

Weekly cisplatin and nab-paclitaxel neoadjuvant chemoradiotherapy increases pathological complete response in locally advanced esophageal squamous cell carcinoma: A real-world study

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Abstract. Although neoadjuvant chemoradiotherapy (nCRT) is the standard treatment regimen for patients with locally advanced esophageal squamous cell carcinoma (LA-ESCC), no consensus exists regarding the optimal chemotherapy regimen. The present study aimed to compare the safety/efficacy of weekly (QW) vs. triweekly (Q3W) cisplatin/nab-paclitaxel nCRT in LA-ESCC. This retrospective study analyzed 136 patients with LA-ESCC who underwent esophagectomy after nCRT (QW, n=32; Q3W, n=104). The data included pathological complete response (pCR), major pathological response (MPR), toxicity, survival and postoperative outcomes. The results demonstrated that QW exhibited significantly higher pCR (56.25 vs. 33.65%; P=0.022) and MPR (81.25 vs. 61.54%; P=0.039) rates than Q3W. Hematological

toxicity rates were lower for QW, including neutropenia of all grades (46.88% vs. 70.81%, P=0.0001) and thrombocytopenia of all grades (18.75% vs. 31.73%, P=0.033). Grade ≥ 3 leukopenia (18.75 vs. 51.92%; P=0.001) and grade ≥ 3 neutropenia (15.62 vs. 38.46%; P=0.016) were less frequent in QW. In addition, the incidence of acute pneumonia of all grades was also lower (0% vs. 16.35%, P>0.05). However, survival outcomes were comparable between the groups, including 1-year overall survival (QW vs. Q3W, 96.6 vs. 100.0%) and progression-free survival (86.5 vs. 85.6%) rates (P>0.05). In conclusion, QW cisplatin/nab-paclitaxel nCRT achieved superior pCR rates and reduced hematological toxicity compared with Q3W dosing in LA-ESCC, thus suggesting its potential use as a safer and more effective neoadjuvant regimen. The survival benefit remains to be validated with an extended follow-up.

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Abbreviations: EC, esophageal cancer; LA-ESCC, locally advanced esophageal squamous cell carcinoma; nCRT, neoadjuvant chemoradiotherapy; pCR, pathological complete response; MPR, major pathological response; OS, overall survival; PFS, progression-free survival

Key words: nCRT, ESCC, pCR, MPR, weekly chemotherapy

Introduction

Esophageal cancer (EC) ranks as the seventh most common cancer and the sixth most lethal cancer worldwide (1). Among the histological subtypes, squamous cell carcinoma (SCC) is predominant in China, accounting for >90% of all cases (2). Esophagectomy is still the cornerstone treatment for locally advanced esophageal SCC (LA-ESCC). However, esophagectomy alone is associated with high rates of recurrence and metastasis, with a 5-year recurrence rate ranging from 50.9 to 68.0% (3,4). The results of the CROSS and NEOCRTEC5010 trials have established the superior survival benefit of neoadjuvant chemoradiotherapy (nCRT) over surgery alone (5,6), a conclusion subsequently confirmed by a network meta-analysis of 6,168 patients (7) that established nCRT as the optimal treatment. nCRT with subsequent surgery has been established as the standard of care for LA-ESCC in China (3,4). Recent clinical studies, such as the ESOPEC (8) and JCOG1109 (9) trials, have underscored the effectiveness of triple chemotherapy protocols compared to that of chemoradiotherapy for the preoperative care of patients with EC, thereby indicating a

potential change in treatment strategies. Despite this progress, nCRT remains essential, especially in cases of extensive or locally advanced tumors wherein radiotherapy can enhance resectability, and for patients who are unable to endure the side effects of triple chemotherapy.

However, the 5-year cumulative incidence of locoregional, distant and total recurrence for patients with LA-ESCC is still high (10). Modifications to chemotherapy agents and regimens have demonstrated promising results (6,7,11). A previous network meta-analysis revealed that nCRT with platinum and paclitaxel is more effective than platinum and 5-fluorouracil for treating EC, especially regarding the treatment of ESCC [hazard ratio (HR), 0.61; 95% confidence interval (CI), 0.41-0.91] (12). Currently, the TP regimen (which includes paclitaxel and cisplatin) is widely used in the clinical setting for chemotherapy and exhibits a lower incidence of radiation esophagitis, along with being a more convenient and well-tolerated approach (13). Albumin-bound paclitaxel, which is characterized by improved solubility, targeted tumor delivery and reduced hypersensitivity reactions, has emerged as a preferred therapeutic agent in nCRT (14).

Nevertheless, the optimal neoadjuvant chemotherapy regimen for LA-ESCC remains undefined due to a lack of direct comparative studies. Thus, the present study retrospectively evaluated the safety and efficacy of weekly (QW) vs. triweekly (Q3W) cisplatin/nab-paclitaxel-based nCRT. The study aimed to refine nCRT regimens to improve outcomes and tolerability in selected populations, thereby addressing an unmet clinical need in settings where CRT remains a viable treatment option.

