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Efficacy and Safety of Nab-Paclitaxel Plus Radiotherapy for Older Patients with Unresectable Stage III Lung Squamous Cell Carcinoma: A Retrospective Cohort Study

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Abstract

Objective

To evaluate the efficacy and safety of nab-paclitaxel plus radiotherapy in older patients with unresectable stage III lung squamous cell carcinoma, with radiotherapy alone and nab-paclitaxel plus platinum and radiotherapy serving as comparator groups.

Methods

This single-center retrospective cohort study included patients aged 65 years or older treated between January 2021 and December 2025. The two comparisons were analyzed separately using propensity score overlap weighting. Survival outcomes were estimated using weighted Cox models, and grade ≥ 3 adverse events were analyzed using weighted modified Poisson regression.

Results

Among 291 patients, 44 received radiotherapy alone, 40 received nab-paclitaxel plus radiotherapy, and 207 received nab-paclitaxel plus platinum and radiotherapy. Compared with radiotherapy alone, nab-paclitaxel plus radiotherapy was associated with longer progression-free survival (HR, 0.50; 95% CI, 0.26–0.95; P = 0.034), whereas no significant difference in overall survival was detected (HR, 0.54; 95% CI, 0.25–1.17; P = 0.118). Compared with the platinum-containing regimen, no significant differences were detected in progression-free survival (HR, 1.09; 95% CI, 0.59–2.02) or overall survival (HR, 1.14; 95% CI, 0.54–2.39). Grade ≥ 3 hematologic toxicity was less frequent with the platinum-sparing regimen (17.0% vs 45.7%; RR, 0.37; 95% CI, 0.16–0.88; FDR-adjusted P = 0.040).

Conclusion

Among older patients with unresectable stage III lung squamous cell carcinoma, nab-paclitaxel plus radiotherapy was associated with longer progression-free survival than radiotherapy alone. Compared with nab-paclitaxel plus platinum and radiotherapy, this regimen showed no statistically significant difference in survival outcomes and was associated with a lower incidence of grade ≥ 3 hematologic toxicity.

Clinical trial registration

Not applicable. This study was a retrospective cohort study and did not involve prospective assignment of participants to an intervention.

Introduction

Lung squamous cell carcinoma is a major subtype of lung cancer. For patients with unresectable stage III disease, treatment requires multidisciplinary management because of clinical heterogeneity [1]. In medically fit patients, concurrent platinum-based chemoradiotherapy is the standard initial treatment, and consolidation immunotherapy is recommended for eligible patients without disease progression after chemoradiotherapy [2–4]. However, concurrent platinum-based chemoradiotherapy can be difficult to deliver in older patients because treatment tolerance varies with physiologic reserve and comorbidities. This issue is clinically relevant because most patients with lung cancer are diagnosed at 65 years of age or older [5]. Older patients also remain underrepresented in clinical trials, which limits the evidence available to guide treatment decisions in this population [6–8].

Radiotherapy alone may provide insufficient disease control in selected older patients. Randomized and pooled evidence suggests that adding chemotherapy to radiotherapy improves survival in older patients with stage III NSCLC [9,10]. However, platinum-based chemoradiotherapy is associated with increased severe toxicity, particularly hematologic toxicity [9,11,12]. Less intensive concurrent regimens therefore warrant evaluation for patients who may not tolerate standard platinum-based treatment.

Nab-paclitaxel has shown antitumor activity in lung squamous cell carcinoma [13]. Early-phase studies have evaluated nab-paclitaxel-based concurrent chemoradiotherapy for locally advanced NSCLC. However, these studies were small, mostly single-arm, and generally combined nab-paclitaxel with a platinum agent [14–16]. Comparative evidence for nab-paclitaxel plus radiotherapy without platinum remains limited, particularly in older patients with unresectable stage III lung squamous cell carcinoma.

Comparative evidence for nab-paclitaxel plus radiotherapy remains limited, particularly in older patients with unresectable stage III lung squamous cell carcinoma. We therefore conducted a retrospective cohort study with two prespecified comparisons: nab-paclitaxel plus radiotherapy versus radiotherapy alone, and nab-paclitaxel plus radiotherapy versus nab-paclitaxel plus platinum and radiotherapy. We evaluated progression-free survival, overall survival, and treatment-related adverse events to provide additional clinical evidence for treatment decision-making in this population.

