ISSN 1948-9366 (online)

World Journal of

Gastrointestinal Surgery

World J Gastrointest Surg 2024 October 27; 16(10): 3074-3380

Published by Baishideng Publishing Group Inc

World Journal of Gastrointestinal Surgery

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AIMS AND SCOPE

The primary aim of *World Journal of Gastrointestinal Surgery* (*WJGS*, *World J Gastrointest Surg*) is to provide scholars and readers from various fields of gastrointestinal surgery with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJGS mainly publishes articles reporting research results and findings obtained in the field of gastrointestinal surgery and covering a wide range of topics including biliary tract surgical procedures, biliopancreatic diversion, colectomy, esophagectomy, esophagostomy, pancreas transplantation, and pancreatectomy, *etc*.

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The *WJGS* is now abstracted and indexed in Science Citation Index Expanded (SCIE, also known as SciSearch®), Current Contents/Clinical Medicine, Journal Citation Reports/Science Edition, PubMed, PubMed Central, Reference Citation Analysis, China Science and Technology Journal Database, and Superstar Journals Database. The 2024 Edition of Journal Citation Reports® cites the 2023 journal impact factor (JIF) for *WJGS* as 1.8; JIF without journal self cites: 1.7; 5-year JIF: 1.9; JIF Rank: 126/292 in surgery; JIF Quartile: Q2; and 5-year JIF Quartile: Q3.

RESPONSIBLE EDITORS FOR THIS ISSUE

NAME OF JOURNAL
World Journal of Gastrointestinal Surgery

ISSN
ISSN 1948-9366 (online)

LAUNCH DATE
November 30, 2009

FREQUENCY
Monthly

EDITORS-IN-CHIEF
Peter Schemmer

EDITORIAL BOARD MEMBERS
https://www.wjgnet.com/1948-9366/editorialboard.htm

PUBLICATION DATE
October 27, 2024

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World J Gastrointest Surg 2024 October 27; 16(10): 3224-3238

DOI: 10.4240/wjgs.v16.i10.3224

ISSN 1948-9366 (online)

ORIGINAL ARTICLE

Retrospective Study

Comparison of efficacy and safety of nab-paclitaxel and oxaliplatin + S-1 and standard S-1 and oxaliplatin chemotherapy regimens for treatment of gastric cancer

Yi-Cong Wang, Long Feng, Gong-Ping Wang, Peng-Jie Yu, Can Guo, Bao-Jia Cai, Yan Song, Ting Pan, Bo-Hao Lin, Yuan-Dong Li, Jing-Jing Xiao

Specialty type: Gastroenterology and hepatology

Provenance and peer review: Unsolicited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's classification

Scientific Quality: Grade A, Grade B, Grade D

Novelty: Grade A, Grade B, Grade B

Creativity or Innovation: Grade A, Grade B, Grade B

Scientific Significance: Grade A, Grade B, Grade C

P-Reviewer: Chen X; Zhou Y

Received: July 1, 2024

Revised: August 12, 2024

Accepted: September 2, 2024

Published online: October 27, 2024

Processing time: 89 Days and 0.2 Hours

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Abstract

BACKGROUND

Gastric cancer (GC) is a relatively frequent clinical phenomenon, referring to malignant tumors emerging in the gastric mucosal epithelial cells. It has a high morbidity and mortality rate, posing a significant threat to the health of patients. Hence, how to diagnose and treat GC has become a heated topic in this research field.

AIM

To discuss the effectiveness and safety of nab-paclitaxel in combination with oxaliplatin and S-1 (P-SOX) for the treatment of GC, and to analyze the factors that may influence its outcomes.

METHODS

A total of 219 eligible patients with advanced GC, who were treated at Qinghai University Affiliated Hospital Gastrointestinal Oncology between January 2018 and March 2020, were included in the study. Among them, 149 patients received SOX regimen and 70 patients received S-1 regimen. All patients underwent both preoperative and postoperative chemotherapy consisting of 2-4 cycles each, totaling 6-8 cycles, along with parallel D2 radical surgical treatment. The patients were followed up for a period of three years or until reaching the event endpoint.

RESULTS

The short-term and long-term efficacy of the P-SOX group was significantly higher than that of the SOX group, and the safety was manageable. Cox multivariate analysis revealed that progression-free survival was associated with perioperative chemotherapy efficacy, tumor diameter ≤ 2cm, high differentiation, and early cTNM (T stands for invasion depth; N stands for node metastasis; M stands for distant invasion) stage.

CONCLUSION

In comparison to the SOX regimen, the P-SOX regimen demonstrates improved short-term and long-term efficacy with tolerable adverse reactions. It is anticipated that the P-SOX regimen will emerge as a first-line chemotherapy option for GC. Patients with GC who receive effective perioperative chemotherapy (Response Evaluation Criteria in Solid Tumors 1.1, Tumor Regression Grade), have a tumor diameter ≤ 2cm, exhibit high degree of differentiation, and are at an early cTNM stage show better prognosis.

Key Words: Nab-paclitaxel; Gastric cancer; Efficacy; Safety

Core Tip: NaB-paclitaxel combined with oxaliplatin + S-1 (P-SOX) regimen is superior to conventional SOX regimen in the treatment of gastric cancer. Progression-free survival was associated with effective perioperative chemotherapy (Response Evaluation Criteria in Solid Tumors 1.1, Tumor Regression Grade), tumor diameter ≤ 2 cm, high differentiation, and early cTNM staging.

Citation: Wang YC, Feng L, Wang GP, Yu PJ, Guo C, Cai BJ, Song Y, Pan T, Lin BH, Li YD, Xiao JJ. Comparison of efficacy and safety of nab-paclitaxel and oxaliplatin + S-1 and standard S-1 and oxaliplatin chemotherapy regimens for treatment of gastric cancer. *World J Gastrointest Surg* 2024; 16(10): 3224-3238
URL: https://www.wjgnet.com/1948-9366/full/v16/i10/3224.htm
DOI: https://dx.doi.org/10.4240/wjgs.v16.i10.3224

INTRODUCTION

Gastric cancer (GC) is one of the most common gastrointestinal tumors, especially in China. Surgical resection is the only possible cure for patients with GC. Most early GC can be treated by endoscopy, and the 5-year survival rate is more than 90%, while the 5-year survival rate of advanced GC is still less than 30% even after surgery-based comprehensive treatment. Therefore, it is difficult to cure GC by surgery alone. Although the comprehensive treatment of surgery, radiotherapy and chemotherapy has achieved significant clinical benefits at present, the overall prognosis of GC is still very poor, and the conventional chemotherapy regimens have not achieved satisfactory results. Therefore, patients with GC urgently need more effective adjuvant chemotherapy. At present, albumin-bound paclitaxel is one of the standard second-line drugs for the treatment of GC. Albumin-bound paclitaxel has been proved to be effective and low toxic, which not only improves the objective response rate (ORR) after tumor chemotherapy, but also shortens the injection time and reduces the side effects of chemotherapy. Therefore, in this study, we reduced the dose of oxaliplatin, which has obvious side effects, and added nab-paclitaxel (P-SOX regimen) to the SOX regimen[1-4].

MATERIALS AND METHODS

Patients

A total of 219 eligible patients with GC, who were treated at Qinghai University Affiliated Hospital Gastrointestinal Oncology between January 2018 and March 2020, were included in the study. Among them, 149 patients received SOX regimen and 70 patients received S-1 regimen. All patients underwent both preoperative and postoperative chemotherapy consisting of 2-4 cycles each, totaling 6-8 cycles, along with parallel D2 radical surgical treatment. The patients were followed up for a period of three years or until reaching the event endpoint.

