Original Article

The efficacy and safety of albumin-bound paclitaxel plus carboplatin as neoadjuvant therapy for potentially resectable lung squamous cell carcinoma: a real-world retrospective cohort study

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Background: In early and locally advanced stage non-small-cell lung cancer (NSCLC), surgery is the cornerstone of curative-intent treatments. And the addition of neoadjuvant or adjuvant chemotherapy can prolong overall survival (OS), albumin-bound paclitaxel plus carboplatin (ab-PC) as neoadjuvant therapy (NAT) has showed favorable effect for resectable lung squamous cell carcinoma (LSCC) with IIIA. However, to date, no study has investigated the efficacy of ab-PC as neoadjuvant chemotherapy in potentially resectable LSCC with IIIA–IIIB. This study aimed to evaluate the efficacy and safety of the regimen in potentially resectable LSCC.

Methods: Enrolled patients with stage IIIA and IIIB potentially resectable LSCC treated with neoadjuvant albumin-bound paclitaxel (nab-P; 100 mg/m^2, days 1, 8, and 15) and carboplatin (6 mg/mL/min, day 1) for two 21-day cycles at the Hunan Cancer Hospital between December 2017 and December 2019. The primary endpoint was the surgery conversion rate (SCR). Secondary endpoints included objective response rate (ORR), margin-free (R0) resection, major pathological response (mPR), and safety.

Results: In total, 49 patients were included in the study, with an overall response rate (ORR) of 67% (33/49). The SCR was 67% (33/49). Only 31 patients underwent surgery eventually, and R0 resection was achieved in 30 patients. Further, 4 (13%) and 11 (35%) of the 31 patients had a pathological complete response (pCR) and mPR, respectively. In total, 23 patients experienced treatment-related adverse events (TRAEs). The most common TRAE was liver disfunction (9 patients, 18%). Only 1 patient (2%) experienced a grade ≥3 TRAE of leukopenia. There were no treatment-related deaths or treatment discontinuations.

Conclusions: In this study, we found a high SCR (67%) and mPR (35%) after ab-PC treatment for stage IIIA and IIIB potentially resectable LSCC. ab-PC maybe considered a neoadjuvant chemotherapy option for potentially resectable LSCC patients.

Keywords: Potentially resectable lung squamous cell carcinoma (potentially resectable LSCC); neoadjuvant chemotherapy; neoadjuvant albumin-bound paclitaxel (nab-P); carboplatin; pathological response

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Introduction

Lung cancer is considered the most common cause of cancer death (1). Non-small cell lung cancer (NSCLC) accounts for nearly 85% of lung cancer cases (2). Lung squamous cell carcinoma (LSCC) is a common subtype of NSCLC. It is estimated that there are over 400,000 new LSCC cases worldwide each year (3). Chemotherapy, radiotherapy, or surgery are common treatments for LSCC. Stage III NSCLC patients are highly heterogeneous and commonly need individual treatment. The patients with stage III can be classified into operable, potentially operable, and inoperable according to the mass size, location, and lymph node. Although surgery is a curative method, only surgery is typically recommended for stage III patients due to high proportion of local recurrence and distant metastases (4,5). For potentially resectable patients, interdisciplinary multimodality management was usually performed and lack of standard therapy.

Neoadjuvant therapy (NAT) is defined as either chemotherapy or radiation administered before surgery, and can downstage tumors and prolong the survival of lung cancer patients with resection (6,7). It may imply that NAT can transform lung cancer patients from potentially resectable to resectable, similarly. Albumin-bound paclitaxel (ab-P), which is a novel solvent-free nanomedicine of taxane, has a favorable tumor-specific killing effect and exhibits minimal toxicity to normal tissues (8). In LSCC patients, ab-P plus platinum is recommend as the first-line treatment and has excellent anti-tumor activity (9,10). Therefore, for stage IIIA and IIIB potentially resectable LSCC, ab-P plus platinum as NAT may be a potentially treatment. However, studies on neoadjuvant ab-P plus carboplatin (nab-PC) as a type of NAT are limited, and the response of potentially resectable LSCC patients to nab-PC is still unknown. We conducted a retrospective study to examine the efficacy and safety of nab-PC in locally advanced potentially resectable LSCC patients. We present the following article in accordance with the STROBE reporting checklist (available at https://tlcr.amegroups.com/article/view/10.21037/tlcr-22-252/rc).