Materials and Methods

Study design and patients

This single-center retrospective cohort study included patients aged 65 years or older with unresectable stage III lung squamous cell carcinoma who received first-line treatment at Shandong Cancer Hospital between January 2021 and December 2025. Clinical, treatment, imaging, laboratory, and follow-up data were obtained from institutional databases. The Ethics Committee of Shandong Cancer Hospital approved the study (Approval No. SDTHEC 202606054) and waived written informed consent. The study was reported according to the STROBE statement [17].

Eligible patients had pathologically confirmed lung squamous cell carcinoma, unresectable stage III disease, no previous resection of the primary tumor, and first-line thoracic intensity-modulated radiotherapy. Patients were excluded for distant metastasis, a previous malignancy, palliative radiotherapy, treatment outside the three prespecified groups, or missing key baseline or outcome data.

Patients were classified as receiving radiotherapy alone, nab-paclitaxel plus radiotherapy, or nab-paclitaxel plus platinum and radiotherapy. Systemic treatment was considered concurrent when administered during thoracic radiotherapy.

Treatment and covariates

All patients received thoracic intensity-modulated radiotherapy. Treatment planning, dose, and systemic therapy were individualized in routine practice. Total radiation dose was categorized as 40–<60 Gy or ≥ 60 Gy.

Patients in the platinum-sparing group received nab-paclitaxel during radiotherapy without platinum. The most common schedule was a fixed dose of 200 mg on days 1 and 8, although alternative schedules were permitted. Patients in the platinum-containing group received nab-paclitaxel with cisplatin or carboplatin during radiotherapy.

Prespecified covariates were age, sex, Eastern Cooperative Oncology Group performance status, smoking history, drinking history, T stage, N stage, immunotherapy use, and radiation dose. Age was analyzed continuously. Performance status was categorized as < 2 or ≥ 2, T stage as T1–T2 or T3–T4, N stage as N0–N1 or N2–N3, and radiation dose as 40–<60 Gy or ≥ 60 Gy.

Outcomes

The primary outcomes were progression-free survival and overall survival. Available serial imaging studies were retrospectively reviewed, and disease progression was determined according to the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1 [18]. Imaging follow-up was not protocol-defined and was performed according to routine clinical practice. Progression-free survival was measured from the initiation of first-line treatment to disease progression or death, whichever occurred first. Overall survival was measured from the same date to death. Patients without an event were censored at the last documented follow-up.

The secondary outcome was treatment-related toxicity. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0. The composite grade ≥ 3 hematologic toxicity endpoint included leukopenia, neutropenia, decreased hemoglobin, or thrombocytopenia. Patients with multiple hematologic events were counted once in the composite endpoint.

Statistical analysis

The two comparisons were analyzed separately. Continuous variables were summarized using means and standard deviations or medians and interquartile ranges. Categorical variables were reported as counts and percentages. Analyses were restricted to complete cases, and missing data were not imputed.

Propensity scores were estimated separately using logistic regression and represented the probability of receiving nab-paclitaxel plus radiotherapy. Both models included age, sex, performance status, smoking history, drinking history, T stage, N stage, immunotherapy use, and radiation dose. Overlap weighting was used to balance measured baseline covariates [19]. Patients receiving nab-paclitaxel plus radiotherapy were weighted by one minus the propensity score, and comparison-group patients were weighted by the propensity score. Balance was assessed using absolute standardized mean differences, with values below 0.10 considered acceptable. Propensity score distributions, Love plots, and effective sample sizes were also examined.

Unweighted and overlap-weighted survival curves were estimated using the Kaplan–Meier method. Risk tables showed the original unweighted numbers at risk. Treatment effects were estimated using overlap-weighted marginal Cox models with robust standard errors. Hazard ratios and 95% confidence intervals were reported. The proportional hazards assumption was evaluated using scaled Schoenfeld residuals, and median follow-up was estimated using the reverse Kaplan–Meier method.

Sensitivity analyses used multivariable Cox models in the original cohorts and adjusted for treatment group, age, performance status, radiation dose, and immunotherapy use.