Inclusion criteria: (1) Inclusion of patients diagnosed with stage II-IV primary gastric adenocarcinoma, as confirmed by imaging and endoscopic biopsy according to the 8th edition of the American Cancer Consortium TNM (T stands for invasion depth; N stands for node metastasis; M stands for distant invasion) Staging Criteria of the International Union Against Cancer, and successful R0 resection (no residual tumor visible to the naked eye or under a microscope); (2) The patients underwent 2-4 cycles of preoperative and postoperative adjuvant chemotherapy, followed by a total of 6-8 cycles of chemotherapy, all in accordance with the National Comprehensive Cancer Network and Chinese Society of Clinical Oncology guidelines for surgical treatment at our hospital; (3) The size of primary tumor lesions can be measured by computed tomography and magnetic resonance imaging, with confirmation through postoperative pathological biopsy; and (4) Eastern Cooperative Oncology Group performance status ≤ 1 and able to tolerate chemotherapy; with acceptable liver, kidney, hematologic and cardiopulmonary function.

Exclusion criteria: (1) Contraindications allergic to chemotherapy drugs or related to chemotherapy, as well as the combination of severe symptoms such as infectious diseases, gastrointestinal bleeding, pyloric obstruction, or gastrointestinal perforation; (2) Patients who have undergone radiotherapy, chemotherapy, biotherapy, or surgery for other malignancies; and (3) Patients whose tumor diameter cannot be accurately measured in cases of incomplete or missing information, or imaging data. The trial adhered to the Declaration of Helsinki and gained the approval of Review Committee of the Affiliated Hospital of Qinghai University ("Kunlun Talents-Plateau Famous Doctors" project in Qinghai Province) and it was also approved by the Clinical Medical Research Center of Qinghai Province, and all enrolled patients were given written informed consent.

RESULTS

Basic patient characteristics

A total of 219 patients were included in the study, with 149 patients allocated to the P-SOX group and 70 patients to the SOX group. As depicted in Table 1, there were no statistically significant discrepancies observed in clinical characteristics such as gender, age, body mass index, degree of differentiation, anesthesia grade, tumor location, laurnen type, preoperative T stage, preoperative N stage, and cTNM stage ($P > 0.05$).

Efficacy and safety

Short-term efficacy: Both groups received 2-4 cycles of preoperative chemotherapy, and the short-term efficacy between the two chemotherapy regimens was evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1, Tumor Regression Grade (TRG) classification. As shown in Table 1, TRG evaluation: In the P-SOX group, 91 cases were effective (grade 0, 1, 2 = 61.1%,) and 58 cases were ineffective (grade 3 = 38.9%), with an ORR of 61.1%. In the SOX group, there were 37 effective cases (grades 0, 1, 2 = 52.9%) and 33 ineffective cases (grade 3 = 47.1%), resulting in an ORR of 52.9%. There was no significant difference between the two groups ($P = 0.250$). According to RECIST 1.1 criteria, in the P-SOX group, there were a total of 83 effective cases [complete response (CR) + partial response (PR) = 55.7%] and 66 ineffective cases (stable disease + aggressive disease = 44.3%) with an ORR of 55 .7% (CR+PR). In contrast, in the SOX group there were a total of 32 effective patients (grade 0, 1, 2 = 45.7%) and 38 ineffective patients (grade 3 = 54.3%) with an ORR of 45.7 %. The ORRs for both P-SOX group (61.1%, 55.7%) were significantly higher than those for SOX group (52.9%, 45.7%), but there was no significant difference between them ($P = 0.167$).

Long-term efficacy: The 1-year, 2-year and 3-year overall survival (OS) rates of the P-SOX group and the SOX group were 94.0% *vs* 92.9%, $P = 0.749$; 79.2% *vs* 70.0%, $P = 0.163$; and 64.4% *vs* 50.7%, $P = 0.071$, respectively (Figure 1A). The 1-year, 2-year and 3-year progression-free survival (PFS) rates of the P-SOX group and the SOX group were 85.9% and 81.4%, $P = 0.433$; 64.2% and 54.3%, $P = 0.157$; and 55.3% and 44.3%, $P = 0.112$, respectively (Figure 1B). OS and PFS in the P-SOX group were significantly greater than those in the SOX group, but there was no significant difference between the two groups ($P > 0.05$).

Safety: The adverse events for all participants are summarized in Table 2. Most side effects were classified as Grades 1-2, with gastrointestinal reactions (77.9% *vs* 78.6%), peripheral neurotoxicity (61.1% *vs* 48.6%), and hair loss (69.1% *vs* 48.6%, $P = 0.013$) being common in the P-SOX and SOX groups, respectively. The incidence of other adverse reactions was between 20% and 40%, and the incidence and severity of hair loss were significantly greater in the P-SOX group than in the SOX group. Except for alopecia ($P = 0.013$), other adverse reactions did not significantly differ between the two groups. Nevertheless, compared with that in the SOX group, the incidence of hematological toxicity above grade 2, such as neutropenia (6.1% *vs* 1.5%), leukopenia (5.4% *vs* 2.8%), thrombocytopenia (6.1% *vs* 4.3%), anemia (2.7% *vs* 0.0%), and grade 2 hepatotoxicity (7.4% *vs* 0.0%), was greater in the P-SOX group, which may have been caused by triple drug therapy in the P-SOX group.

Single-factor and multifactor Cox regression analysis: Univariate Cox regression analysis of baseline characteristics and short-term efficacy assessment (RECIST 1.1, TRG) in 149 patients revealed that PFS was significantly associated with RECIST 1.1, TRG, tumor diameter, degree of differentiation, lymph node metastasis, T stage, and cTNM stage ($P < 0.05$). The multivariate Cox regression analysis demonstrated that PFS was significantly associated with RECIST 1.1 [valid *vs* invalid, hazard ratio (HR): 0.507, 95%CI: 0.300–0.856, $P = 0.011$], TRG (invalid *vs* valid, HR: 1.949; 95%CI: 1.159-3.276; $P = 0.012$), tumor diameter (≥ 5 cm *vs* ≤ 2 cm, HR: 3.281; 95%CI: 1.401-7.685; $P = 0.006$; ≥ 5 cm *vs* 2-5 cm, HR: 2.503; 95%CI:

Table 1 Basic patient characteristics and short-term efficacy, *n* (%)

