Possible Issues found in NCCN Guidelines for Non-Small Cell Lung Cancer, Version 3.2020

1. MS-31

Original text:

This meta-analysis evaluated 13 randomized trials; the HR suggests that overall survival in the preoperative chemotherapy arm is similar to the surgery alone arm (HR, 0.84; 95% CI, 0.77–0.92; P = .0001).[620]

Corrected text:（2021 年版で訂正予定）

This meta-analysis evaluated 13 randomized trials; the HR suggests that overall survival in the preoperative chemotherapy arm is longer than the surgery alone arm (HR, 0.84; 95% CI, 0.77–0.92; P = .0001).[620]

Related text in the reference:

Results: Thirteen randomized control trials, 6 of which were new ones, were included into this meta-analysis. The overall survival of NSCLC patients in neoadjuvant chemotherapy arm were improved significantly, comparing with those in surgery-alone arm (combined HR = 0.84; 95% confidence interval, 0.77-0.92; p = 0.0001).

URL: https://www.ncbi.nlm.nih.gov/pubmed/20107424

2. MS-53

Original text:

Long-term data from KEYNOTE-001 show that 5-year survival is approximately 23% for treatment-naïve and 15.5% for patients with metastatic NSCLC who were previously treated with pembrolizumab monotherapy; for patients with PD-L1 levels of 50% or more, 5-year overall survival is about 29.6% and 25%, respectively.[11]

Corrected text: **（2021 年版で訂正予定）**

Long-term data from KEYNOTE-001 show that 5-year survival for patients with metastatic NSCLC is approximately 23% for patients who received first-line pembrolizumab monotherapy and 15.5% for patients who received subsequent pembrolizumab monotherapy; for patients with PD-L1 levels of 50% or more, 5-year overall survival is about 29.6% and 25%, respectively.[11]

Related text in the reference:

We enrolled 101 treatment-naive and 449 previously treated patients. Median follow-up was 60.6 months (range, 51.8 to 77.9 months). At data cutoff—November 5, 2018—450 patients (82%) had died. Median OS was 22.3 months (95% CI, 17.1 to 32.3 months) in treatment-naive patients and 10.5 months (95% CI, 8.6 to 13.2 months) in previously treated patients. Estimated 5-year OS was 23.2% for treatment-naive patients and 15.5% for previously treated patients. In patients with a PD-L1 tumor proportion score of 50% or greater, 5-year OS was 29.6% and 25.0% in treatment-naive and previously treated patients, respectively.

PATIENTS AND METHODS

Patients who were eligible for the previously treated cohorts had experienced treatment failure while receiving one or more or two or more systemic therapies for advanced disease, depending on the cohort.

URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6768611/

3. MS-58

Original text:

CheckMate 227, a phase 3 randomized trial, compared first-line nivolumab/ipilimumab, nivolumab monotherapy, and chemotherapy in patients with metastatic nonsquamous or squamous NSCLC who had high TMB levels (≥10 mutations/megabase), PS 0 to 1, and no EGFR mutations or ALK fusions.[187]

Modified text: （2021 年版で訂正予定）

CheckMate 227, a phase 3 randomized trial in patients with metastatic nonsquamous or squamous NSCLC who had PS 0 to 1 and no EGFR mutations or ALK fusions, compared nivolumab/ipilimumab, nivolumab monotherapy, and chemotherapy for patients with PD-L1 expression levels of 1% or more. Nivolumab/ipilimumab, nivolumab/chemotherapy, and chemotherapy alone were also compared for patients with PD-L1 expression levels less than 1%. In addition, first-line nivolumab/ipilimumab and chemotherapy were compared as one of the co-primary analyses in the patients who had high TMB levels (≥10 mutations/megabase).[187]

Related text in the reference (187)**:**

In CheckMate 227, a randomized, open-label, phase 3 trial, we evaluated nivolumab or nivolumab-based regimens as first-line treatment for advanced NSCLC. Part 1 of the trial has two independent primary end points. We reported the primary end point of progression-free survival with nivolumab plus ipilimumab, as compared with chemotherapy, in patients with a high tumor mutational burden (≥10 mutations per megabase) previously.[11]

Methods

Eligibility criteria for CheckMate 227 have been described previously.[11] Patients were adults with squamous or nonsquamous stage IV or recurrent NSCLC and an Eastern Cooperative Oncology Group (ECOG) performance-status score of 0 or 1 (on a 5-point scale, with higher scores indicating greater disability).[12] None of the patients had received previous systemic anticancer therapy for advanced or metastatic disease. Key exclusion criteria were the presence of EGFR mutations or known ALK translocations sensitive to targeted therapy, autoimmune disease, or untreated or symptomatic central nervous system metastases.

Patients who had PD-L1 expression in 1% or more of tumor cells were enrolled in Part 1a of the trial, and those with a PD-L1 expression level of less than 1% were enrolled in Part 1b. In Part 1a, patients were randomly assigned in a 1:1:1 ratio to receive nivolumab (at a dose of 3 mg per kilogram of body weight every 2 weeks) plus ipilimumab (at a dose of 1 mg per kilogram every 6

weeks), nivolumab monotherapy (240 mg every 2 weeks), or platinum-doublet chemotherapy every 3 weeks for up to four cycles. In Part 1b, patients were randomly assigned in a 1:1:1 ratio to receive nivolumab plus ipilimumab, nivolumab (360 mg every 3 weeks) plus platinum-doublet chemotherapy (every 3 weeks for up to four cycles), or platinum-doublet chemotherapy alone (every 3 weeks for up to four cycles).

URL:
https://www.nejm.org/doi/10.1056/NEJMoa1910231?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed