	91 (79.1)
Resection margin status, n (%)	
R0 (≥ 1 mm)	105 (91.3)
R1 (< 1 mm)	10 (8.7)
Lymphovascular invasion, n (%)	
Present	20 (17.4)
Absent	86 (74.8)
Unknown	9 (7.8)
Perineural invasion, n (%)	
Present	24 (20.9)
Absent	82 (71.3)
Unknown	9 (7.8)
Microsatellite status, n (%)	
Microsatellite stable	78 (67.8)
Microsatellite instability	8 (7.0)
Unknown	29 (25.2)

AJCC, American Joint Committee on Cancer; APR, abdominoperineal resection; ASA, American Society of Anesthesiologists; cTNM, clinical tumour–node–metastasis; LAR, low anterior resection; MRI, magnetic resonance imaging; TME, total mesorectal excision; TRG, tumour regression grade; WHO, World Health Organization; ypTNM, pathological tumour–node–metastasis after neoadjuvant treatment.

3.2 Incidence of MRI-suspected LPLNs and associations with clinicopathological variables

Among the 115 included patients, 21 (18.3%) had MRI-suspected LPLNs prior to neoadjuvant treatment. After neoadjuvant treatment, 6 of these patients (28.6%) still had MRI-suspected LPLNs on post-treatment MRI (Table 2). One patient without pre-treatment MRI-suspected LPLNs developed MRI-suspected LPLNs on post-treatment MRI. Associations between MRI-suspected LPLNs and clinicopathological variables are detailed in Table 3. Pre-treatment MRI-suspected LPLNs were associated with a higher clinical stage at diagnosis (P = 0.028) and with persistent LPLN suspicion on post-treatment MRI (P < 0.001), but not with the other clinicopathological variables.

Table 2
Lateral pelvic lymph node status on MRI before and after neoadjuvant treatment

LPLN status after neoadjuvant treatment	**Negative before treatment (n = 94)**	**Positive before treatment (n = 21)**	**Total (N = 115)**
Negative	81 (86.2)	10 (47.6)	91 (79.1)
Positive	1 (1.1)	6 (28.6)	7 (6.1)
Not assessable	12 (12.8)	5 (23.8)	17 (14.8)
Total	94 (100)	21 (100)	115 (100)

Percentages are column percentages. LPLN, lateral pelvic lymph node; MRI, magnetic resonance imaging.

Table 3
Clinicopathological characteristics according to pre-treatment MRI-suspected lateral pelvic lymph node involvement

Characteristic	No MRI-suspected LPLN (n = 94)	MRI-suspected LPLN (n = 21)	P value
Baseline characteristics			
Age, y, mean	64.3	57.4	0.008
Clinical stage (cTNM, AJCC 7th edition), n (%)			0.028
Stage IIa	20 (21.3)	1 (4.8)	
Stage IIIa	5 (5.3)	1 (4.8)	
Stage IIIb	60 (63.8)	14 (66.7)	
Stage IIIc	9 (9.6)	5 (23.8)	
MRI-suspected mesorectal nodes, n (%)			0.558
Present	73 (77.7)	18 (85.7)	
Absent	21 (22.3)	3 (14.3)	
CEA at diagnosis, ng/mL, mean	6.0	11.3	0.307
Restaging after neoadjuvant treatment			
MRI-suspected LPLN status, n (%)			< 0.001
Negative	81 (86.2)	10 (47.6)	
Positive	1 (1.1)	6 (28.6)	
Not assessable	12 (12.8)	5 (23.8)	
MRI-suspected mesorectal nodes, n (%)			0.556
Present	24 (25.5)	6 (28.6)	
Absent	59 (62.8)	10 (47.6)	
Unknown	11 (11.7)	5 (23.8)	
CEA after neoadjuvant treatment, ng/mL, mean	3.2	4.4	0.604
Pathological findings			
Pathological stage (ypTNM, AJCC 7th edition), n (%)			0.441
Stage 0	17 (18.1)	4 (19.0)	

Characteristic	No MRI-suspected LPLN (n = 94)	MRI-suspected LPLN (n = 21)	P value
Baseline characteristics			
Stage I	30 (31.9)	8 (38.1)	
Stage II	23 (24.5)	6 (28.6)	
Stage III	24 (25.5)	3 (14.3)	
Pathological mesorectal lymph node metastasis, n (%)			> 0.99
Present	20 (21.3)	4 (19.0)	
Absent	74 (78.7)	17 (81.0)	
Tumour regression grade (Dworak TRG), n (%)			0.975
TRG 0	3 (3.2)	1 (4.8)	
TRG 1	12 (12.8)	2 (9.5)	
TRG 2	21 (22.3)	5 (23.8)	
TRG 3	35 (37.2)	9 (42.9)	
TRG 4	19 (20.2)	4 (19.0)	
Unknown	4 (4.3)	0 (0.0)	
Tumour differentiation (WHO classification), n (%)			0.891
Undifferentiated	3 (3.2)	0 (0.0)	
Poorly differentiated	8 (8.5)	2 (9.5)	
Moderately differentiated	56 (59.6)	16 (76.2)	
Well differentiated	20 (21.3)	3 (14.3)	
Unknown	7 (7.4)	0 (0.0)	
Lymphovascular invasion, n (%)			0.352
Present	18 (19.1)	2 (9.5)	
Absent	68 (72.3)	18 (85.7)	
Unknown	8 (8.5)	1 (4.8)	
Perineural invasion, n (%)			0.386
Present	18 (19.1)	6 (28.6)	

Characteristic	No MRI-suspected LPLN (n = 94)	MRI-suspected LPLN (n = 21)	P value
Baseline characteristics			
Absent	68 (72.3)	14 (66.7)	
Unknown	8 (8.5)	1 (4.8)	
Adjuvant treatment and follow-up			
Adjuvant chemotherapy, n (%)			0.810
Yes	45 (47.9)	11 (52.4)	
No	49 (52.1)	10 (47.6)	
CEA at first follow-up, ng/mL, mean	1.7	5.6	0.648

AJCC, American Joint Committee on Cancer; CEA, carcinoembryonic antigen; cTNM, clinical tumour–node–metastasis; LPLN, lateral pelvic lymph node; MRI, magnetic resonance imaging; TRG, tumour regression grade; WHO, World Health Organization; ypTNM, pathological tumour–node–metastasis after neoadjuvant treatment.

3.3 Survival outcomes

The median postoperative follow-up was 73 months. Kaplan–Meier analysis showed no significant difference in OS between patients with and without pre-treatment MRI-suspected LPLNs (log-rank P = 0.88). Similarly, no significant difference was observed in DFS according to LPLN status (log-rank P = 0.73) (Fig. 2).

3.4 Recurrence patterns

During follow-up, 27 patients (23.5%) developed recurrence; one patient had both locoregional and distant recurrence. Distant recurrence occurred in 23 patients (20.0%), and locoregional recurrence occurred in 5 patients (4.3%). Lateral pelvic lymph node recurrence was observed in 3 patients (2.6%) (Table 4). Only 2 out of 21 patients (9.5%) developed LPLN recurrence and 1 patient (1.1%) without pre-treatment MRI-suspected LPLNs developed an LPLN recurrence. Recurrence patterns according to LPLN status are summarised in Table 4.

Table 4
Patterns of recurrence according to pre-treatment MRI-suspected lateral pelvic lymph node involvement

Recurrence	No MRI-suspected LPLN (n = 94)	MRI-suspected LPLN (n = 21)	Total (N = 115)
Locoregional recurrence, n (%)	3 (3.2)	2 (9.5)	5 (4.3)
Local recurrence	2 (2.1)	0 (0.0)	2 (1.7)
Lateral pelvic lymph node recurrence	1 (1.1)	2 (9.5)	3 (2.6)
Distant recurrence, n (%)	18 (19.1)	5 (23.8)	23 (20.0)
Any recurrence, n (%)	20 (21.3)	7 (33.3)	27 (23.5)

One patient had both locoregional and distant recurrence, so the category counts sum to more than the number of patients with any recurrence. LPLN, lateral pelvic lymph node; MRI, magnetic resonance imaging.

4. Discussion

In this study, MRI-suspected LPLNs were identified in 18.3% of patients with LARC treated with neoadjuvant treatment followed by TME. Reported prevalence rates in the literature vary widely, ranging from less than 10% to more than 50% [16]. This variability is largely attributable to differences in MRI definitions of nodal positivity, including variations in size thresholds and the use of additional morphologic criteria [14, 16]. In studies applying size criteria comparable to ours (short-axis ≥ 7 mm before treatment and ≥ 5 mm after neoadjuvant treatment), prevalence rates generally range between 15% and 25% [6, 16, 17]. With an observed rate of 18.3%, our findings fall within the range described in cohorts using similar imaging definitions.

