

Systematic literature review (SLR) of randomized controlled trials (RCTs) of immuno-oncology (IO) for first-line (1L) esophageal squamous cell carcinoma (ESCC) in adults patients

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ABSTRACT

Title: Systematic Literature Review (SLR) of Randomized Controlled Trials (RCTs) of Immuno-oncology (IO) for First-Line (1L) Esophageal Squamous Cell Carcinoma (ESCC) in Adults Patients

Objectives: Addition of IO agents to chemotherapy improves outcomes for patients with 1L unresectable, locally advanced, or metastatic ESCC. Current guidelines provide only two IO treatment options for patients. We conducted an SLR of efficacy, safety, and health-related quality of life (HRQoL) outcomes among IO regimens in this patient population.

Methods: Embase, Ovid MEDLINE®, and Cochrane CENTRAL were searched from inception to June 2023 for English-language RCTs of IO regimens for 1L ESCC. Hand searches of health technology assessment agencies, conference proceedings, and trial registries were also conducted. Study selection was performed in duplicate. Study details, patient characteristics, and outcomes of interest were extracted.

Results: Of 3,746 records identified, 8 RCTs investigating 8 IO agents (tislelizumab, nivolumab, pembrolizumab, serplulimab, toripalimab, sintilimab, camrelizumab and sugemalimab) in combination with chemotherapy were included.

All trials reported improvements in overall survival (OS), progression-free survival (PFS), and objective response rate (ORR) for IO agents plus chemotherapy versus chemotherapy alone at median follow-up times ranging from 7.1 to 32.2 months. Among IO plus chemotherapy arms, median OS, median PFS, and ORR ranged from 12.6 to 17.4 months, 5.7 to 8.4 months, and 43.8% to 72.1%, respectively. Corresponding results in chemotherapy only arms were 9.8 to 12.8 months, 5.3 to 5.8 months, and 27% to 62.1%, respectively. Survival and response benefits of IO agents were observed in the majority of key subgroups: programmed death-ligand 1 expression, race/geography, and disease status. Incidence of treatment-related adverse events ranged from 80% to 99.3% and 90% to 98.1% for IO plus chemotherapy and chemotherapy alone arms, respectively. HRQoL data were reported by five trials using various instruments.

Conclusions: Adding IO agents to chemotherapy has clinical benefits for 1L ESCC patients extending across key patient subgroups. Availability of additional IO agents may provide options to address unmet need.