Materials and methods

Patients. The present retrospective study analyzed data from all eligible patients with LA-ESCC who were treated at the Shandong Cancer Hospital and Institute (Jinan, China) between January 2016 and December 2022. To conduct this study, the researchers reviewed relevant medical records from August 2023 to February 2024. The inclusion criteria involved patients with histologically confirmed, potentially resectable thoracic ESCC that was clinically staged as T1-3N1-2M0 or T4N0M0 (American Joint Committee on Cancer Staging System) (15). Eligible participants were aged between 18 and 70 years, exhibited a Karnofsky performance score of ≥ 90 (16) and exhibited adequate organ function, including hematological parameters (absolute neutrophil count $\geq 1.5 \times 10^9/l$, platelet count $\geq 100 \times 10^9/l$ and hemoglobin ≥ 90 g/l), hepatic function [total bilirubin ≤ 1.5 times upper limit of normal (ULN), AST/ALT ≤ 2.5 times ULN] and renal function (serum creatinine ≤ 1.5 times ULN or creatinine clearance ≥ 50 ml/min). Patients were excluded if they had a history of other malignancies, were unsuitable for surgery due to comorbidities or had received previous chemotherapy and/or radiotherapy treatments. All methods were performed in accordance with relevant guidelines and regulations. Furthermore, the study protocol was reviewed and approved by the Ethics Committee of Shandong Cancer Hospital and Institute (approval no. SDTHEC202308051).

NCRT. Nab-paclitaxel at a dosage of 60 mg/m² in combination with cisplatin at a dosage of 25 mg/m² was administered weekly; alternatively, nab-paclitaxel at a dosage of 260 mg/m² in

combination with cisplatin at a dosage of 75 mg/m², according to body surface area, was intravenously administered every 3 weeks (17,18). All patients with EC received three-dimensional conformal radiotherapy or intensity-modulated radiation therapy involving field irradiation. Patients typically underwent radiation therapy with a total dose of 40 Gy administered in 2-Gy fractions (based on NEOCRTEC5010 trials); alternatively, a total dose of 41.4 Gy in 1.8-Gy fractions (based on CROSS trials) was utilized (5,6).

Surgery. After completing nCRT, eligible patients underwent surgery within 4 to 6 weeks. Surgical approaches included McKeown or Ivor Lewis esophagectomy, which was complemented by two-field lymphadenectomy and comprehensive total mediastinal lymph node dissection. Depending on the case, various chest manipulation techniques were utilized, including thoracoscopic, robot-assisted or mediastinoscopic approaches to ensure precision and adaptability to the patient's condition.

Pathological analysis. The pathological examination report included the type and extent of the tumor, proximal and distal resection margins, tumor regression grade (Mandard score) (19), and lymph node status, including the location and number of therapeutic effects. Pathological complete response (pCR) was defined as the absence of evidence of residual tumor cells at the primary site and the resected lymph nodes of the surgical specimen. A $\leq 10\%$ residual viable tumor indicated a major pathological response (MPR). Microscopically negative surgical margins were defined as an R0 resection. Incomplete resection was defined as the presence of microscopically positive surgical margins (R1) and gross macroscopic residual tumor tissue (R2).

Efficacy evaluation. Overall survival (OS) time was calculated from the date of diagnosis to the date of death from any cause. Progression-free survival (PFS) time was calculated from the date of treatment initiation to the date of locoregional progression, distant metastasis or death from any cause. Effectiveness was assessed by using the pCR rate, R0 resection rate, and 1-year OS and PFS rates.

Toxicity evaluation. The toxicities were graded according to the US Department of Health and Human Services Common Terminology Criteria for Adverse Events version 5.0 (20), whereas the Clavien-Dindo classification system was used to assess postoperative complications (21).

Statistical analysis. Categorical variables are presented as numerical values (percentages), and comparisons are made using either the χ^2 test or Fisher's exact test, depending on the specific circumstances. To control the overall Type I error rate, the Bonferroni correction method was applied to compare the incidence of adverse events between the two groups. The Kaplan-Meier method was used to construct survival curves, and the log-rank test was used to compare these curves. Univariate analysis followed by multivariate analysis was performed with the Cox proportional hazards model. $P < 0.05$ was considered to indicate a statistically significant difference. The data were analyzed using SPSS software, version 27 (IBM Corp.).

Table I. Patient characteristics.

Variables	Total (n=136)	QW (n=32)	Q3W (n=104)	P-value
Age, years, n (%)				0.912
<65	84 (61.76)	19 (59.38)	65 (62.50)	
≥65	52 (38.24)	13 (40.63)	39 (37.50)	
Sex, n (%)				0.844
Male	110 (80.88)	25 (78.12)	85 (81.73)	
Female	26 (19.12)	7 (21.88)	19 (18.27)	
ECOG, n (%)				0.144
0	47 (34.56)	15 (46.88)	32 (30.77)	
1	89 (65.44)	17 (53.13)	72 (69.23)	
Smoking, n (%)				0.300
Yes	64 (47.06)	12 (37.50)	52 (50.00)	
No	72 (52.94)	20 (62.50)	52 (50.00)	
Drinking, n (%)				0.269
Yes	69 (50.74)	13 (40.63)	56 (53.85)	
No	67 (49.26)	19 (59.38)	48 (46.15)	
Tumor location, n (%)				0.556
Upper	4 (2.94)	1 (3.13)	3 (2.88)	
Middle	35 (25.74)	6 (18.75)	29 (27.88)	
Lower	97 (71.32)	25 (78.13)	72 (69.23)	
Clinical T stage, n (%)				0.164
T2	5 (3.68)	1 (3.13)	4 (3.85)	
T3	126 (92.65)	28 (87.50)	98 (94.23)	
T4a	5 (3.68)	3 (9.38)	2 (1.92)	
Clinical N stage, n (%)				0.062
N0	47 (34.56)	9 (28.13)	38 (36.54)	
N1	62 (45.59)	12 (37.50)	50 (48.08)	
N2	27 (19.85)	11 (34.38)	16 (15.38)	
Stage, n (%)				0.070
II	53 (38.97)	18 (56.25)	35 (33.65)	
III	78 (57.35)	13 (40.63)	65 (62.50)	
IVA	5 (3.68)	1 (3.13)	4 (3.85)	
Completed chemotherapy, n (%)	116 (85.29)	30 (93.75)	86 (82.69)	0.159