Variables	Total (*n* = 219)	P-SOX (*n* = 149)	SOX (*n* = 70)	*Z*	*P* value
Age				2.674	0.102
≤ 60	142 (64.8)	102 (68.5)	40 (57.1)		
> 60	77 (35.2)	47 (31.5)	30 (42.9)		
Sex				0.514	0.473
Male	184 (84)	127 (85.2)	57 (81.4)		
Female	35 (16)	22 (14.8)	13 (18.6)		
BMI				0.278	0.598
18.5–24	140 (63.9)	97 (65.1)	43 (61.4)		
< 18.5 or > 24	79 (36.1)	52 (34.9)	27 (38.6)		
ASA				0.168	0.681
1+2	178 (81.3)	120 (80.5)	58 (82.9)		
3	41 (18.7)	29 (19.5)	12 (17.1)		
RECIST 1.1				1.906	0.167
Ineffective	104 (47.5)	66 (44.3)	38 (54.3)		
Effective	115 (52.5)	83 (55.7)	32 (45.7)		
TRG				1.324	0.250
Effective	128 (58.4)	91 (61.1)	37 (52.9)		
Ineffective	91 (41.6)	58 (38.9)	33 (47.1)		
Tumor location				0.260	0.878
Lower	76 (34.7)	51 (34.2)	25 (35.7)		
Upper	69 (31.5)	46 (30.9)	23 (32.9)		
Middle	74 (33.8)	52 (34.9)	22 (31.4)		
Differentiation				1.883	0.390
Poorly	101 (46.1)	64 (43)	37 (52.9)		
Moderate	72 (32.9)	52 (34.9)	20 (28.6)		
Well	46 (21)	33 (22.1)	13 (18.6)		
cT stage				0.384	0.825
2	60 (27.4)	42 (28.2)	18 (25.7)		
3	117 (53.4)	80 (53.7)	37 (52.9)		
4	42 (19.2)	27 (18.1)	15 (21.4)		
cN stage				0.155	0.694
Negative	76 (34.7)	53 (35.6)	23 (32.9)		
Positive	143 (65.3)	96 (64.4)	47 (67.1)		
cTNM[1]				1.170	0.557
II	120 (54.8)	83 (55.7)	37 (52.9)		
III	52 (23.7)	37 (24.8)	15 (21.4)		
IV	47 (21.5)	29 (19.5)	18 (25.7)		
Tumor diameter				2.196	0.333
≤ 2	55 (25.1)	33 (22.1)	22 (31.4)		
2-5	91 (41.6)	64 (43)	27 (38.6)		
≥ 5	73 (33.3)	52 (34.9)	21 (30)		

Laurnen				3.274	0.195
Enteric	42 (19.2)	29 (19.5)	13 (18.6)		
Mixed type	98 (44.7)	72 (48.3)	26 (37.1)		
Diffuse	79 (36.1)	48 (32.2)	31 (44.3)		

[1]Tumor location is classified as upper 1/3, middle 1/3, lower 1/3, diffuse TNM staging according to the American Cancer Consortium.
ASA: American Society of Anesthesiologists Score; BMI, body mass index; RECIST: Response Evaluation Criteria in Solid Tumors; TRG: Tumor Regression Grade; P-SOX: Nab-paclitaxel and oxaliplatin + S-1; SOX: Standard S-1 and oxaliplatin.

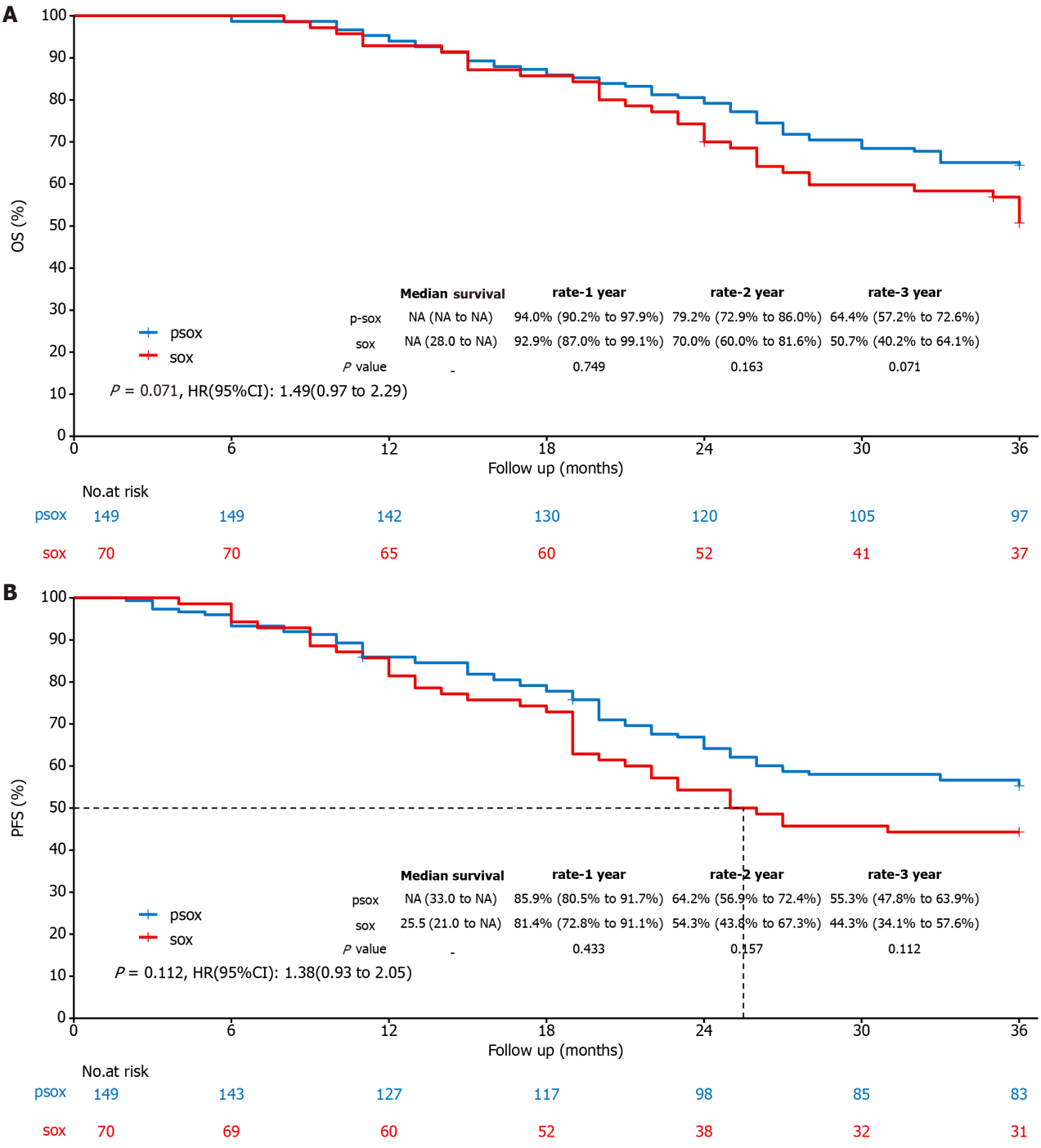

Figure 1 Comparison of overall survival and progression-free survival between the two groups. A: Overall survival; B: Progression-free survival. P-SOX: Nab-paclitaxel and oxaliplatin + S-1; SOX: Standard S-1 and oxaliplatin; HR: Hazard ratio; PFS: Progression-free survival; OS: Overall survival.