Crude and overlap-weighted adverse-event incidences were calculated. Relative risks were estimated using overlap-weighted modified Poisson regression with robust standard errors [20]. Relative risks were not estimated when either group had no events. Safety P values were adjusted using the Benjamini–Hochberg false discovery rate procedure [21]. All tests were two-sided. For survival analyses, a nominal P value below 0.05 was considered statistically significant. For safety analyses, statistical significance was assessed using the FDR-adjusted P value. Analyses were performed using R version 4.4.0.

Results

Patient selection and study population

A total of 7,702 patients aged 65 years or older with cancer who received radiotherapy at Shandong Cancer Hospital between January 2021 and December 2025 were screened. Patients were excluded for a diagnosis other than lung squamous cell carcinoma (n = 6,841), disease other than unresectable stage III lung cancer (n = 329), treatment outside the three prespecified groups (n = 204), missing key data (n = 36), or a prior malignancy (n = 1). The final cohort included 291 patients (Fig. 1).

Among 291 patients, 44 received radiotherapy alone, 40 received nab-paclitaxel plus radiotherapy, and 207 received nab-paclitaxel plus platinum and radiotherapy. Comparison 1 compared radiotherapy alone with nab-paclitaxel plus radiotherapy, whereas Comparison 2 compared nab-paclitaxel plus radiotherapy with nab-paclitaxel plus platinum and radiotherapy. Comparison 1 included 84 patients, and Comparison 2 included 247 patients.

Comparison 1 included 52 progression-free survival (PFS) events and 37 deaths. Comparison 2 included 134 PFS events and 81 deaths. Median follow-up was 24.2 months (95% CI, 19.3–27.9) and 28.2 months (95% CI, 25.3–31.7), respectively. Further follow-up and event data are provided in Supplementary Table S6.

Baseline characteristics and covariate balance

Baseline characteristics are presented in Table 1. Before weighting, age showed the largest imbalance in both comparisons. In Comparison 1, mean age was 78.7 years with radiotherapy alone and 75.5 years with nab-paclitaxel plus radiotherapy (absolute standardized mean difference [SMD], 0.642). In Comparison 2, mean age was 75.5 years with nab-paclitaxel plus radiotherapy and 69.0 years with the platinum-containing regimen (absolute SMD, 1.693).

After overlap weighting, all prespecified covariates had absolute SMDs below 0.10 (Fig. 2). Propensity score distributions are shown in Supplementary Figure S1. Effective sample sizes were 33.21 and 33.00 in Comparison 1 and 28.05 and 73.54 in Comparison 2 (Supplementary Table S6).

Survival outcomes in Comparison 1

Nab-paclitaxel plus radiotherapy was associated with a lower hazard of progression or death than radiotherapy alone (HR, 0.50; 95% CI, 0.26–0.95; P = 0.034) (Fig. 3A and Table 2). The OS difference was not statistically significant (HR, 0.54; 95% CI, 0.25–1.17; P = 0.118) (Fig. 3B and Table 2).

The proportional hazards assumption was not violated for PFS (P = 0.800) or OS (P = 0.880) (Supplementary Table S5). In the unweighted multivariable analyses, the adjusted HRs were 0.59 for PFS (95% CI, 0.31–1.14; P = 0.117) and 0.53 for OS (95% CI, 0.24–1.15; P = 0.109) (Table 2). Unweighted Kaplan–Meier analyses showed similar patterns (Supplementary Figure S2).

Survival outcomes in Comparison 2

No statistically significant difference was detected between nab-paclitaxel plus radiotherapy and the platinum-containing regimen. The overlap-weighted HR was 1.09 for PFS (95% CI, 0.59–2.02; P = 0.772) and 1.14 for OS (95% CI, 0.54–2.39; P = 0.736) (Fig. 3C and D; Table 2).

The proportional hazards assumption was not violated for PFS (P = 0.541) or OS (P = 0.066) (Supplementary Table S5). In the unweighted multivariable analyses, the adjusted HRs were 1.27 for PFS (95% CI, 0.72–2.26; P = 0.412) and 1.17 for OS (95% CI, 0.55–2.52; P = 0.682) (Table 2). Unweighted Kaplan–Meier analyses also showed no significant differences (Supplementary Figure S3).