QW, weekly; Q3W, tri-weekly; ECOG, Eastern Cooperative Oncology Group; T, tumor; N, node.

Results

Patient characteristics. A total of 136 patients with LA-ESCC were included in the present study, with 32 patients in the QW group and 104 in the Q3W group. The baseline characteristics of the patients are summarized in Table I. In this study population, 61.76% (84/136) of the patients were <65 years, and 80.88% (110/136) were male. A majority of the patients (131; 96.32%) were classified as having clinical stage T3 or T4 disease, and 89 patients (65.44%) exhibited lymph node involvement. Among the participants, 64 patients (47.06%) were smokers, and 69 patients (50.74%) consumed alcoholic beverages. The majority of the tumors were located in the lower esophagus (71.32%), and 57.35% of the patients presented with stage III disease. Baseline characteristics were

well balanced across the treatment groups, with no significant differences being observed in terms of age, sex, ECOG performance status, smoking history, alcohol consumption history, tumor location, or clinical T and N stages. Among the patients, 30 patients (93.75%) in the QW group and 86 patients (82.69%) in the Q3W group completed chemotherapy (P=0.159), with no significant difference in the rates of chemotherapy incompleteness being observed between the groups.

Toxicity of concurrent chemoradiotherapy. The overall adverse events recorded during nCRT are summarized in Table II. Compared with the QW group, the Q3W group had a higher incidence of hematological adverse events of all grades, particularly neutropenia (P=0.0001) and thrombocytopenia (P=0.033). Similarly, in the Q3W group, the incidence of grade 3 or

Table II. Treatment compliance and major toxicities.

Event	QW (n=32)		Q3W (n=104)		P-value ^a	Adjusted P-value
	Any grade	Grade 3 or 4	Any grade	Grade 3 or 4		
Leukopenia, n (%)	24 (75.00)	6 (18.75) ^b	89 (85.58)	54 (51.92)	0.163	1.000
Neutropenia, n (%)	15 (46.88)	5 (15.63) ^c	83 (79.81)	40 (38.46)	0.0001	0.0016
Anemia, n (%)	18 (56.25)	0 (0.00)	58 (55.77)	2 (1.92)	0.962	1.000
Thrombocytopenia, n (%)	6 (18.75)	0 (0.00)	33 (31.73)	3 (2.88)	0.033	0.528
Lymphocytopenia, n (%)	29 (90.63)	18 (56.25)	97 (93.27)	69 (66.35)	0.699	1.000
Transaminase increased, n (%)	2 (6.25)	0 (0.00)	4 (3.85)	0 (0.00)	0.626	1.000
Creatinine increased, n (%)	1 (3.13)	0 (0.00)	2 (1.92)	0 (0.00)	0.556	1.000
Decreased appetite, n (%)	6 (18.75)	0 (0.00)	27 (25.96)	3 (2.88)	0.405	1.000
Nausea or vomiting, n (%)	17 (53.13)	1 (3.13)	51 (49.04)	2 (1.92)	0.686	1.000
Esophagitis, n (%)	18 (56.25)	0 (0.00)	46 (44.23)	0 (0.00)	0.234	1.000
Acute pneumonia, n (%)	0 (0.00)	0 (0.00)	17 (16.35)	1 (0.96)	0.012	0.192
Diarrhea, n (%)	1 (3.13)	0 (0.00)	7 (6.73)	0 (0.00)	0.680	1.000
Constipation, n (%)	1 (3.13)	0 (0.00)	17 (16.35)	0 (0.00)	0.072	1.000
Neurotoxicity, n (%)	13 (40.63)	1 (3.13)	58 (55.77)	4 (3.85)	0.134	1.000

^aTwo-sided P-value from the χ^2 test or exact test (when the expected frequency is <5) for 'any grade.' Among all Grade 3 or 4 adverse events, χ^2 tests were performed only for leukopenia and neutropenia (^bP=0.001 and ^cP=0.016); the percentages of other Grade 3 or 4 events were used for descriptive purposes only and were not included in the χ^2 tests. P<0.05 is statistically significant. The corrected P-value was calculated as the original P-value multiplied by 16 (Bonferroni's method), with a corrected significance threshold of $\alpha=0.05/16=0.003125$. Corrected P<0.003125 was considered statistically significant; if the corrected P-value was greater than 1, it was set to 1.

Table III. Postoperative complications.

