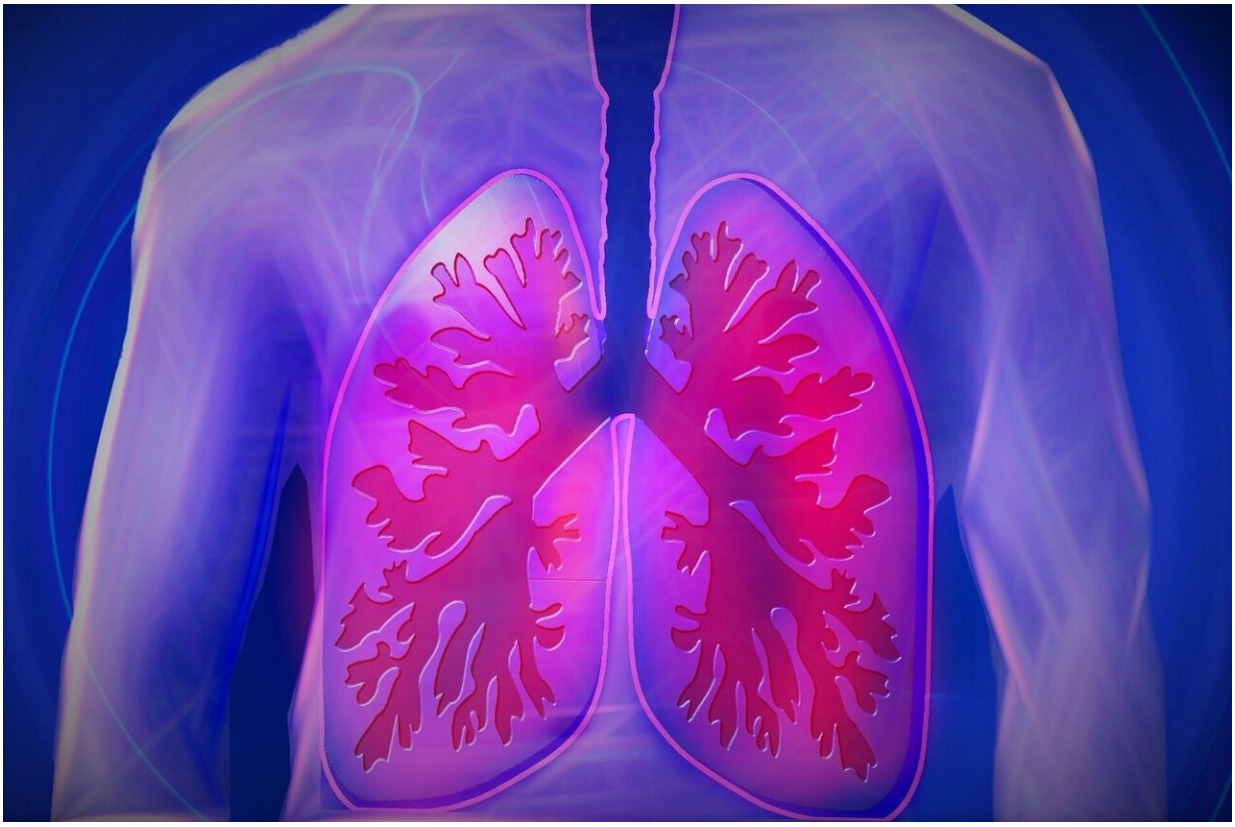
Understanding surgical outcomes of perioperative durvalumab in AEGEAN study

September 11 2023



Credit: CC0 Public Domain

Adding perioperative durvalumab to neoadjuvant chemotherapy did not adversely impact surgery in patients with resectable NSCLC and was associated with a tolerable surgical safety profile, according to research

presented from the phase 3 AEGEAN trial at the International Association for the Study of Lung Cancer 2023 World Conference on Lung Cancer in Singapore.

"The AEGEAN trial demonstrated a clinically meaningful improvement in EFS with the addition of perioperative durvalumab to neoadjuvant chemotherapy, alongside significantly improved pathological complete response (pCR) and major pathological response (MPR).

Understanding surgical outcomes can further inform the use of this treatment and is an important consideration for patients and physicians," said Tetsuya Mitsudomi, MD, Division of Thoracic Surgery, Department of Surgery, Kindai University Faculty of Medicine, Osaka-Sayama, Japan

The AEGEAN trial is a double-blind, placebo-controlled phase 3 study that evaluated the use of perioperative durvalumab in combination with neoadjuvant chemotherapy compared to neoadjuvant chemotherapy alone. The trial involved adults with treatment-naïve resectable NSCLC (stage II-IIIB[N2]; AJCC 8th ed) and ECOG PS 0/1.

Patients were randomized to receive either neoadjuvant durvalumab 1,500 mg or placebo intravenously (IV) alongside platinum-based CT prior to surgery. Following surgery, patients received durvalumab 1,500 mg or placebo IV, respectively. The primary endpoints of the trial were pathological complete response and event-free survival.

The study randomized 802 patients with treatment- naïve resectable NSCLC (stage II-IIIB[N2] and ECOG PS 0/1). Efficacy analyses were performed in the modified intent-to-treat population which comprised 740 patients with no documented EGFR mutations/ALK gene rearrangements (366 in the durvalumab arm and 374 in the placebo arm).

Lobectomy, sleeve resection, or bilobectomy were allowed as planned surgery (at enrollment); the protocol was amended with enrollment ongoing to exclude patients with tumors classified as T4 for any reason other than size (>7 cm) or whose planned surgery was pneumonectomy (originally allowed).

In the modified intent-to-treat population, 80.6% and 80.7% underwent surgery, respectively; 77.6% and 76.7% completed surgery, with disease progression the most common reason for canceled (6.8% vs. 7.8%) or non-completed (1.4% vs. 2.1%) surgery.

Among treated patients who underwent surgery, 17.3% and 22.2% had delayed surgery, most commonly for logistical reasons (e.g., scheduling issues; 9.5% vs. 12.3%). The median time from the last neoadjuvant treatment dose to surgery was the same in each arm (34.0 days).

Among patients who underwent surgery, similar proportions in the durvalumab and placebo arms had open (49.2% vs. 50.7%) and minimally invasive procedures (49.2% vs. 47.0%); lobectomy (including sleeve resection and bilobectomy) was the most common procedure (88.1% vs. 85.4%), followed by pneumonectomy (9.2% vs. 9.6%). Among patients who completed surgery, a numerically higher proportion had R0 resection in the durvalumab versus placebo arm (94.7% vs. 91.3%).

According to Dr. Mitsudomi, it is encouraging to see these comprehensive outcomes described in a robust phase 3 trial which showed that adding perioperative durvalumab to neoadjuvant CT did not adversely impact the feasibility, type, extent, or timing of surgery in patients with R-NSCLC and was associated with a tolerable surgical safety profile. Further, the addition of durvalumab resulted in numerically higher R0 resection rates.

AEGEAN data from outcomes for patients with documented EGFR mutations are also being presented at IASLC 2023 World Conference on Lung Cancer.

Provided by International Association for the Study of Lung Cancer