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Oesophageal

Adjuvant Nivolumab in Resected Oesophageal or Gastroesophageal Junction Cancer

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BACKGROUND

No adjuvant treatment has been established for patients who remain at high risk for recurrence after neoadjuvant chemoradiotherapy and surgery for oesophageal or gastroesophageal junction cancer.

METHODS

We conducted CheckMate 577, a global, randomized, double-blind, placebo-controlled phase III trial to evaluate a checkpoint inhibitor as adjuvant therapy in patients with oesophageal or gastroesophageal junction cancer. Adults with resected (R0) stage II or III oesophageal or gastroesophageal junction cancer who had received neoadjuvant chemoradiotherapy and had residual pathological disease were randomly assigned in a 2:1 ratio to receive nivolumab (at a dose of 240 mg every two weeks for 16 weeks, followed by nivolumab at a dose of 480 mg every four weeks) or matching placebo. The maximum duration of the trial intervention period was one year. The primary end point was disease-free survival.

RESULTS

The median follow-up was 24.4 months. Among the 532 patients who received nivolumab, the median disease-free survival was 22.4 months (95% confidence interval [CI], 16.6 to 34.0), as compared with 11.0 months (95% CI, 8.3 to 14.3) among the 262 patients who received placebo (hazard ratio for disease recurrence or death, 0.69; 95% CI, 0.56 to 0.86; $P < 0.001$). Disease-free survival favoured nivolumab across multiple prespecified subgroups. Grade 3 or 4 adverse events that were considered by the investigators to be related to the active drug or placebo occurred in 71 of 532 patients (13%) in the nivolumab group and 15 of 260 patients (6.0%) in the placebo group. The trial regimen was discontinued because of adverse events related to the active drug or placebo in 9.0% of the patients in the nivolumab group and 3.0% of those in the placebo group.

CONCLUSIONS

Among patients with resected oesophageal or gastroesophageal junction cancer who had received neoadjuvant chemoradiotherapy, disease-free survival was significantly longer among those who received nivolumab adjuvant therapy than among those who received placebo.