Variables	Total (n=136)	QW (n=32)	Q3W (n=104)	P-value
Overall	38 (27.94)	8 (25.00)	30 (28.85)	0.842
Anastomotic leak, n (%)	23 (16.91)	3 (9.38)	20 (19.23)	0.303
Pneumonia, n (%)	8 (5.88)	2 (6.25)	6 (5.77)	>0.999
Pleural effusion, n (%)	5 (3.68)	1 (3.13)	4 (3.85)	>0.999
Pericardial effusion, n (%)	3 (2.21)	2 (6.25)	1 (0.96)	0.138
Pneumothorax, n (%)	1 (0.74)	0 (0.00)	1 (0.96)	>0.999
Acute myocardial infarction, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	
Acute respiratory failure, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	
Chylothorax, n (%)	3 (2.21)	2 (6.25)	1 (0.96)	0.138
Intestinal obstruction, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	
Atelectasis, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	
Atrial fibrillation, n (%)	1 (0.74)	0 (0.00)	1 (0.96)	>0.999

QW, weekly; Q3W, tri-weekly.

higher leukopenia (P=0.001) and neutropenia (P=0.016) was significantly higher than in the QW group. Furthermore, the incidence of acute pneumonia was higher than in the QW regimen (P=0.012); however, no significant differences were observed between the two groups regarding other non-hematological adverse events, such as esophagitis (P=0.234), decreased appetite (P=0.405), nausea or vomiting (P=0.686), diarrhea (P=0.680), constipation (P=0.072), and neurotoxicity (P=0.134). No deaths related to chemotherapy or radiotherapy were observed in either group. After adjustment for multiple

comparisons, neutropenia was the only endpoint showing a statistically significant difference (adjusted P=0.0016). There were no significant differences between the two groups in other adverse events (including leukopenia, thrombocytopenia and acute pneumonia) (all adjusted P>0.003).

Postoperative complications. Table III presents a summary of postoperative complications according to the Clavien-Dindo classification. The overall incidence of complications across all grades was 27.94%, with no significant difference being

Table IV. Pathological findings before and after propensity score matching analysis.

Variables	Before PSM				After PSM			
	Total (n=136)	QW (n=32)	Q3W (n=104)	P-value	Total (n=95)	QW (n=32)	Q3W (n=63)	P-value
Thoracic procedure, n (%)				0.469				0.288
Thoracoscopic	65 (47.79)	18 (56.25)	47 (45.19)		46 (48.42)	18 (56.25)	28 (44.44)	
Open	71 (52.21)	14 (43.75)	57 (54.81)		49 (51.58)	14 (43.75)	35 (55.56)	
Residual tumor status, n (%)				0.720				>0.999
R0	125 (91.91)	29 (90.63)	96 (92.31)		87 (91.58)	29 (90.63)	58 (92.06)	
R1/R2	11 (8.09)	3 (9.38)	8 (7.69)		8 (8.42)	3 (9.38)	5 (7.94)	
pCR, n (%)				0.022 ^a				0.014 ^a
Yes	53 (38.97)	18 (56.25)	35 (33.65)		37 (38.95)	18 (56.25)	19 (30.16)	
No	83 (61.03)	14 (43.75)	69 (66.35)		58 (61.05)	14 (43.75)	44 (69.84)	
MPR, n (%)				0.039 ^a				0.102
Yes	90 (66.18)	26 (81.25)	64 (61.54)		67 (70.53)	26 (81.25)	41 (65.08)	
No	46 (33.82)	6 (18.75)	40 (38.46)		28 (29.47)	6 (18.75)	22 (34.92)	
ypT stage, n (%)				0.110				0.059
T0	63 (46.32)	19 (59.38)	44 (42.31)		42 (44.21)	19 (59.38)	23 (36.51)	
T1	23 (16.91)	7 (21.88)	16 (15.38)		19 (20.00)	7 (21.88)	12 (19.05)	
T2	38 (27.94)	4 (12.50)	34 (32.69)		27 (28.42)	4 (12.50)	23 (36.51)	
T3	12 (8.82)	2 (6.25)	10 (9.62)		7 (7.37)	2 (6.25)	5 (7.94)	
Lymph nodes involved, n (%)				0.356				0.134
N0	111 (81.62)	26 (81.25)	85 (81.73)		77 (81.05)	26 (81.25)	51 (80.95)	
N1	21 (15.44)	4 (12.50)	17 (16.35)		16 (16.84)	4 (12.50)	12 (19.05)	
N2	4 (2.94)	2 (6.25)	2 (1.92)		2 (2.11)	2 (6.25)	0 (0.00)	
ypStage, n (%)				0.139				0.097
0	53 (38.97)	18 (56.25)	35 (33.65)		37 (38.95)	18 (56.25)	19 (30.16)	
I	47 (34.56)	7 (21.88)	40 (38.46)		33 (34.74)	7 (21.88)	26 (41.27)	
II	10 (7.35)	2 (6.25)	8 (7.69)		7 (7.37)	2 (6.25)	5 (7.94)	
III	26 (19.12)	5 (15.63)	21 (20.19)		18 (18.95)	5 (15.63)	13 (20.63)	

^aP<0.05. QW, weekly; Q3W, tri-weekly; pCR, pathological complete response; MPR, major pathological response; PSM, propensity score matching; N, node; ypT, pathological tumor stage; ypStage, overall pathological stage.

observed between the QW and Q3W groups (25.0 vs. 28.85%, respectively; P=0.842). The most frequently observed major postoperative complications included anastomotic leakage (16.91%), pneumonia (5.88%), pleural effusion (3.68%), pericardial effusion (2.21%) and chylothorax (2.21%). Overall, there were no significant differences observed between the two groups with respect to the incidence of postoperative complications.