Methods

Patients

This study was carried out in accordance with the principles of the Declaration of Helsinki (as revised in 2013) and was approved by Hunan Cancer Hospital Institutional Review Board (IRB) Committee (No. 274). All the patients signed the informed consent. Patients diagnosed with LSCC were enrolled from Hunan Cancer Hospital between December 2017 to December 2019. The inclusion criteria included ≥18 years of age; Potentially resection (definition: stage IIIA–IIIB patients with more than one mediastinal lymph node station involved, or large masses with suspected infiltration of vital organs/who are difficult to resection as determined by discussion with team of surgeons); Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; two-cycle ab-P plus platinum as pre-operative treatment.

Treatment and assessment

All patients received nab-P (100 mg/m^2 on days 1, 8, and 15) plus carboplatin (6 mg/mL/min on day 1) as NAT for a 21-day cycle. Definitions for T (primary tumor), N (regional lymph nodes), stage and residual tumor after treatment were descripted according to the 8th edition Lung Cancer Stage Classification (11). Changing tumors were assessed using computed tomography (CT) per the Response Evaluation Criteria in Solid Tumors (RECIST, version 1.1) within 21 days of the 2 NAT cycles. The surgery conversion rate (SCR) was defined the proportion of patients from potentially resection to resection. The overall response rate (ORR) was calculated as the total percentage of patients with a complete response (CR) or partial response (PR). The disease control rate (DCR) was calculated as the total percentage of patients with a CR, PR, or stable disease (SD). Adverse events were documented and graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE, version 4.0). The whole treatment pathway should be discussed into a multidisciplinary tumor board with the active participation of two experienced thoracic surgeon. After surgery, the tumors were representatively sampled with 1 section per centimeter diameter of the tumor, and reviewed by two pathologists by light microscopy for histologic diagnosis and to determine the extent of the effect of the treatment, including necrosis, fibrosis, and inflammation (12). Pathological CR (pCR) was defined as an absence of any viable tumor cells, and major pathological response (mPR) was defined as no more than 10% residual viable tumor.