Regarding oncological outcomes, pre-treatment MRI-suspected LPLNs were not significantly associated with worse OS or DFS in this cohort. The prognostic value of baseline MRI-suspected LPLNs remains unclear and appears to be highly dependent on treatment context.

In a recent systematic review and meta-analysis, Lee et al. reported that pre-treatment MRI-suspected LPLN metastasis was associated with increased local recurrence and decreased DFS and OS [18]. However, substantial heterogeneity was observed across studies, particularly in imaging definitions and size thresholds, which limits their interpretation [18]. Moreover, all studies included in the meta-analysis were conducted before widespread TNT adoption.

Most contemporary TNT-based data suggest a more nuanced perspective. In the cohort reported by Peacock et al., all patients with MRI-suspected LPLNs received TNT and were managed using an MRI-directed strategy [19]. LPLN recurrence rates were low and no significant differences in OS or DFS were observed between patients who underwent LPLND and those managed without dissection [19]. Similarly,

in the post hoc analysis of the OPRA trial, baseline MRI-suspected LPLN involvement was not associated with higher rates of local recurrence or distant metastasis in patients treated with TNT, and isolated lateral pelvic failure was uncommon [20]. Taken together, these data suggest that while MRI-suspected LPLNs may be associated with increased local recurrence in certain pre-TNT settings, their independent impact on long-term survival appears attenuated [19, 20]. Our findings are consistent with this evolving paradigm, as we observed a higher risk of LPLN recurrence in the group of patients with suspected LPLN on baseline MRI (9.5% vs 1.1%). However, we did not observe a significant difference in OS or DFS according to baseline MRI suspicion. This could be explained by the similar rate of distant metastases in both groups (19.1% and 23.8% in the groups without and with MRI-suspected LPLNs, respectively).

This interpretation must nevertheless be considered in light of the limitations of our study. The main limitations of this study include its retrospective and single-centre nature, and the limited size of the study population. In addition, neoadjuvant strategies evolved during the study period, including the introduction of TNT, resulting in treatment heterogeneity.

The available literature remains limited regarding the management of LPLN in the era of TNT. Most TNT-based protocols have been developed and implemented in Western centres, where routine lateral pelvic lymph node dissection is not standard practice. Consequently, robust data evaluating the prognostic impact of persistent MRI-suspected LPLNs after TNT, and the potential survival benefit of adding selective LPLND in this setting, are scarce.

Future prospective studies with standardised radiological criteria and homogeneous TNT-treated populations are needed to clarify whether persistent MRI-suspected LPLNs after TNT independently affect overall and disease-free survival, and whether surgical clearance of these nodes translates into improved oncological outcomes.

5. Conclusion

In this single-centre retrospective study, MRI-suspected LPLNs were identified in 18.3% of patients with LARC treated with neoadjuvant therapy followed by TME. Baseline MRI suspicion was not associated with worse OS or DFS. These findings suggest that, in the context of contemporary multimodal treatment, the prognostic impact of MRI-suspected LPLNs may be less pronounced than previously reported. The clinical relevance of LPLN disease likely depends on treatment intensity and response rather than baseline imaging alone. Prospective studies with standardised radiological criteria and homogeneous TNT protocols are needed to determine whether persistent LPLN enlargement after treatment carries independent prognostic significance and whether selective LPLND improves oncological outcomes.

Declarations

Declaration of Interest:

none.

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Competing interests:

The authors have no relevant financial or non-financial interests to disclose.

Ethics approval:

This retrospective study involving human participants was performed in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. The study was approved by the ethics committee of the Institut Jules Bordet (approval number OM011; internal reference CE3807; 21 March 2024).

Consent to participate:

The requirement for informed consent was waived by the ethics committee in view of the retrospective nature of the study and the use of anonymised routine clinical data.

Consent to publish:

Not applicable; no individually identifiable data are reported.

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none.