Pathological assessment. An R0 resection was achieved in 29 out of the 32 patients (90.62%) in the QW group and in 96 out of the 104 patients (92.31%) in the Q3W group (P=0.72) (Table IV). The histological tumor response was assessed in all 136 resected primary tumors. Overall, 53 patients (38.97%) achieved a pCR, with a significantly higher pCR rate being observed in the QW group than in the Q3W group (56.25 vs.

33.65%, respectively; P=0.022). No statistically significant differences were observed between the groups regarding thoracic surgery, resection margins, T stage, N stage or yp stage (all P>0.05). MPR was observed in 66.18% of the patients across the entire cohort and was more common in the QW group than in the Q3W group (81.25 vs. 61.54%, respectively; P=0.039) (Table IV).

To further control for confounding factors, propensity score matching (PSM) with a 1:2 ratio was performed. The QW and Q3W groups therefore included 32 and 63 patients, respectively. After matching, no statistically significant difference was observed between the two groups in terms of R0 resection rates (QW vs. Q3W=90.62 vs. 92.06%; P>0.999). The pCR rate in the QW group was 56.25% (18/32), which was significantly higher than the 30.16% (19/63) reported in the Q3W group (P=0.014). In terms of the MPR rate, the QW group

Table V. Univariate and multivariate regression analyses of progression-free survival.

Variables	Univariate analysis		Multivariate analysis	
	P-value	HR (95% CI)	P-value	HR (95% CI)
Chemotherapy regimen	0.692	1.220 (0.457-3.253)	-	-
Radiation dose	0.171	1.498 (0.840-2.674)	-	-
Sex	0.427	0.613 (0.183-2.051)	-	-
Age	0.511	1.303 (0.591-2.871)	-	-
Tumor location	0.243	1.726 (0.691-4.314)	-	-
ECOG	0.705	1.176 (0.507-2.726)	-	-
Smoking status	0.869	1.069 (0.485-2.356)	-	-
Drinking status	0.269	1.570 (0.705-3.497)	-	-
TRG	0.005 ^a	1.927 (1.224-3.033)	0.534	1.289 (0.580-2.865)
MPR	<0.001 ^a	0.133 (0.053-0.333)	0.043 ^a	0.311 (0.100-0.962)
Lymph nodes	0.332	0.649 (0.271-1.555)	-	-
pCR	0.005 ^a	0.123 (0.029-0.523)	0.737	1.551 (0.120-20.075)
cT	0.063	1.409 (0.982-2.022)	-	-
cN	0.134	1.635 (0.860-3.109)	-	-
cTNM	<0.001 ^a	2.213 (1.564-3.130)	0.027 ^a	2.768 (1.124-6.820)
ypT	0.068	1.367 (0.977-1.911)	-	-
ypN	0.343	1.359 (0.721-2.562)	-	-
ypTNM	0.001 ^a	2.027 (1.360-3.020)	0.012 ^a	1.851 (1.142-3.000)
Surgical approach	0.945	0.981 (0.575-1.675)	-	-
Postoperative complications	0.151	1.796 (0.807-3.999)	-	-

HR, hazard ratio; CI, confidence interval; ypN, pathological node stage; ypT, pathological tumor stage; ypStage, overall pathological stage; cT, clinical tumor stage; cN, clinical node stage; cTNM, clinical TNM stage; pTNM, pathological TNM stage; pCR, pathological complete response; MPR, major pathological response; TRG, tumor regression grade; ECOG, Eastern Cooperative Oncology Group.

achieved a response rate of 81.25% (26/32), which was higher than the 65.08% (41/63) reported in the Q3W group, although the difference was not statistically significant ($P=0.102$). After matching, no significant differences were observed between the two groups in terms of thoracic surgery, resection margin status, T stage, N stage or yp stage ($P>0.05$; Table IV).

The distribution of clinical and pathological TNM stages is shown in Fig. 1A comparison of the clinical stage prior to nCRT with the pathological stage after nCRT revealed a downstaging rate of 80.14%. The proportion of patients with pathological stage II or lower disease significantly increased from 38.97% at the time of clinical staging to 80.88% at the time of pathological staging ($P=0.02$).

Survival. No significant differences were observed in terms of PFS ($P=0.692$; HR, 0.821; 95% CI, 0.308-2.189) or OS ($P=0.829$; HR, 0.845; 95% CI, 0.182-3.912) between the QW and Q3W groups (Fig. 2A and B). Furthermore, the 1-year OS rates were 96.6% for the QW group and 100% for the Q3W group ($P=0.247$), whereas the 1-year PFS rates were 86.5 and 85.6% in the QW and Q3W groups, respectively ($P=0.937$). Univariate analysis revealed that clinical TNM stage (cTNM), pathological TNM stage (ypTNM), tumor regression grade, MPR, and pCR were significant predictors of PFS ($P<0.05$). In the multivariate analysis, cTNM (HR, 2.768; 95% CI, 1.124-6.820; $P=0.027$), ypTNM (HR, 1.851;

95% CI, 1.142-3.000; $P=0.012$), and MPR (OR, 0.311; 95% CI, 0.100-0.962; $P=0.043$) were independently associated with PFS. These findings are summarized in Table V. Univariate Cox regression analysis for OS with respect to all variables revealed no significant differences ($P>0.05$) (Table VI).