Treatment-related adverse events

Comparison 1

Any grade ≥ 3 treatment-related adverse event occurred in 11 of 40 patients (27.5%) receiving nab-paclitaxel plus radiotherapy and 8 of 44 patients (18.2%) receiving radiotherapy alone. The overlap-weighted incidences were 25.9% and 18.6%, respectively (RR, 1.40; 95% CI, 0.56–3.46; nominal P = 0.474; FDR-adjusted P = 0.857) (Supplementary Table S2).

At least one grade ≥ 3 hematologic adverse event occurred in 8 of 40 patients (20.0%) receiving nab-paclitaxel plus radiotherapy and 1 of 44 patients (2.3%) receiving radiotherapy alone. The overlap-weighted incidences were 20.9% and 1.7%, respectively (RR, 12.02; 95% CI, 1.50–96.38; nominal P = 0.022; FDR-adjusted P = 0.087) (Table 3). The association did not remain statistically significant after FDR adjustment.

Weighted incidences are presented as nab-paclitaxel plus radiotherapy versus the corresponding comparator. An RR below 1 favors nab-paclitaxel plus radiotherapy. NE indicates that the RR was not estimable because one group had no events.

Abbreviations: CI, confidence interval; FDR, false discovery rate; NE, not estimable; RR, risk ratio; RT, radiotherapy.

Relative risks for individual hematologic adverse events could not be estimated because one group had no events. No significant differences were detected in grade ≥ 3 radiation esophagitis or radiation pneumonitis (Supplementary Table S2).

Comparison 2

At least one grade ≥ 3 hematologic adverse event occurred in 8 of 40 patients (20.0%) receiving nab-paclitaxel plus radiotherapy and 112 of 207 patients (54.1%) receiving the platinum-containing regimen. The overlap-weighted incidences were 17.0% and 45.7%, respectively (RR, 0.37; 95% CI, 0.16–0.88; nominal P = 0.024; FDR-adjusted P = 0.040) (Table 3).

Grade ≥ 3 leukopenia and neutropenia were numerically less frequent with nab-paclitaxel plus radiotherapy, but neither difference was statistically significant. Grade ≥ 3 hemoglobin decrease was also less frequent (weighted incidence, 0.2% vs 17.7%; RR, 0.009; 95% CI, 0.001–0.104; nominal and FDR-adjusted P < 0.001). No grade ≥ 3 thrombocytopenia occurred in the nab-paclitaxel plus radiotherapy group, and the RR was therefore not estimated (Table 3).

The overlap-weighted incidence of any grade ≥ 3 treatment-related adverse event was 22.4% with nab-paclitaxel plus radiotherapy and 51.0% with the platinum-containing regimen (RR, 0.44; 95% CI, 0.21–0.90; nominal P = 0.025). This association did not remain statistically significant after FDR adjustment (P = 0.075) (Supplementary Table S4).

Discussion

Older patients with unresectable stage III lung squamous cell carcinoma often face a difficult balance between disease control and treatment tolerance. Evidence for less intensive concurrent treatment strategies remains limited in this population. In this retrospective cohort study, nab-paclitaxel plus radiotherapy was associated with longer progression-free survival than radiotherapy alone, although no significant difference in overall survival was detected. Compared with nab-paclitaxel plus platinum and radiotherapy, nab-paclitaxel plus radiotherapy showed no significant difference in progression-free or overall survival and was associated with a lower incidence of grade ≥ 3 hematologic toxicity. These findings are hypothesis-generating and do not establish equivalence or non-inferiority between the two concurrent treatment strategies.

Nab-paclitaxel plus radiotherapy was associated with longer progression-free survival than radiotherapy alone. This finding is consistent with JCOG0301, which showed a survival benefit from low-dose carboplatin plus radiotherapy in older patients [9,22]. A meta-analysis and real-world studies also supported the addition of chemotherapy to radiotherapy in this population [10,23]. Our study extends this evidence to older patients with squamous histology treated with nab-paclitaxel without platinum. However, no significant overall survival difference was detected. The limited number of deaths, competing non-cancer mortality, subsequent treatment, immunotherapy, and residual confounding may have contributed. Thus, the results suggest better disease control but do not establish an overall survival benefit.