Author Contribution

A.M.B. and G.L. conceived the study. G.L. designed the study. A.M.B. acquired the data and F.B. contributed to patient recruitment and data collection. A.V.S. performed the radiological review of the MRI studies. M.M., A.C. and F.S. performed data quality control. M.M. and G.L. analysed and interpreted the data, and M.M. performed the statistical analysis. A.M.B., A.C., F.M. and G.L. prepared the manuscript, and A.C. edited it. All authors reviewed and approved the final manuscript.

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Data Availability

The datasets generated and analysed during the current study are not publicly available because they contain identifiable clinical information that could compromise the privacy of research participants. De-identified data are available from the corresponding author on reasonable request, subject to approval by the ethics committee of the Institut Jules Bordet.

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Figures

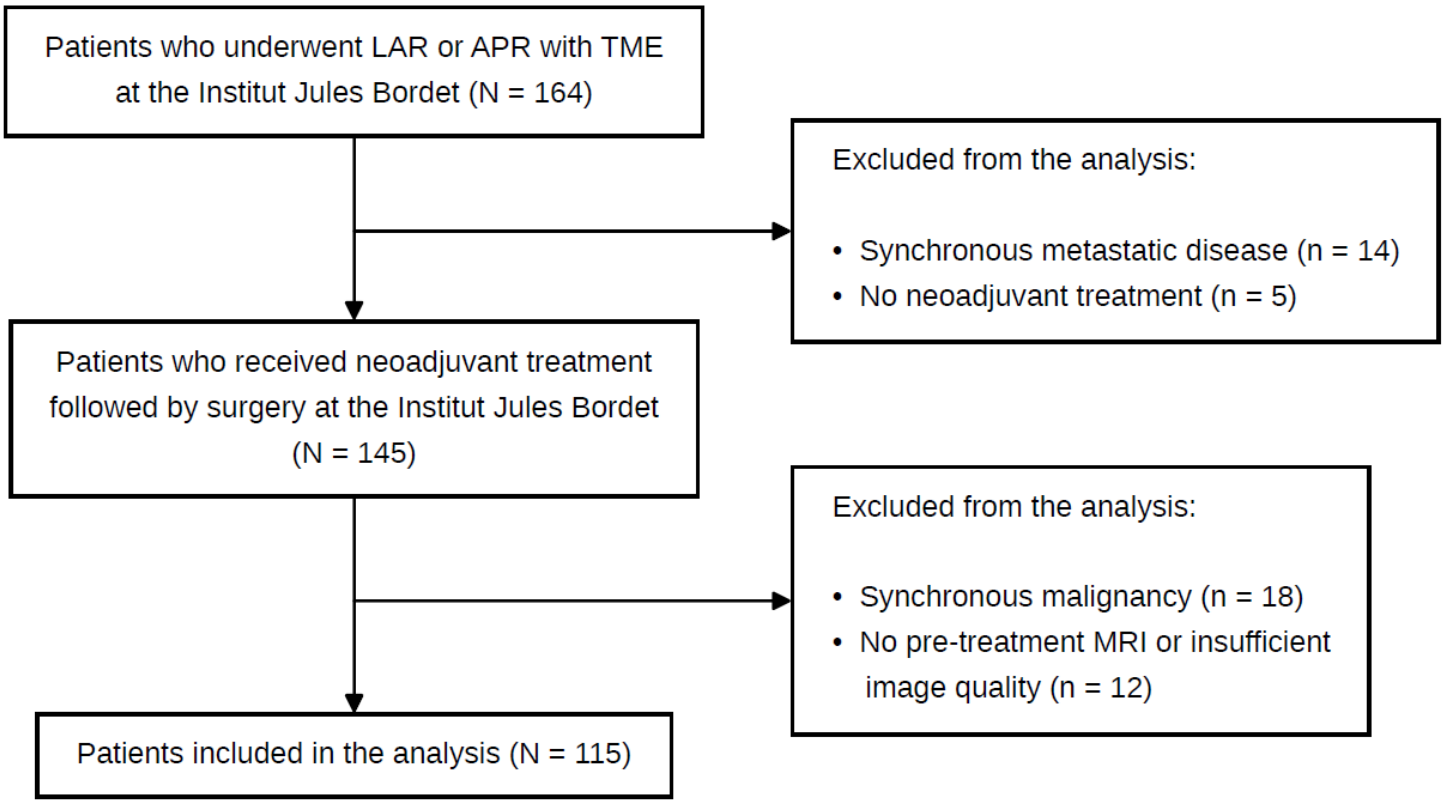


Figure 1

Flowchart of patient selection and inclusion

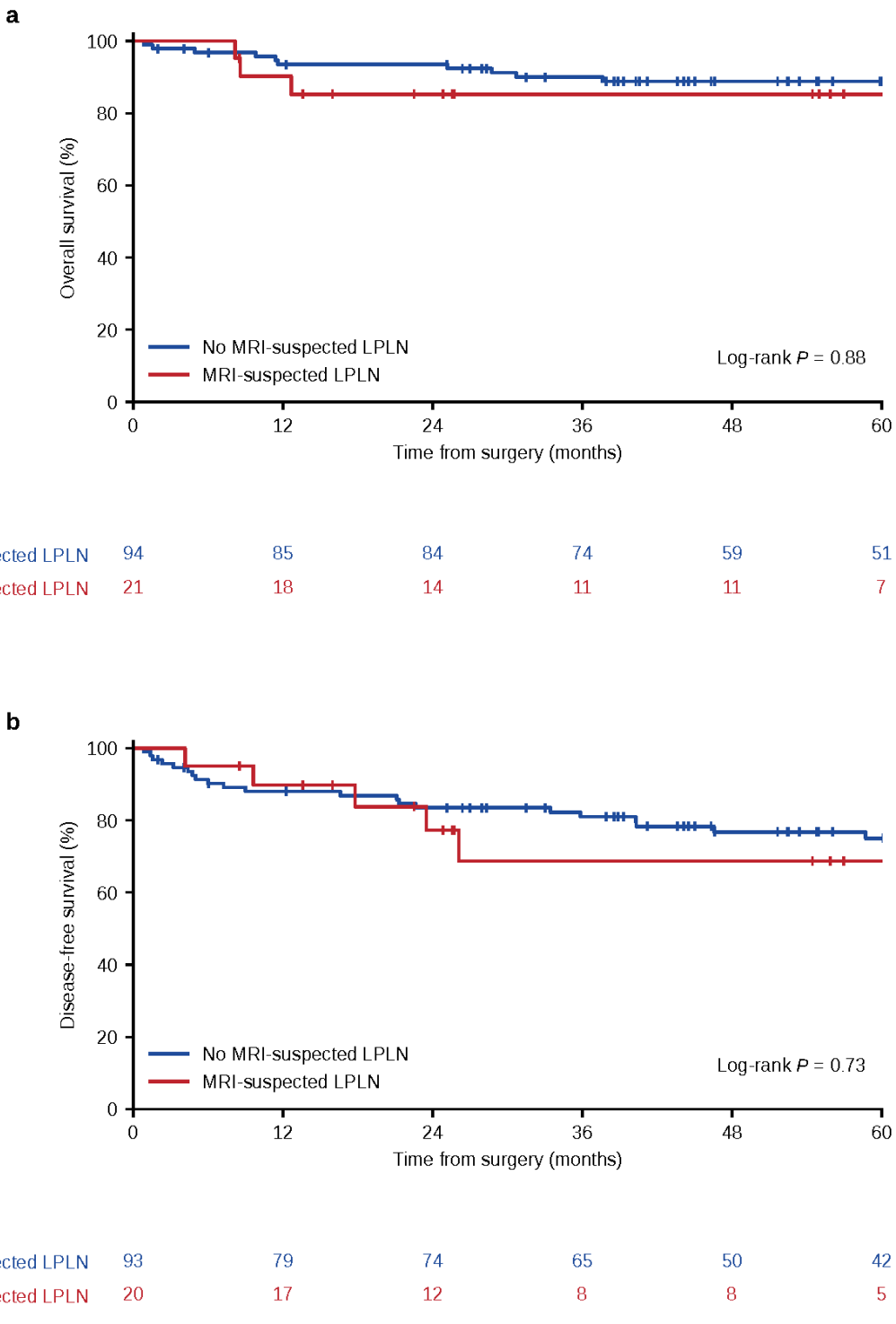


Figure 2

Kaplan–Meier survival curves according to pre-treatment MRI-suspected lateral pelvic lymph node (LPLN) involvement: a overall survival, b disease-free survival; curves compared using the log-rank test