Table 2 Side effects associated with nab-paclitaxel and oxaliplatin + S-1 and standard S-1 and oxaliplatin treatment, *n* (%)

Variables	Total (*n* = 219)	P-SOX (*n* = 149)	SOX (*n* = 70)	*P* value
Fewer neutrophils				0.598
0	168 (77.4)	115 (77.2)	53 (77.9)	
1	37 (17.1)	24 (16.1)	13 (19.1)	
2	2 (0.9)	1 (0.7)	1 (1.5)	
3	6 (2.8)	5 (3.4)	1 (1.5)	
4	4 (1.8)	4 (2.7)	0 (0)	
Fewer white blood cells				0.418
0	141 (64.4)	95 (63.8)	46 (65.7)	
1	50 (22.8)	33 (22.1)	17 (24.3)	
2	18 (8.2)	13 (8.7)	5 (7.1)	
3	9 (4.1)	8 (5.4)	1 (1.4)	
4	1 (0.5)	0 (0)	1 (1.4)	
Fewer platelets				0.985
0	158 (72.1)	106 (71.1)	52 (74.3)	
1	49 (22.4)	34 (22.8)	15 (21.4)	
2	7 (3.2)	5 (3.4)	2 (2.9)	
3	5 (2.3)	4 (2.7)	1 (1.4)	
Anemia				0.415
0	146 (66.7)	102 (68.5)	44 (62.9)	
1	56 (25.6)	35 (23.5)	21 (30)	
2	13 (5.9)	8 (5.4)	5 (7.1)	
3	4 (1.8)	4 (2.7)	0 (0)	
Nausea and vomiting				0.856
0	48 (21.9)	33 (22.1)	15 (21.4)	
1	123 (56.2)	81 (54.4)	42 (60)	
2	43 (19.6)	31 (20.8)	12 (17.1)	
3	5 (2.3)	4 (2.7)	1 (1.4)	
Live toxicity				0.057
0	168 (76.7)	113 (75.8)	55 (78.6)	
1	40 (18.3)	25 (16.8)	15 (21.4)	
2	11 (5)	11 (7.4)	0 (0)	
alopecia				0.013
0	82 (37.4)	46 (30.9)	36 (51.4)	
1	114 (52.1)	85 (57)	29 (41.4)	
2	23 (10.5)	18 (12.1)	5 (7.1)	
Peripheral sensory neuropathy				0.052
0	94 (42.9)	58 (38.9)	36 (51.4)	
1	87 (39.7)	59 (39.6)	28 (40)	
2	35 (16)	30 (20.1)	5 (7.1)	
3	3 (1.4)	2 (1.3)	1 (1.4)	

PSOX: Nab-paclitaxel and oxaliplatin + S-1; SOX: Standard S-1 and oxaliplatin.

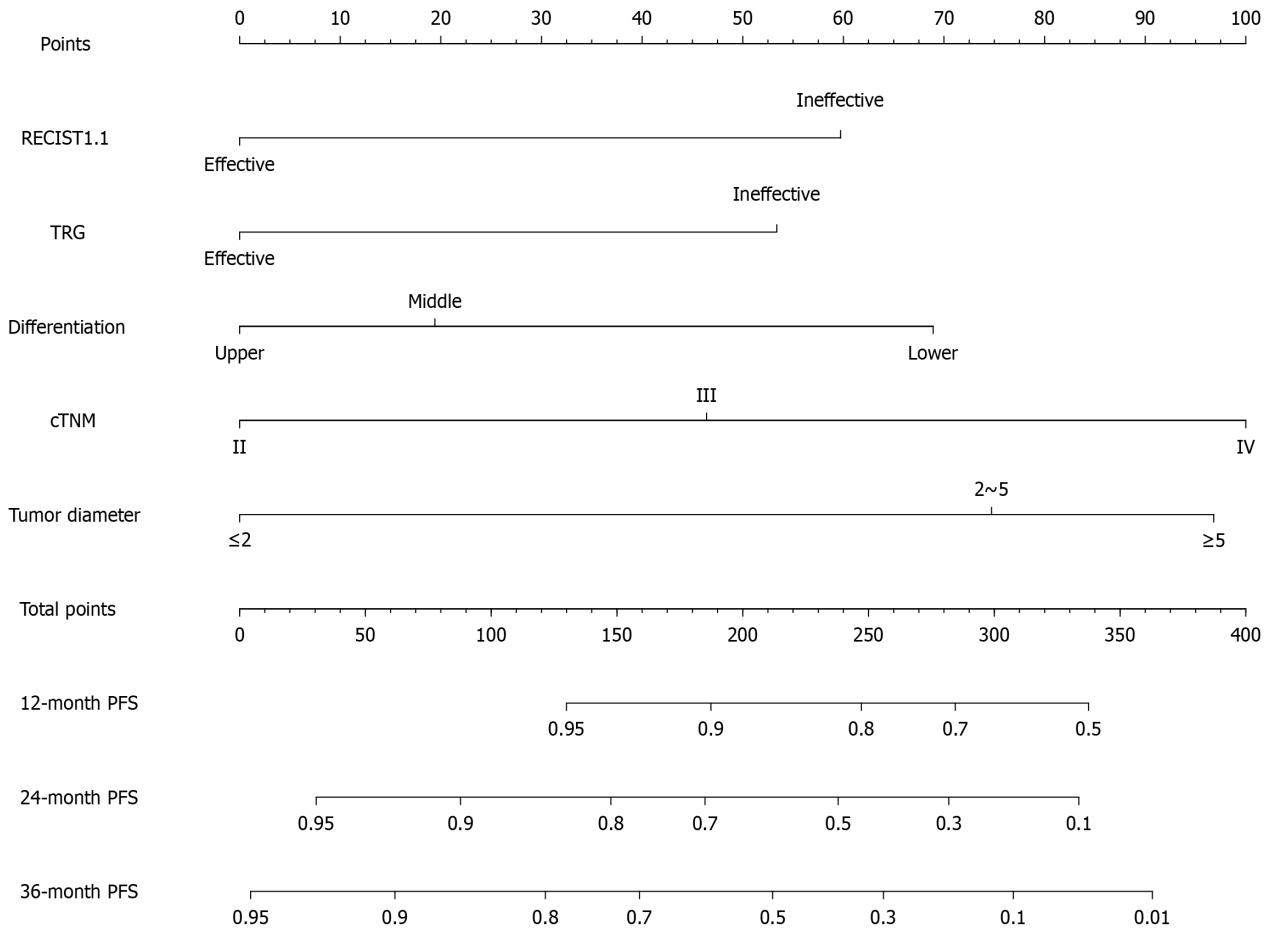

Figure 2 Progression-free survival nomogram (Nab-paclitaxel and oxaliplatin + S-1). PFS: Progression-free survival; RECIST: Response Evaluation Criteria in Solid Tumors; TRG: Tumor Regression Grade.

1.077-5.819; P = 0.033), differentiation degree (high *vs* low, HR: 0.443; 95%CI: 02000–980; P = 0044) and cTNM stage (IV *vs* II, HR: 3015; 95%CI: 1577–5765; P = 00001), with statistically significant differences (P < 005), as shown in Table 3 and Table 4.

PFS model building: Based on univariate and multivariate Cox regression analyses, the final five independent risk factors screened out were used to construct a nomogram, as shown in Figure 2. Points at the top of the figure represent the score value, and the corresponding points were obtained by drawing an upward vertical line of various risk factors below. According to the sum of the corresponding factor scores, the corresponding interval of the total points below was found. According to the probability of PFS occurring at the bottom of the figure corresponding to the total score, the 1-, 2-, and 3-year PFS of the patient was estimated. In the corresponding risk column, a lower value is indicate that P-SOX chemotherapy would be more meaningful for the patient. Among these patients, those with effective perioperative chemotherapy (RECIST 1.1, TRG), a tumor diameter ≤ 2 cm, a high degree of differentiation, and cTNM Stage II gastric cancer had the highest PFS and greatest benefit.