No significant difference in progression-free or overall survival was detected between nab-paclitaxel plus radiotherapy and the platinum-containing regimen. The sensitivity analyses showed a similar pattern. Previous studies of nab-paclitaxel-based chemoradiotherapy were small, mostly single-arm, and included platinum [14–16]. Our findings should be interpreted cautiously because the nab-paclitaxel plus radiotherapy group was small. The confidence intervals were wide, so clinically important differences in survival between the two concurrent regimens cannot be excluded.

Compared with radiotherapy alone, nab-paclitaxel plus radiotherapy showed a numerically higher incidence of grade ≥ 3 hematologic toxicity, although the association did not remain statistically significant after FDR adjustment. In contrast, compared with the platinum-containing regimen, the platinum-sparing regimen was associated with less grade ≥ 3 hematologic toxicity. This finding is clinically relevant in older patients, who often have limited bone marrow reserve and lower tolerance of intensive chemoradiotherapy. However, event numbers were small, and no clear differences were

detected in severe radiation pneumonitis or esophagitis. These results suggest better hematologic tolerability relative to the platinum-containing regimen but do not establish superior overall safety.

This study addressed two clinically relevant comparisons in older patients with unresectable stage III lung squamous cell carcinoma. Survival and toxicity outcomes were evaluated together. Overlap weighting improved balance in measured baseline characteristics. The findings therefore provide real-world comparative evidence for a platinum-sparing nab-paclitaxel regimen, although they mainly apply to patients in the overlap population.

Several limitations should be acknowledged. The retrospective, single-center design may have introduced residual confounding and treatment-selection bias. Frailty, organ function, nutritional status, and geriatric assessment were not fully captured. Treatment delivery was not uniform, including chemotherapy dose and schedule, platinum selection, radiotherapy dose, immunotherapy, and subsequent treatment. The small platinum-sparing group and reduced effective sample size limited precision. Disease progression was retrospectively reassessed according to RECIST version 1.1, but imaging intervals were not protocol-defined. Adverse events were obtained from routine clinical records, and quality-of-life outcomes were unavailable. These findings therefore require confirmation in prospective multicenter studies with standardized treatment and follow-up.

Conclusion

In older patients with unresectable stage III lung squamous cell carcinoma, nab-paclitaxel plus radiotherapy was associated with longer progression-free survival than radiotherapy alone. Compared with nab-paclitaxel plus platinum and radiotherapy, the platinum-sparing regimen was associated with less grade ≥ 3 hematologic toxicity. These findings support prospective evaluation of this regimen in selected older patients who may not tolerate platinum-based chemoradiotherapy.

Abbreviations

CI
confidence interval
HR
hazard ratio.

Declarations

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None.

Author contributions

Shuqiao Zheng and Huiwen Yang collected the clinical data. Shuqiao Zheng performed the statistical analysis and drafted the manuscript. Feifei Liu, Yingxin Liu, Linlin Yang, Yiyue Xu, and Linlin Wang contributed to data interpretation and manuscript revision. Linlin Wang conceived and supervised the study. All authors interpreted the results, critically revised the manuscript, approved the final version, and agreed to be accountable for all aspects of the work.

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Declaration of conflicting interests

The authors declare that there is no conflict of interest.

Ethics approval

This study was approved by the Ethics Committee of Shandong Cancer Hospital (Approval No. SDTHEC 202606054). The requirement for written informed consent was waived because of the retrospective nature of the study.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Tables

Tables 1 to 3 are available in the Supplementary Files section.