Discussion

nCRT is the preferred treatment modality for patients diagnosed with LA-ESCC (4,6). Despite evidence demonstrating improved OS and higher complete resection rates with various nCRT regimens compared with surgery alone (4,6), head-to-head comparisons evaluating oncological efficacy and toxicity between different nCRT protocols remain limited (22). To address this research gap, a comparative analysis of the safety and clinical efficacy of QW cisplatin/nab-paclitaxel vs. Q3W cisplatin/nab-paclitaxel as preoperative chemotherapy regimens was conducted in the present study.

The results indicate that hematological adverse events were less frequent in the QW group during nCRT. Specifically, patients in the Q3W cohort experienced significantly higher rates of grade ≥ 3 leukopenia and neutropenia compared with those in the QW cohort (51.92 vs. 18.75%, $P=0.001$; 38.46 vs. 15.63%, $P=0.016$, respectively). These findings align with those in the study Münch *et al* (23), which reported a similar incidence ($\sim 20\%$) of grade ≥ 3 leukopenia and neutropenia

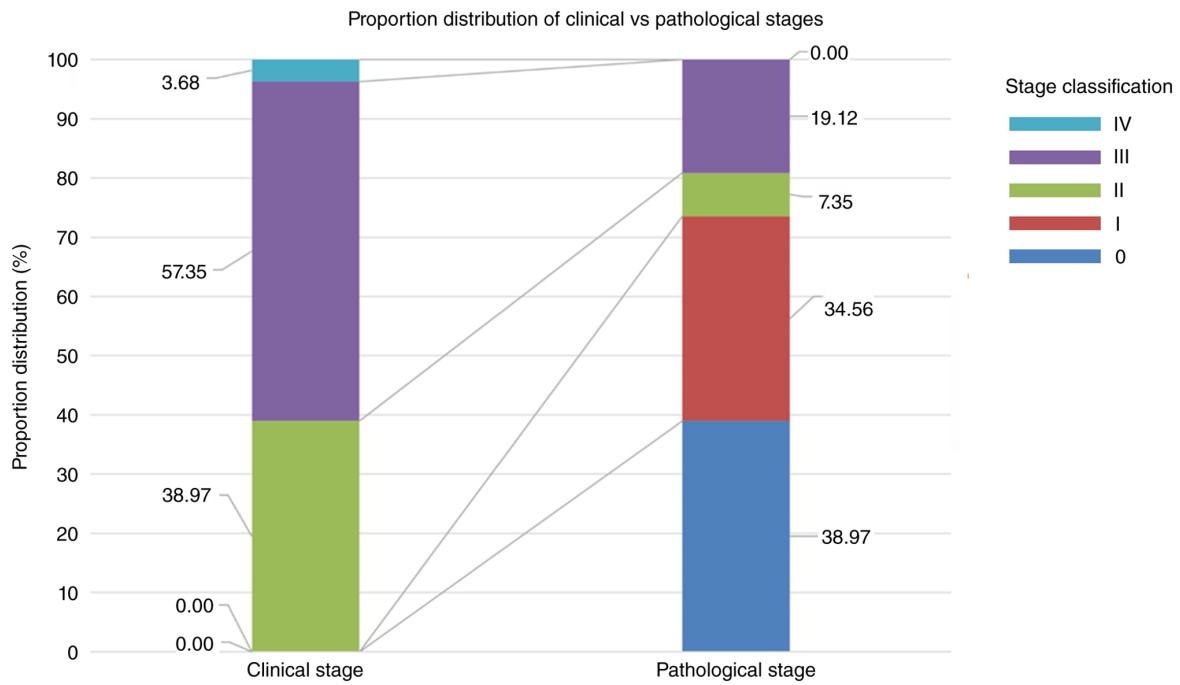


Figure 1. Clinical staging at initial diagnosis vs. postoperative pathological staging. The downstaging rate reached 80.14%, and the proportion of patients with stage II or III disease decreased from 96.32 to 26.47%.

Table VI. Univariate regression analyses of overall survival.

Variables	Univariate analysis	
	P-value	HR (95% CI)
Chemotherapy regimen	0.828	1.185 (0.256-5.487)
Radiation dose	0.201	1.689 (0.756-3.776)
Sex	0.500	0.493 (0.063-3.857)
Age	0.807	0.858 (0.251-2.933)
Tumor location	0.872	1.105 (0.328-3.720)
ECOG	0.695	1.304 (0.346-4.917)
Smoking status	0.873	1.102 (0.336-3.611)
Drinking status	0.623	1.347 (0.411-4.415)
TRG	0.056	1.997 (0.982-4.062)
MPR	0.054	0.299 (0.087-1.020)
Lymph nodes	0.121	0.377 (0.110-1.292)
pCR	0.087	0.166 (0.021-1.300)
cT	0.866	0.833 (0.100-6.953)
cN	0.465	1.351 (0.603-3.027)
cTNM	0.807	0.876 (0.302-2.537)
ypT	0.471	1.221 (0.710-2.100)
ypN	0.089	2.111 (0.892-4.995)
ypTNM	0.431	1.224 (0.740-2.025)
Surgical approach	0.999	1.001 (0.445-2.251)
Postoperative complications	0.198	2.183 (0.666-7.160)