Statistical analysis

A descriptive analysis was conducted for the patients

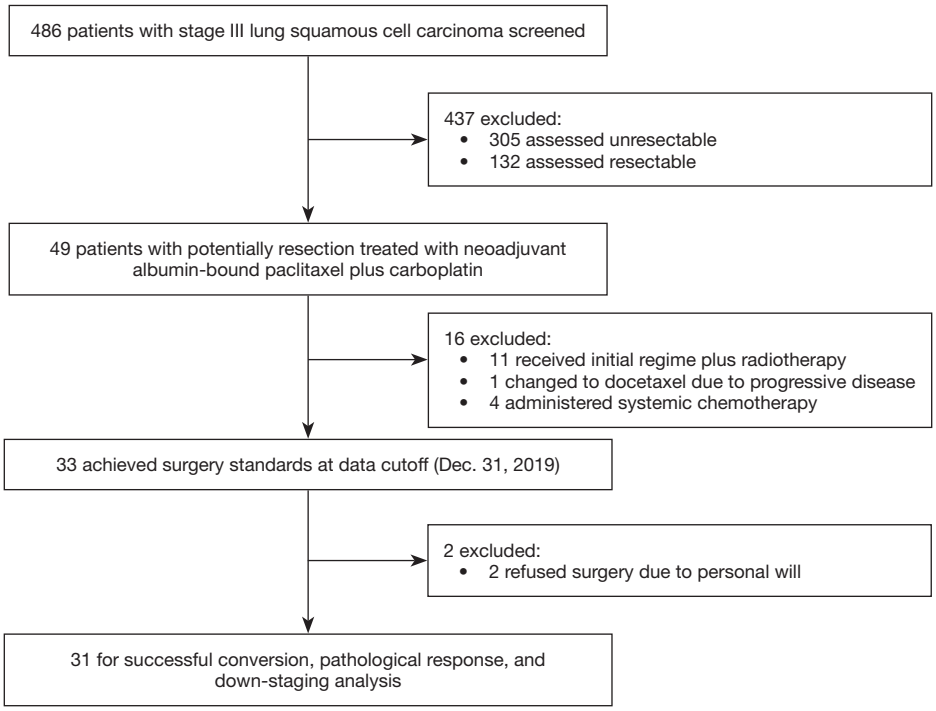

Figure 1 The diagram of this study.

baseline characteristics, surgical outcomes and safety evaluation. Continuous variables were expressed as medians (ranges). Categorical variables were expressed as numbers (percentages). The comparisons of baseline characteristics of pathological response subgroups were conducted with the Fisher's exact test. The relationship between the status clinical response and pathological response were conducted with Pearson correlation coefficient analysis. The statistical analyses were performed using SPSS version 22. The P values are two-sided, and the significance level was set at 0.05 for all analyses.

Results

Patient characteristics

In total, 486 patients with stage IIIA–IIIB LSCC who had been treated at the Hunan Cancer Hospital were retrospectively screened. Among them, 437 patients who had a tumor that was initially considered resectable (n=132) or unresectable (n=305) were excluded. Thus, 49 patients were included in this retrospective cohort study (see *Figure 1*). Of the 49 patients, 42 were male (86%) and 7 were female (14%). The patients had a median age of 51 (range, 31–75) years, and an ECOG performance status of 0 or 1. The majority of patients were smoking (40, 82%), stage IIIA (55%) and N2 status (72%) Comorbidities were observed in 17 of the 49 patients. The most frequent comorbidities were chronic obstructive pulmonary disease (6% of the 49 patients) and hypertension (6% of the 49 patients) (see *Table 1*).

Efficacy

All 49 patients were eligible for treatment response evaluations. Of the 49 patients, 33 achieved a PR, but none achieved a CR. The ORR was 67%. Additionally, 15 patients (31%) achieved SD, and had a DCR of 98%. Only 1 patient (2%) had progressive disease (PD) during NAT (see *Figure 2A*).

In total, 33 (67%) patients were considered eligible for surgery after 2-cycle of NAT, but 2 of those patients refused surgery. Of the 2 patients, 1 patient refused surgery due to the cost, and the other due to his personal wishes. Ultimately, 31 patients received surgery, of whom 30 patients received R0 resection. The clinical response results of the 31 patients who underwent surgery are shown in *Figure 2B*. Notably, 22 (71%) of the 31 patients achieved a PR. The most common surgery procedure was thoracotomy

Table 1 Demographic and patient characteristics

Characteristics	Patients (n=49)
Median age (years), median [range]	51 [31–75]
Sex, n [%]	
Male	42 [86]
Female	7 [14]
Smoking status, n [%]	
Non-smoker	9 [18]
Smoker	40 [82]
ECOG, n [%]	
0	22 [45]
1	27 [55]
Comorbidities, n [%]	
Yes	17 [35]
Chronic obstructive pulmonary disease	3 [6]
Diabetes	2 [4]
Hypertension	3 [6]
Other	9 [18]
No	32 [65]
Stage, n [%]	
IIIA	27 [55]
IIIB	22 [45]
Baseline N, n [%]	
0	6 [12]
1	8 [16]
2	35 [72]

ECOG, Eastern Cooperative Oncology Group.

