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Efficacy of immune checkpoint inhibitors in female patients with cancer: a systematic review and meta-analysis

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Abstract

Immune checkpoint inhibitors (ICIs) have transformed advanced cancer management by providing durable responses and significant survival benefits. However, sex-based differences in treatment outcomes remain poorly understood. In this systematic review and meta-analysis of 78 phase III randomized controlled trials including 56,332 patients, we specifically assessed the efficacy of ICIs in female patients. Overall, female patients experienced a overall survival (OS) benefit from immunotherapy (hazard ratio (HR)=0.80, 95% confidence interval (CI): 0.76-0.84, $P<0.0001$), although considerable heterogeneity was observed across studies. Subgroup analyses showed no statistically significant differences in OS benefit across the examined stratification factors. Notably, we found female with squamous cell carcinoma did not demonstrate a statistically significant survival benefit from ICIs (HR=0.86, 95% CI: 0.71-1.04). Male patients demonstrated a more pronounced benefit (HR=0.77, 95% CI: 0.74-0.80, $P<0.0001$), although no improvement was noted in melanoma and glioblastoma. These findings highlight meaningful sex-based disparities in immunotherapy efficacy and underscore the need to integrate sex as a biological variable in clinical decision-making. Greater inclusion of women in clinical trials, identification of sex-specific biomarkers, and development of tailored strategies are essential to optimize immunotherapy outcomes and advance personalized cancer care.

Keywords: female patients with cancer; immune checkpoint inhibitors; meta-analysis; sex disparities; squamous cell carcinoma.

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