HR, hazard ratio; CI, confidence interval; ypN, pathological node stage; ypT, pathological tumor stage; ypStage, overall pathological stage; cT, clinical tumor stage; cN, clinical node stage; cTNM, clinical TNM stage; pTNM, pathological TNM stage; pCR, pathological complete response; MPR, major pathological response; TRG, tumor regression grade; ECOG, Eastern Cooperative Oncology Group.

among patients treated according to the CROSS protocol. Additionally, other studies have reported rates of grade ≥ 3 leukopenia and neutropenia ranging from 30 to 43% with Q3W regimens, which is consistent with the present observations (13,24). This collective evidence underscores the increased risk of hematological complications associated with Q3W regimens, thus highlighting the necessity for vigilant monitoring during nCRT. Furthermore, no significant differences were observed in postoperative complications between the two groups, and this finding is consistent with prior research, thereby confirming the comparable safety profiles of the regimens (14,24,25).

Compared with Q3W regimen, the incidence of pneumonitis was lower in the QW group (0% vs. 16.35%, $P=0.012$). Studies by Chen *et al.* and Liang *et al.* have shown that the concurrent use of paclitaxel increases the risk of radiation pneumonitis (26,27). Notably, the incidence of symptomatic radiation pneumonia was markedly higher in the QW TC and paclitaxel plus fluorouracil regimens than in the Q3W TP regimen (21.5, 26.1 and 4.7%, respectively; $P<0.001$) (13). This discrepancy may be attributed to higher radiation doses and larger target volumes in these protocols. Neurotoxicity is a known adverse reaction of both albumin-bound paclitaxel and standard paclitaxel. Studies have shown that its incidence in the Chinese population can reach as high as 76% (18). The incidence of neurotoxicity observed in this study was 52.21%, which is significantly lower than the aforementioned reference rate; this may be related to the retrospective design of this study and incomplete medical records for some patients. Furthermore, some studies have shown that, compared with conventional paclitaxel formulations, albumin-bound paclitaxel can significantly reduce the risk of hypersensitivity reactions, rash, myelosuppression, and peripheral neuropathy (28-30).