(21, 68%) followed by video-assisted thoracoscopic surgery (10, 32%). In total, 23 patients (74%) underwent lobectomy and the remaining 8 (26%) underwent pneumonectomy. Of the patients, 21 (68%) patients had lower pathological TNM stage experienced NAT. Of the patients, 8 (36%) of 22 had nodal clearing (downstaging from N2 to N0) at the time of surgery, 9 (41%) had nodal downstaging N2 to N1, and 1 (17%) of 6 had nodal downstaging of N1 to N0.

The median length of stay for operations was 14 (range, 7–43) days, and the mean operation time was 153 (range, 61–208) minutes (see *Table 2*). Of the 16 patients (7 with SD, 8 with PR, 1 with PD) who were considered unresectable due to location and size of changing mass, 11 received adjuvant chemoradiation, 4 continued to receive nab-PC as systemic chemotherapy, and 1 with PD was changed to docetaxel (75 mg/m^2 every 3 weeks). Of the 2 patients who met the surgery standard but refused surgery, 1 underwent adjuvant chemoradiation and the other continued nab-PC treatment.

In total, 11 (35%) of 31 patients achieved a mPR. Of the 11 patients who achieved a mPR, 5 achieved a pCR (see *Figure 2C*). The patients that achieved a mPR had an 82% ORR. There was no correlation between the radiographic objective response and mPR of the resected patients (correlation coefficient =0.54; P<0.05; see *Figure 2D*). And the pathology response was unrelated to gender, histology type, stage, or smoking history (see *Table 3*).

Safety

The adverse events are summarized in *Table 4*. Most of the adverse events were grades 1–2. In total, 23 patients experienced treatment-related adverse events (TRAEs), of whom 7 (14%) had hematologic toxicities, 1 (2%) had grade 4 leukopenia but subsequently continued to receive the common dose of nab-PC after the treatment of granulocyte-macrophage colony-stimulating factor, 2 (4%) had grades 1–2 leukopenia toxicity, and 4 (8%) had grades 1–2 anemia but continued the NAT. The non-hematologic toxicities included liver disfunction (9, 18%), nausea or vomiting (2, 4%), diarrhea (1, 2%), fatigue (1, 4%), and sinus tachycardia (1, 2%). No grade 5 hematologic or non-hematologic toxicities were observed. Three of 31 patients with resection had post-operative infection and nobody developed death within 30- or 90-day of surgery.

Particular case report

In this study, one 40-year-old female patient was diagnosed with stage IIIB (T3N2M0) LSCC. The results of the thoracic CT scan showed a 5.2×2.3-cm lung mass adjacent to the heart. Based on these results, the patient was not considered a suitable candidate for surgery (see *Figure 3*). She received 2-cycle of nab-PC as neoadjuvant regime. After 2 months, the tumor adjacent to the heart achieved a PR. The mass was then wholly resected by video-assisted thoracoscopic surgery. The pathology response was evaluated as a pCR with ypT0N0M0 (see *Figure 3*).