Figures

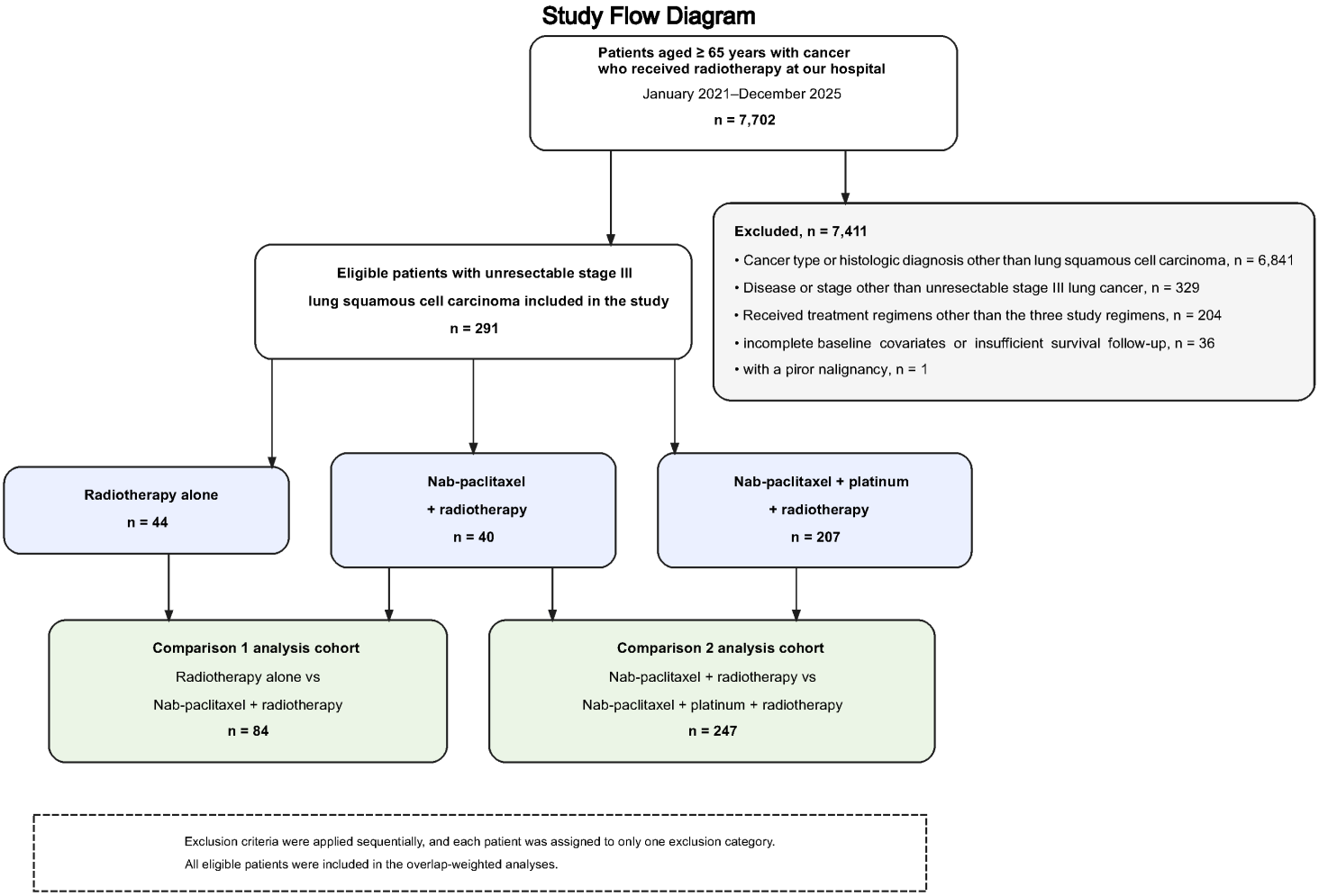


Figure 1

Patient selection flowchart.

Flowchart showing patient screening, exclusion, and final inclusion in the study cohort. Patients were classified into radiotherapy alone, nab-paclitaxel plus radiotherapy, and nab-paclitaxel plus platinum and radiotherapy groups.