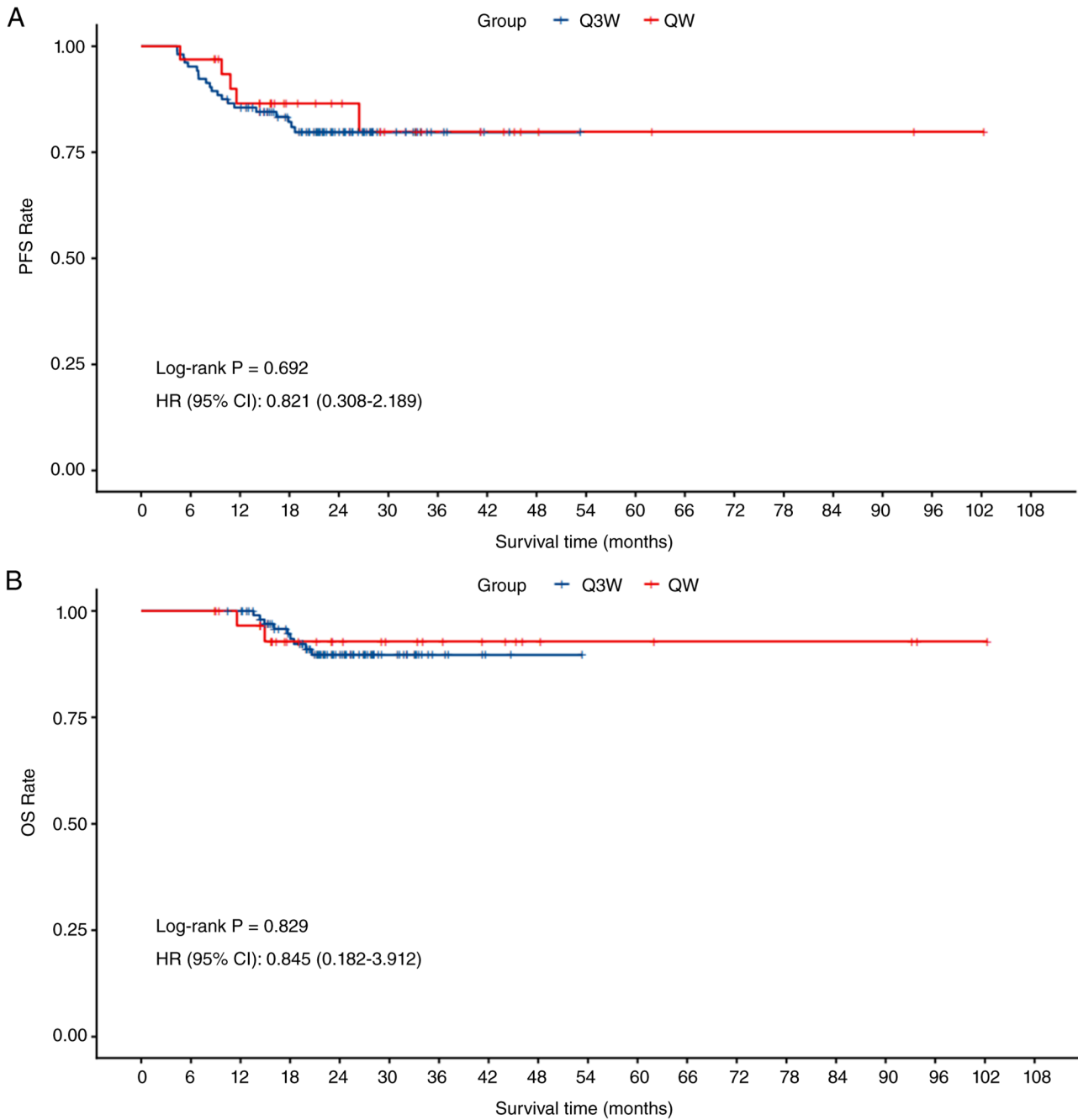


Figure 2. Kaplan-Meier curves for (A) PFS and (B) OS in the QW vs. Q3W nab-paclitaxel groups. There were no statistically significant differences in PFS (P=0.692) or OS (P=0.829) between the two groups. PFS, progression-free survival; OS, overall survival; QW, weekly; Q3W, tri-weekly; CI, confidence interval; HR, hazard ratio.

Although previous studies have underscored the efficacy of the TP regimen in various settings (31,32), this regimen has not demonstrated a survival advantage compared with other platinum-based therapies combined with paclitaxel in the context of definitive chemoradiotherapy (33). Consistent with these findings, the present study revealed no significant differences in OS or PFS between the QW and Q3W treatment groups. This result aligns with the broader literature, thus suggesting that both regimens are comparably effective in achieving long-term outcomes for patients undergoing nCRT.

In the present study, 56.25% of the patients treated with the QW regimen achieved a pCR compared with a rate of 33.65% of patients treated with the Q3W regimen, thereby

demonstrating a significant difference. The pCR rate for these lesions was significantly higher than the rates reported in the studies by Blom *et al* (34) and van Meerten *et al* (35), which observed comparable outcomes of 24-25% in patients undergoing nCRT. Additionally, a recent systematic review and meta-analysis evaluating nCRT for ESCC reported a pooled pCR prevalence of 32% across 21 studies, with a range from 8 to 66% being observed (36). This result underscores the variability in pCR rates based on treatment protocols, patient populations and study designs. The present results demonstrate that the QW regimen is located on the higher end of this spectrum, thus suggesting its potential for improved tumor regression outcomes. Given the recognized importance of the

MPR in EC prognosis and treatment assessment (37,38), the present study provides novel insights into MPR outcomes. In contrast to prior studies (34,35), which reported MPR rates of 51-61%, the present study identified a significantly higher MPR rate in the QW group (81.25%) than in the Q3W group (61.54%) ($P=0.039$). We hypothesize that the superior pCR and MPR rates observed in the QW group may be associated with better overall tolerability and the use of albumin-bound paclitaxel for administration. As an effective radiosensitizer, albumin-bound paclitaxel has demonstrated promise in enhancing radiotherapy outcomes (39,40). Furthermore, the consistent drug delivery design of the QW regimen likely minimizes systemic drug level fluctuations, thereby augmenting radiosensitization effects. Improved dose intensity, reduced toxicity and better treatment adherence in the QW group may also contribute to these favorable outcomes. These findings suggest that the combination of albumin-bound paclitaxel with radiotherapy could significantly improve the efficacy of nCRT (40). Based on the reduced toxicity profile and enhanced therapeutic outcomes, the QW regimen is recommended as a viable and potentially superior option for neoadjuvant therapy in patients with EC.

The present study has several limitations that warrant consideration. First, the retrospective design, single-center nature and sample size imbalance between the two groups may introduce bias. Although PSM was used to balance the two cohorts, some residual imbalance persisted between the groups. Furthermore, the relatively short follow-up period resulted in immature OS data, thereby limiting in-depth exploration of long-term outcomes between the groups. Therefore, large-scale, multicenter prospective studies are needed to validate the findings of this investigation.

The findings of this study underscore the potential of a QW regimen involving albumin-bound paclitaxel and cisplatin as an nCRT strategy for patients with LA-ESCC. This approach demonstrated an encouraging pCR rate, thus reflecting its efficacy. Additionally, its tolerability and manageable safety profile further support its clinical utility. When considering recent advances advocating the use of triple-agent chemotherapy for select patient populations, these results provide crucial insights into refining nCRT protocols for those in whom such regimens remain viable. The advantages of the QW administration schedule, such as improved treatment adherence, reduced fluctuations in systemic drug levels and potential radiosensitization benefits, highlight its promise as a tailored therapeutic option for ESCC. Future prospective studies with larger cohorts are necessary to confirm these findings.

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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

LL and XJ performed data collection, statistical analysis and edited the original draft. JN was responsible for conceptualization and reviewing and editing the manuscript. YY conducted the data analysis and developed the tracking and data collection programs. YW and KZ were responsible for data collection, as well as data analysis and interpretation. JL executed the esophagectomy. HZ and JY made substantial contributions to conception, design, data acquisition, analysis, and interpretation; drafted and critically revised the manuscript; approved the final version to be published; and agreed to be accountable for all aspects of the work, ensuring proper investigation and resolution of any accuracy or integrity concerns. LL and XJ confirm the authenticity of all the raw data.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and International Good Clinical Practice Guidelines. The need for informed consent was waived by the Ethics Committee of Shandong Cancer Hospital and Institute (Jinan, China) due to the retrospective nature of the study.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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