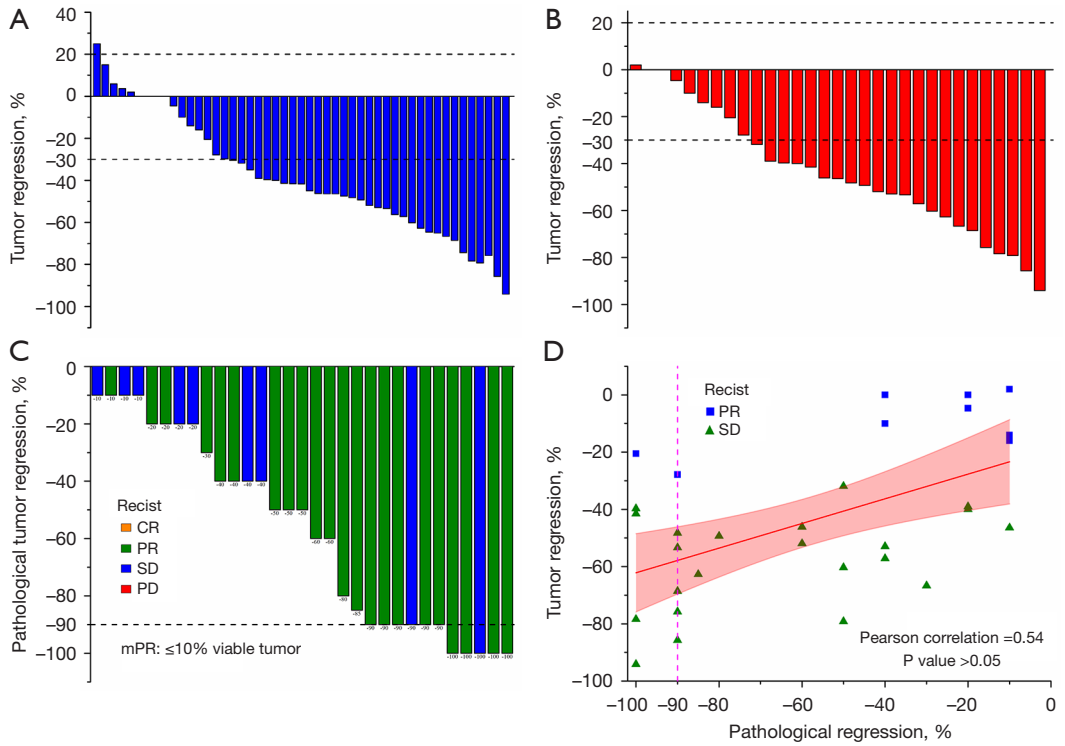

Figure 2 The clinical and pathological assessment of response to NAT. (A,B) Waterfall plots of radiographic percentage changes in overall (n=49) or surgical population (n=31) tumor size from the baseline after 2-cycle of NAT with nab-PC. The dashed black line at the 20%-point depicts the cutoff for PD. The dashed black line at the −30%-point depicts the cutoff for PR. (C) The proportion of mPR/no mPR (≤10% viable tumor/>10% viable tumor) and pCR/no pCR (0% viable tumor/>0% viable tumor) in resected patients after neoadjuvant nab-PC. (D) The correlation between the radiographic response and the pathologic response. The two-sided P value from Pearson correlation coefficient analysis. CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; mPR, major pathological response; NAT, neoadjuvant therapy; nab-PC, neoadjuvant albumin-bound paclitaxel plus carboplatin; pCR, pathological complete response.

Discussion

For patients with potentially rececTable stage III NSCLC, receiving curative surgery is difficult limited with the surgeon and the tumor's location. Here, our study showed that neoadjuvant nab-PC was a potentially feasible treatment to provide the opportunity for complete surgical resection for these patients.

In localized or loco-regional NSCLC patients, neoadjuvant chemotherapy has shown a significant survival advantage over surgery alone with a hazard ratio of 0.8 and a 5-year overall survival (OS) rate improvement of 5.4% (13). However, a series of clinical trials have proven that while a paclitaxel- and carboplatin-based neoadjuvant approach has OS or disease-free survival (DFS) benefits, the toxicity and chemotherapy sensitivity may limit the utility of the traditional combination of paclitaxel and carboplatin (14). nab-P, which is a novel solvent-free nanomedicine of taxane, has already shown potent anti-tumor activity and has been widely used in NSCLC (15-17). Previous research studies have assessed the efficacy of nab-PC in advanced LSCC patients, including stage IIIA–IIIB patients, and found ORRs of 41–46% (9,18,19). However, in our study, the ORR reached 65.31%. The differences in the ORRs may be related to the limited numbers patients.