Nomogram for assessment and validation: Time-dependent receiver operating characteristic (ROC) curve analysis was used to calculate the area under the ROC curve (AUC), C-index, and other indicators for evaluating discrimination efficacy. As shown in Figure 3, the 12-month AUC was 0.765 (95%CI: 0.661-0.870), the 24-month AUC was 0.797 (95%CI: 0.724-0.870), and the 36-month AUC was 0.815 (95%CI: 0.747-0.882). The C-index of the overall model was determined to be 0.743 (95%CI: 0.687–0.799), indicating a good predictive effect of the nomogram model.

The constructed nomogram underwent bootstrap resampling verification 1000 times, and a calibration curve was generated to assess its degree of calibration, as shown in Figure 4, which demonstrated a good fit. The probability of PFS predicted by the nomogram and the actual probability of PFS in gastric cancer patients treated with P-SOX chemotherapy did not significantly differ.

Table 3 Single-factor Cox regression analysis

Variable	Z	HR (95%CI)	*P* value
Age			
≤ 60		Reference	
> 60	0.853	1.247 (0.751-2.069)	0.393
Sex			
Male		Reference	
Female	-0.350	0.882 (0.437-1.782)	0.727
BMI			
18.5–24		Reference	
< 18.5 or > 24	0.333	1.089 (0.659-1.799)	0.739
ASA			
1+2		Reference	
3	-0.192	0.941 (0.503-1.758)	0.848
RECIST 1.1			
Ineffective		Reference	
Effective	-3.803	0.379 (0.230-0.625)	< 0.001
TRG			
Effective		Reference	
Ineffective	3.329	2.278 (1.403-3.698)	0.001
Tumor location			
Lower		Reference	
Upper	-1.622	0.579 (0.300-1.120)	0.105
Middle	0.996	1.319 (0.765-2.277)	0.319
Differentiation			
Poorly		Reference	
Moderate	-0.752	0.819 (0.487-1.378)	0.452
Well	-2.555	0.365 (0.168-0.791)	0.011
cT stage			
2		Reference	
3	1.105	1.432 (0.757-2.707)	0.269
4	3.594	3.721 (1.817-7.618)	< 0.001
cN stage			
Negative		Reference	
Positive	2.097	1.786 (1.039-3.072)	0.036
cTNM			
II		Reference	
III	2.132	1.935 (1.055-3.550)	0.033
IV	4.508	3.724 (2.103-6.597)	< 0.001
Tumor diameter			
≤ 2		Reference	
2-5	2.178	2.503 (1.096-5.715)	0.029
≥ 5	3.061	3.619 (1.588-8.248)	0.002

Laurnen			
Enteric		Reference	
Mixed type	-0.276	0.906 (0.447-1.833)	0.783
Diffuse	1.506	1.705 (0.852-3.415)	0.132

BMI: Body mass index; RECIST: Response Evaluation Criteria in Solid Tumors; TRG: Tumor Regression Grade; HR: Hazard ratio.

Table 4 Multi-factor Cox regression analysis

Variable	*Z*	HR (95%CI)	*P* value
RECIST 1.1			
Ineffective		Reference	
Effective	-2.544	0.507 (0.300-0.856)	0.011
TRG			
Effective		Reference	
Ineffective	2.518	1.949 (1.159-3.276)	0.012
Differentiation			
Poorly		Reference	
Moderate	-1.624	0.628 (0.358-1.101)	0.104
Well	-2.010	0.443 (0.200-0.980)	0.044
cT stage			
2		Reference	
3	1.263	1.520 (0.794-2.909)	0.206
4	1.834	2.041 (0.952-4.376)	0.067
cN stage			
Negative		Reference	
Positive	1.725	1.645 (0.934-2.895)	0.085
cTNM			
II		Reference	
III	1.383	1.575 (0.827-2.997)	0.167
IV	3.338	3.015 (1.577- 5.765)	0.001
Tumor diameter			
≤ 2		Reference	
2-5	2.131	2.503 (1.077-5.819)	0.033
≥ 5	2.736	3.281 (1.401-7.685)	0.006

RECIST: Response Evaluation Criteria in Solid Tumors; TRG: Tumor Regression Grade; HR: Hazard ratio.

Furthermore, decision curve analysis was developed to evaluate the clinical application value of the model and quantify the net benefit within the threshold probability range. According to Figure 5, the performance of the model is good at 1 year, 2 years, and 3 years, indicating that the model has good clinical value.

In this study, all subjects' nomogram scores were calculated according to the established model; R software was used to determine the best cutoff value of the nomogram, according to which all patients in the P-SOX group were risk stratified (low-risk and high-risk groups) on the basis of their respective nomogram scores. The results revealed that the prognosis of the high-risk group was significantly worse than that of the low-risk group at different time points (HR: 5.323, 95%CI: 3·238–8·750, $P < 0001$), as illustrated in Figure 6 and Figure 7.

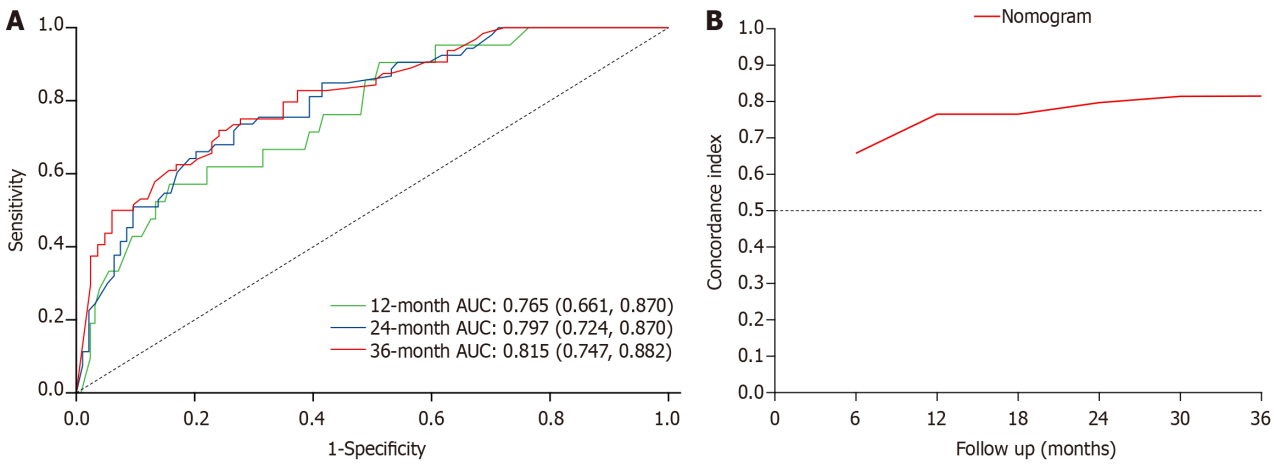

Figure 3 Progression-free survival receiver operating characteristic curve. A: Sensitivity; B: Concordance index. AUC: The area under the operating characteristic curve.