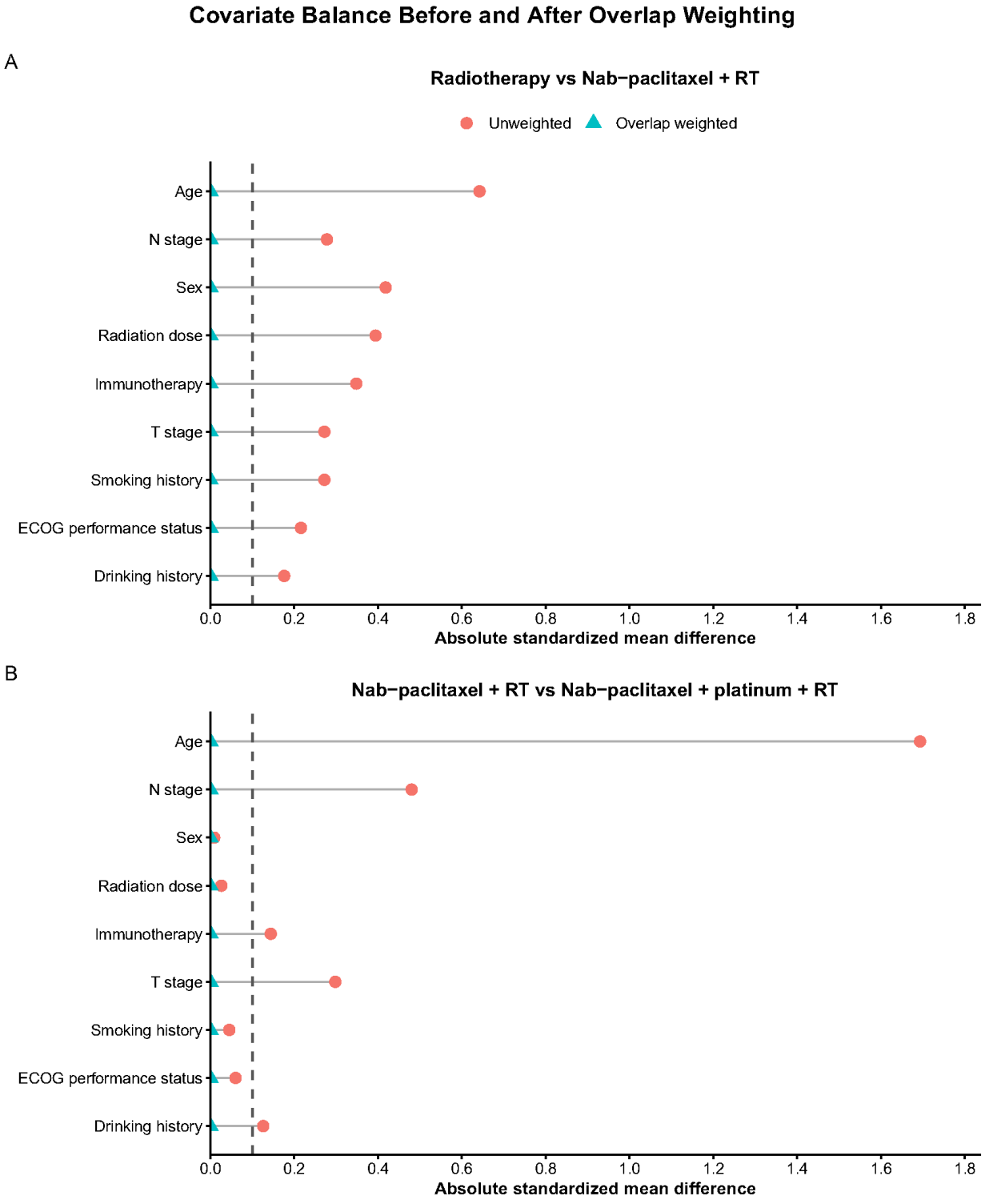


Figure 2

Covariate balance before and after overlap weighting.

Love plots showing absolute standardized mean differences before and after propensity score overlap weighting in Comparison 1 and Comparison 2. Comparison 1 compared radiotherapy alone with nab-paclitaxel plus radiotherapy. Comparison 2 compared nab-paclitaxel plus radiotherapy with nab-

paclitaxel plus platinum and radiotherapy. The dashed vertical line indicates an absolute standardized mean difference of 0.10.