All 49 patients who underwent high risk of surgery were evaluated by a surgeon at enrollment. After 2 cycles of nab-PC, 33 (67%) changed from high- to low-risk surgery candidates. Of the 22 patients with N2 at the baseline, 8 (36%) showed nodal clearing. The mPR results are also encouraging, and reached up to 35%. mPR is an ideal endpoint for characterizing the anti-tumor activity of neoadjuvant chemotherapy and serves as a predictor of survival (12,20,21). The pathological response of nab-PC as a NAT has been little investigated in LSCC patients. In our

Table 2 Surgical outcomes of resected patients

Surgical outcomes	Patients (n=31)
Median hospital days in surgery, median [range]	14 [7–43]
Median operation time (minutes), median [range]	153.5 [61–208]
Surgical procedure, n [%]	
Thoracotomy	21 [68]
Video-assisted thoracoscopic surgery	10 [32]
Extent of resection, n [%]	
Lobectomy	23 [74]
Pneumonectomy	8 [26]
R0 resection, n [%]	
Yes	30 [97]
No	1 [3]
Down TNM stage, n [%]	
Yes	21 [68]
No	10 [32]
Down N stage, n/N [%]	
N2–N0	8/22 [36]
N2–N1	9/22 [41]
N1–N0	1/6 [17]
Surgical complications, n [%]	
Yes	4 [13]
No	27 [87]
Pulmonary infection, n [%]	4 [13]

report, we found a mPR and pCR rate of 35% and 13%, respectively, which is consistent with the finding of previous studies on neoadjuvant chemotherapy in stage III NSCLC patients (22,23). Thus, patients with potentially resectable tumors could benefit from neoadjuvant chemotherapy with manageable toxic effects, and a subsequent surgery could provide a promising treatment.

Recent developments in immunotherapy have shown that it produces a robust response in advanced NSCLC patients (24,25). Further, early research has found that neoadjuvant immune checkpoint inhibitor (ICI) monotherapy has a survival benefit, and that 19–45% of patients achieved a mPR and 5–15% achieved a pCR (26-28). Further, research has shown that more than half of enrolled patients with resectable NSCLC who received a combination of neoadjuvant immunotherapy and chemotherapy achieved a

Table 4 Neoadjuvant adverse events

Any TRAE	G1–2, n [%]	≥G3, n [%]
Diarrhea	1 [2]	0
Liver dysfunction	9 [18]	0
Nausea and vomiting	2 [4]	0
Fatigue	2 [4]	0
Leukopenia	2 [4]	1 [2]
Anemia	4 [8]	0
Sinus tachycardia	2 [4]	0

TRAE, treatment-related adverse event.

Table 3 Patients' characteristic correlations between mPR and non-mPR at the baseline

Characteristics	mPR (n=11)	Non-mPR (n=20)	P value
Age (years), median [IQR]	54 [40–70]	56 [43–67]	
Sex, n			1
Male	10	17	
Female	1	3	
Smoking history, n			0.631
Yes	10	16	
No	1	4	
Clinic stage, n			1
IIIA	7	13	
IIIB	4	7	

mPR, major pathological response.