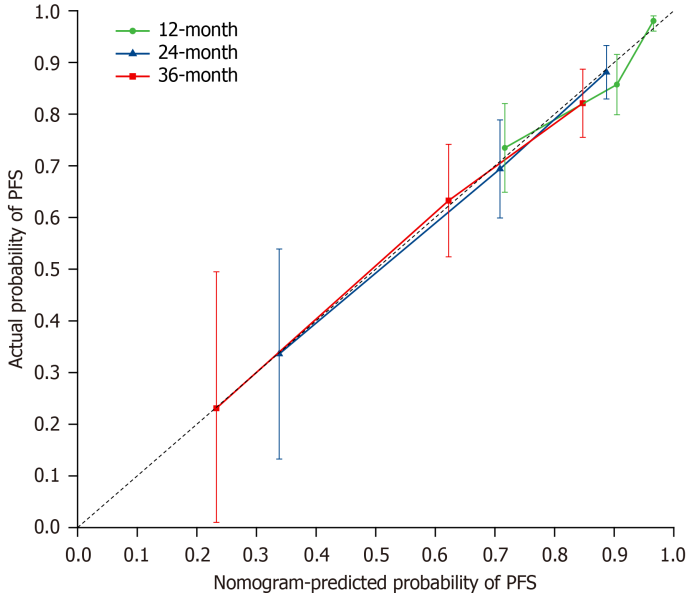

Figure 4 Calibration curve for progression-free survival. PFS: Progression-free survival.

DISCUSSION

The exploration of effective and low-toxicity chemotherapy regimens has been a hot topic in gastric cancer research, and the SOX regimen is the preferred first-line chemotherapy for the treatment of GC in Asia. Albumin-bound paclitaxel is considered a standard second-line treatment for gastric cancer. Clinical and experimental studies have demonstrated that nab-paclitaxel has a higher tumor retention rate and lower toxicity than solvent-based paclitaxel. Additionally, its antitumor activity surpasses that of the current standard chemotherapy drug oxaliplatin[5]. Triple chemotherapy has been believed to be more effective than double chemotherapy, resulting in higher tumor remission rates but also greater toxic side effects. However, these two outcomes can be achieved through adjustments in medication, dosage, and administration methods. In a study on albumin-bound paclitaxel combined with the FOLFOX regimen for gastric cancer, a complete remission rate of 16.3% and a partial remission rate of 38.8% were reported, but the degree of toxicity was high [6]. Sato *et al*[7], in a study on albumin-bound paclitaxel combined with a fluoropyrimidine-based chemotherapy regimen for gastric cancer, reported that the tumors regressed well, and the most common Grade 3/4 toxicities were anemia (8.8%), neutropenia (5.9%), loss of appetite (5.9%) and peripheral sensory neuropathy (5.9%). The study demonstrated that triweekly low-dose albumin-conjugated paclitaxel in fluoropyrimidine-based chemotherapy regimens is effective in treating progressive gastric cancer, is well tolerated, has an acceptable safety profile, and is feasible. Moreover, another Phase II trial of albumin paclitaxel combined with Tegio in the treatment of metastatic gastric cancer reported similar results, with an ORR of 58.9% and good efficacy; the main adverse effects were hematologic toxicity, gastrointestinal reactions, and peripheral neurotoxicity, which were tolerated by patients with a manageable safety profile[8]. In this study, we comprehensively compared the short-term and long-term efficacy and safety of the P-SOX and SOX chemo-

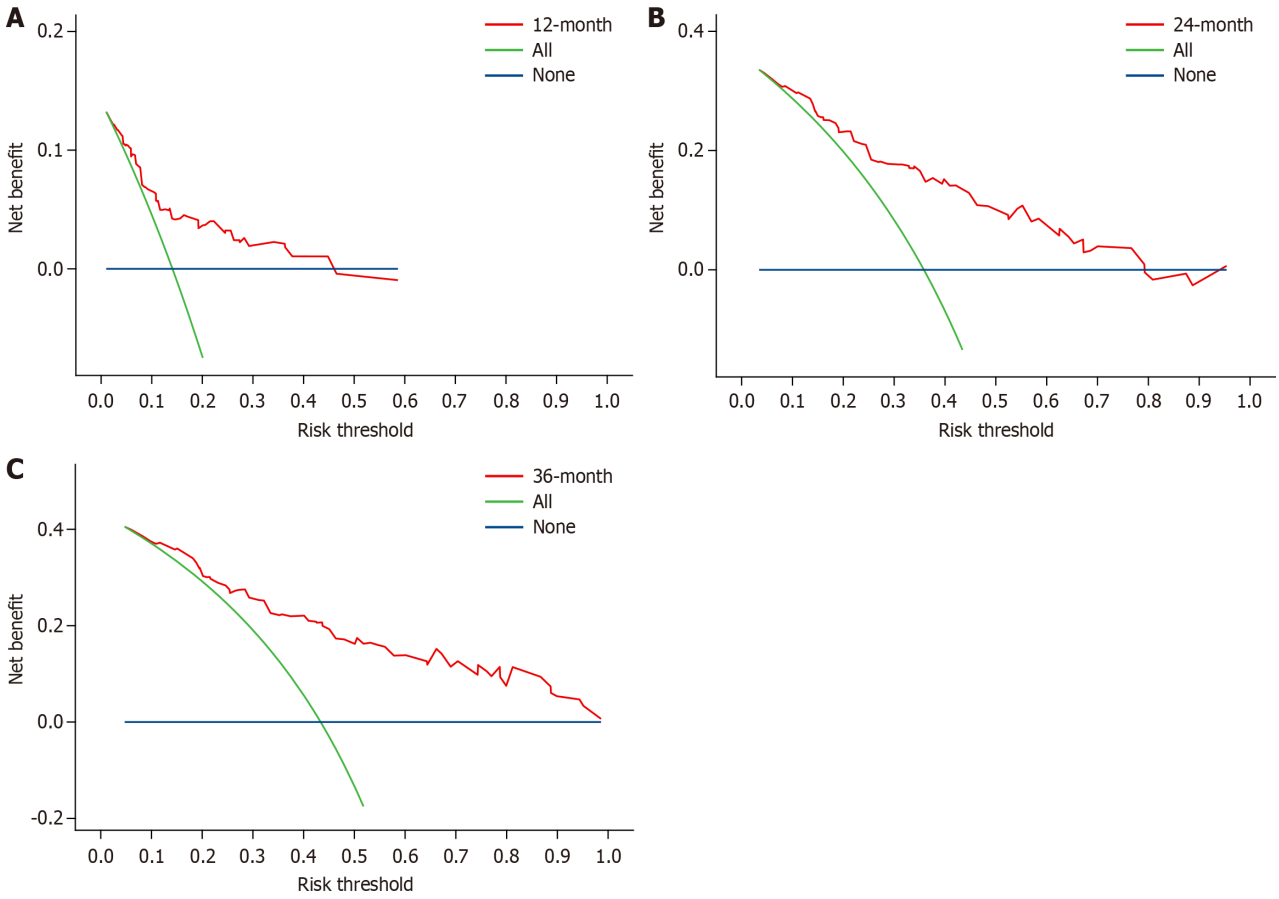

Figure 5 Decision curve analysis curves of progression-free survival. A: 1 year; B: 2 years; C: 3 years.

therapy regimens, investigated the factors associated with PFS, and developed a nomogram. The ORRs in the P-SOX and SOX groups were 61.1% and 52.9%, respectively, in the TRG assessment and 55.7% and 45.7%, respectively, in the RECIST 1.1 assessment. The perioperative efficacy in the P-SOX group was greater than that in the SOX group, although the difference was not statistically significant ($P > 0.05$). However, in terms of safety, most of the side effects were below grade 3. The incidence rates of gastrointestinal reactions, peripheral neurotoxicity and alopecia were greater in both groups, with a greater incidence and severity of alopecia in the P-SOX group ($P = 0.013$). Other adverse reactions did not significantly differ between the two groups, with the exception of alopecia. However, the incidence of hematological toxicity above Grade 2 was greater in the P-SOX group due to triple drug administration, resulting in more toxic side effects, which could be tolerated after symptomatic treatment[8,9].