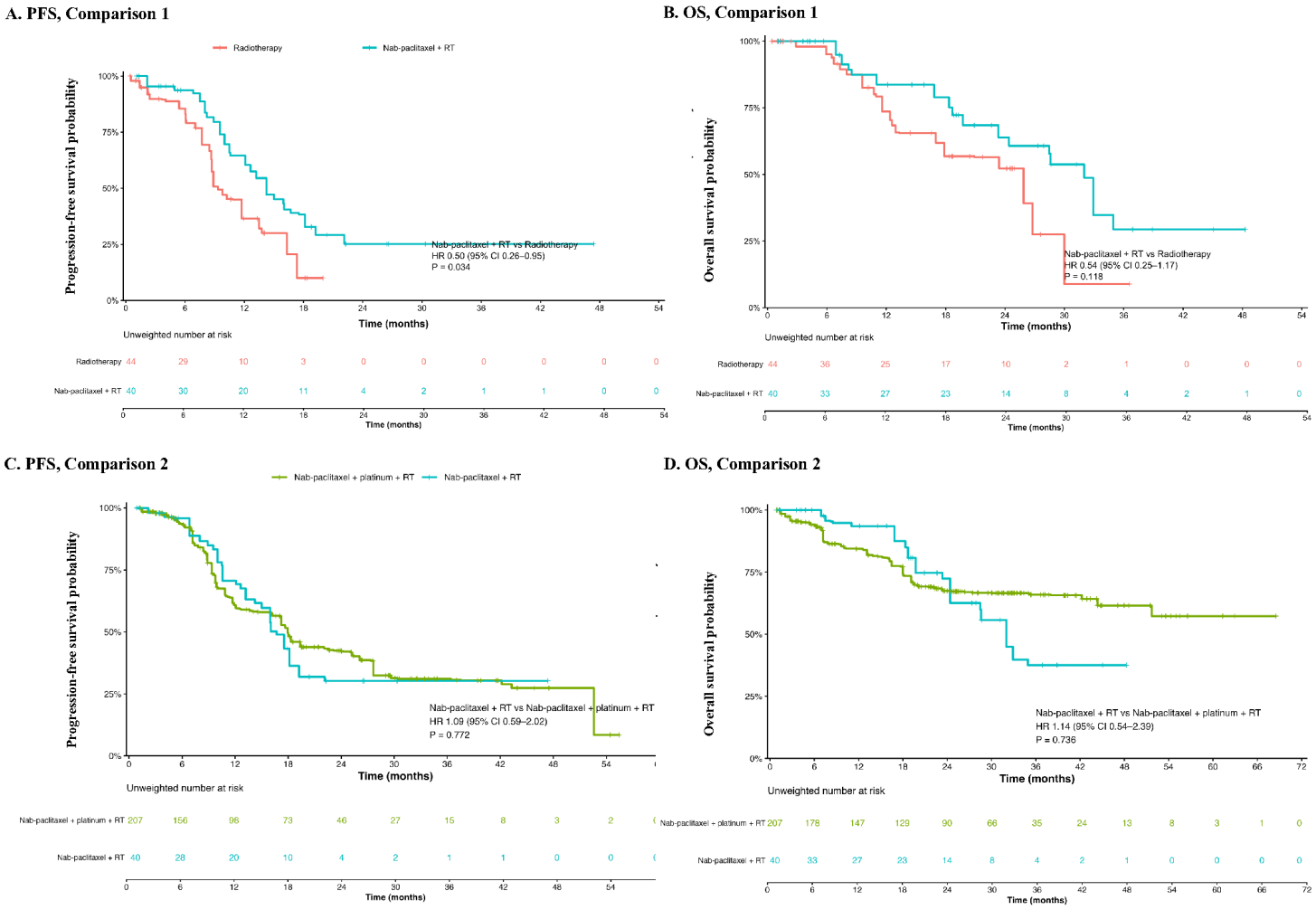


Figure 3

Overlap-weighted survival outcomes in the two prespecified comparisons.

(A) Progression-free survival and (B) overall survival in Comparison 1, comparing radiotherapy alone with nab-paclitaxel plus radiotherapy. (C) Progression-free survival and (D) overall survival in Comparison 2, comparing nab-paclitaxel plus radiotherapy with nab-paclitaxel plus platinum and radiotherapy. Risk tables display the original unweighted numbers at risk. HRs and P values were estimated using overlap-weighted Cox regression.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.docx
- Table2.docx

- Table3.docx
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