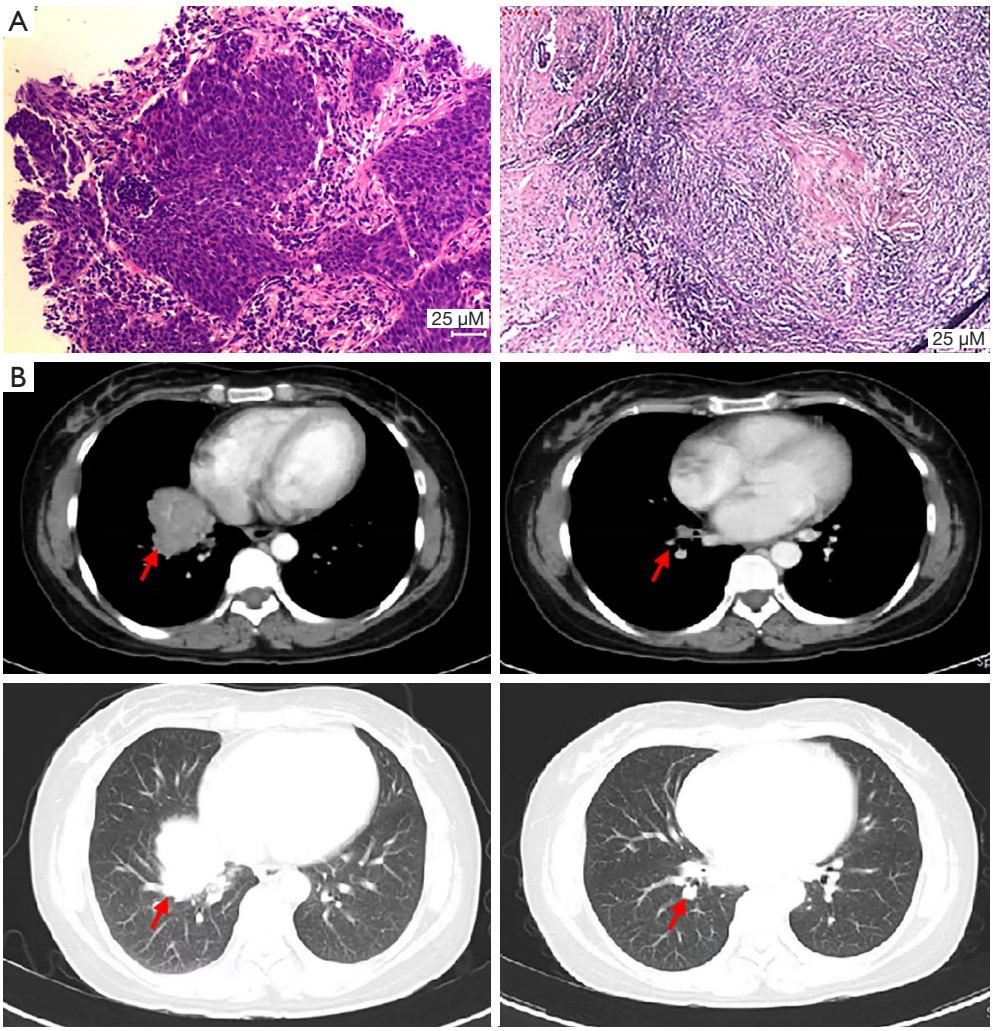

Figure 3 Special case report: pathological images and radiological evaluation of the resected patient before and after 2-cycle of nab-PC combination therapy. (A) The diagnostic (left) and resected (right) tissue of HE staining of patient [bars: 25 μm (10×10)]; (B) the radiological evaluation before (left) and after (right) neoadjuvant treatment. The red arrows show the mass. nab-PC, neoadjuvant albuminbound paclitaxel plus carboplatin; HE, hematoxylin-eosin.

mPR (29,30). Thus, chemotherapy plus ICIs as NAT show great promise in the treatment of patients with potentially resectable LSCC.

The present study had several limitations. First, as a retrospective study, bias could not be avoided. Second, as the sample size was small, a multivariable analysis was not conducted to adjust for confounders. Third, as only patients treated at the Hunan Cancer Hospital were included in the study, the results may lack generalizability to other regions. Forth, as only short-term efficacy endpoints (SCR, ORR, and mPR), this study may not show these patients survival benefits. This study still implied that nab-PC may be considered a neoadjuvant regimen option for potentially resectable LSCC, and has promising anti-tumor activity and acceptable safety. And the ab-PC plus immunotherapy may be a promising treatment for potentially resectable LSCC patients as NAT.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tlcr.amegroups.com/article/view/10.21037/tlcr-22-252/rc

Data Sharing Statement: Available at https://tlcr.amegroups.com/article/view/10.21037/tlcr-22-252/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tlcr.amegroups.com/article/view/10.21037/tlcr-22-252/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was carried out in accordance with the principles of the Declaration of Helsinki (as revised in 2013) and was approved by Hunan Cancer Hospital Institutional Review Board (IRB) Committee (No. 274). All the patients signed the informed consent.

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