Many scholars have studied the efficacy and safety of the combination of albumin-paclitaxel and Tegio in treating advanced gastric cancer and have confirmed that this regimen can improve PFS and OS to a certain extent in patients with advanced gastric cancer[1,8,9]. Furthermore, Masaki Nakamura and other Japanese researchers confirmed the good efficacy of the combination of P-SOX, and oxaliplatin in treating peritoneal metastasis of GC in a Phase 1 clinical trial[10]. The results of the Phase III PRODIGY study in South Korea suggested that the combination of paclitaxel, oxaliplatin, and S-1 had significant positive implications for the treatment of the Asian GC population. The efficacy and safety of this combination were found to be excellent, indicating its potential for widespread use[11]. This study revealed that the 3-year OS and PFS rates in the P-SOX and SOX groups were 64.4% *vs* 50.7% and 55.3% *vs* 44.3%, respectively, with no statistically significant difference observed in long-term efficacy between the two groups. However, the OS and PFS rates at 1, 2, and 3 years in the P-SOX group were greater than those in the SOX group. The data analysis results confirmed the effectiveness of the P-SOX regimen, which was found to improve patients' OS and PFS compared with the SOX regimen to a certain extent. In conclusion, we believe that the P-SOX regimen can significantly enhance both short- and long-term efficacy for gastric cancer patients compared with the SOX program. Although the P-SOX regimen has greater associated side effects than the SOX program, most patients can tolerate it.

The OS histogram of patients with gastric cancer constructed by Ma *et al*[12] (639 patients who underwent surgery combined with adjuvant chemotherapy) revealed that a late TNM stage was a significant prognostic factor correlated with decreased OS, and multidrug combined chemotherapy was associated with significantly greater OS than single-drug chemotherapy[12]. A retrospective analysis conducted in Japan revealed that the 5-year OS rates for patients who underwent surgical resection for GC with pathological stages IA, IB, II, IIIA, IIIB and IV GC were 91.5%, 83.6%, 70.6%, 53.6%, 34.8% and 16.4%, respectively[13]. Wang *et al*[14] utilized multicenter data to construct an OS histogram of patients with GC (838 patients who received neoadjuvant chemotherapy combined with surgery), and their findings indicate that patients with poor TRG regression have worse OS as the pathological T and N stage progresses[14]. Similarly, another

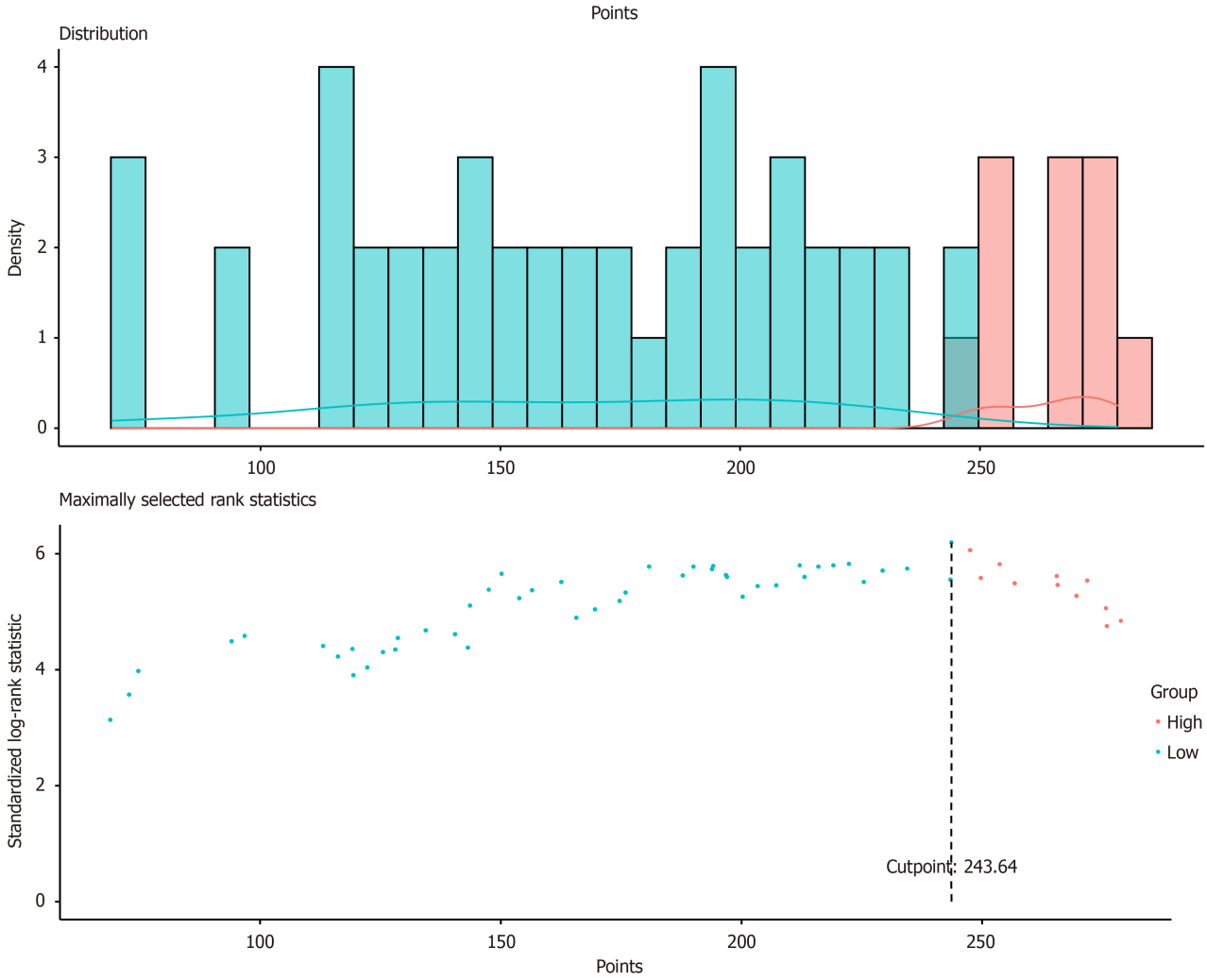

Figure 6 Kaplan-Meier survival curves for the verification of risk stratification.

study revealed that ypN stage ($P < 0.001$) and tumor pathological regression ($P = 0.004$) were significant risk factors for early recurrence of GC[15]. These findings collectively suggest that advanced TNM stage, ineffective perioperative chemotherapy, and failure to achieve tumor regression are the primary factors contributing to poor prognosis or recurrence.

The enlargement of a tumor indicates an increased likelihood of local or distant invasion and places a greater burden on the patient's body. In clinical practice, the T stage is closely associated with tumor size. As we all know, the TNM staging system is based on the TNM. TNM staging remains fundamental in the international consensus for assessing the prognosis and recurrence of tumor patients, with advanced stages typically indicating poor OS and PFS. Clearly, reducing tumor stage through preoperative chemotherapy can enhance patient prognosis and reduce recurrence rates, making tumor pathological or clinical response regression crucial. The degree of tumor differentiation reflects how similar tumor cells are to normal cells and serves as an important indicator for evaluating prognosis and malignant potential. It is generally believed that highly differentiated tumors have a more favorable prognosis.

An international multicenter study found that young age, high degree of differentiation, small tumor diameter, more intraoperative lymph nodes dissection, low pT stage, low pN stage, and adjuvant chemotherapy were positively correlated with PFS[16]. Another recent multicenter study conducted in China indicated that younger age, lower tumor site, lower T stage, and extensive lymph node dissection were identified as independent prognostic factors for GC[17].

Moreover, several studies of the OS of patients with gastric cancer in the SEER database, including both early- and advanced-stage patients, have yielded consistent results[18-20]. The evaluation of patient prognosis based on TNM stage has limitations in terms of accuracy and precision, leaving room for improvement. Our study, which is based on preoperative and postoperative chemotherapy combined with radical surgery using the P-SOX protocol, revealed that patients with GC who received effective perioperative chemotherapy (RECIST 1.1, TRG), had a tumor diameter ≤ 2cm, high degree of differentiation, and early cTNM stage experienced the highest PFS and derived the most benefit. Additionally, our model demonstrated excellent performance in both evaluation and internal verification. This serves as a valuable supplement to the TNM system and can assist clinicians in more specific prognostic evaluations.

Of course, the results of numerous studies on the prognosis of GC may exhibit inconsistencies due to variations in data sources, data analysis and processing methods, geographical regions, and other factors[21-27]. For instance, relevant research has indicated that the prognosis of GC is also associated with age, tumor location, lymph node invasion, ASA assessment, abnormal BMI, number of lymph nodes removed during surgery, chemotherapy regimen, postoperative

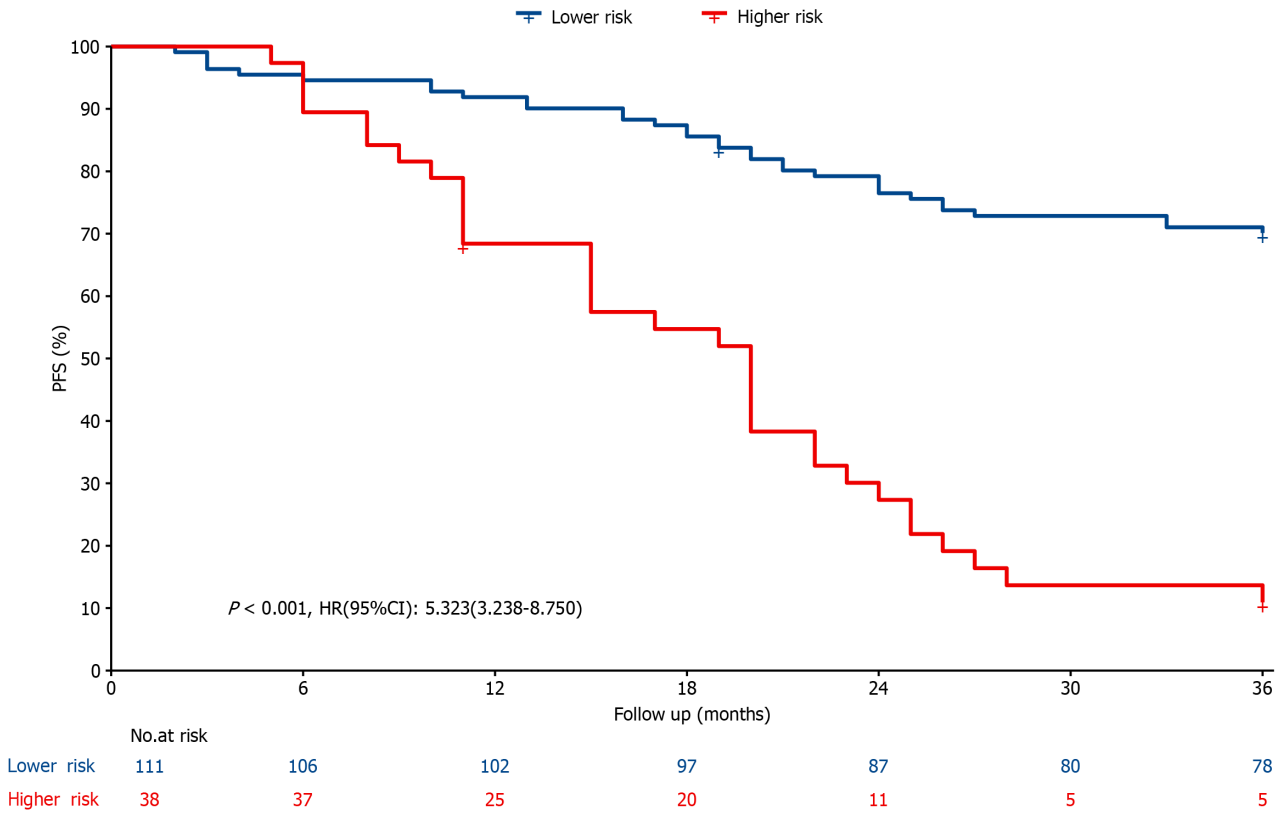

Figure 7 Kaplan-Meier survival curves for the verification of risk stratification. PFS: Progression-free survival; HR: Hazard ratio.

complications, and various other factors. Based on this situation, we expect numerous scholars to explore a convenient and recognized optimal standard with high accuracy in the future.

CONCLUSION

In comparison to the SOX regimen, the P-SOX regimen exhibits potential for enhancing both short-term and long-term efficacy while maintaining manageable tolerability of adverse reactions, thus holding promise as a prospective first-line chemotherapy protocol for GC. Patients with GC who have undergone effective perioperative chemotherapy (RECIST 1.1, TRG), exhibit tumor diameters ≤ 2cm, high degrees of differentiation, and early cTNM stages (undergoing P-SOX chemotherapy in combination with surgery) demonstrate a more favorable prognosis. The current study also has some limitations: Due to the retrospective nature of the study, some patients' case data were incomplete for various reasons and could not be included in the analysis, leading to an inability to accurately gain the rate of surgical resection after perioperative chemotherapy. As a result, the study only included patients who underwent both preoperative and postoperative chemotherapy in combination with radical surgery, which caused a certain degree of selection bias. The small sample size and single-center studies lack sufficient persuasiveness, thus warranting the need for future multi-center and large-scale phase III trials.

FOOTNOTES

Author contributions: Wang YC, Feng L, Wang GP designed the study and drafted the manuscript; Wang YC, Feng L, Wang GP, Guo C, Cai BJ, Song Y, Pan T, Lin BH, Li YD, Xiao JJ, and Yu PJ interpreted the data and prepared figures and table; Yu PJ designed and organized the study, interpreted the data and revised the manuscript. All authors read and approved the final manuscript.

Supported by The Department of Science and Technology of Qinghai Province, No. 2018-SF-113; and "Kunlun Talents-Plateau Famous Doctors" Project in Qinghai Province.

Institutional review board statement: The trial adhered to the Declaration of Helsinki and gained the approval of Review Committee of the Affiliated Hospital of Qinghai University ("Kunlun Talents-Plateau Famous Doctors" project in Qinghai Province) and it was also approved by the Clinical Medical Research Center of Qinghai Province, and all enrolled patients were given written informed consent (P-SL-2022-035).

Informed consent statement: All patients sign the informed consent form, and I will provide the main version of the informed consent form later.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: This article is willing to jointly promote the development of gastrointestinal surgery with the journal, while complying with all the regulations of the journal.

Country of origin: China

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S-Editor: Liu H
L-Editor: A
P-Editor: Wang WB

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