

Clinical trial enrollment and survival outcomes in gynecologic malignancies: a trial-stratified matched cohort analysis

Anna Nguyen; Denise Danos, PhD; Annasophia Molina; Courtney Harding; Tara Castellano, MD; Amma Agyemang, MD, PhD; Amelia M. Jernigan, MD

Objectives: To evaluate whether clinical trial enrollment is associated with progression-free survival (PFS) and overall survival (OS) among patients with gynecologic malignancies.

Methods: We performed an IRB-approved retrospective matched cohort study of adults with gynecologic malignancies. Twenty-four patients enrolled across seven clinical trials were matched 1:1 to 24 patients who were screened and eligible for the same trial, had the same cancer type, and did not enroll. Patients who participated in more than one trial were excluded. OS was measured from trial screening to death, with survivors censored at the last known date alive. PFS was measured from trial screening to progression or death, with patients without documented progression censored at the last oncology follow-up. Baseline characteristics were compared using t tests, Wilcoxon rank-sum tests, or Fisher exact tests as appropriate. OS and PFS were evaluated using Cox proportional hazards models stratified by trial; a second model adjusted for age and race. We excluded one enrolled patient with an erroneous death date from survival analyses.

Results: The cohort included 24 enrolled and 24 non-enrolled patients. Cancer type was identical between groups: 66.7% endometrial, 25.0% ovarian/fallopian tube/primary peritoneal, and 8.3% cervical. Documented progression occurred in 12.5% of enrolled patients versus 41.7% of non-enrolled patients ($p=0.0490$), while death occurred in 12.5% versus 33.3%, respectively ($p=0.1681$). In trial-stratified Cox analysis, enrollment was associated with a lower estimated hazard of progression or death (PFS HR 0.22, 95% CI 0.05-1.06; $p=0.0595$) and death (OS HR 0.25, 95% CI 0.05-1.22; $p=0.087$). After adjustment for age and race, the estimates remained similar for PFS (HR 0.20, 95% CI 0.03-1.21; $p=0.0799$) and OS (HR 0.23, 95% CI 0.04-1.36; $p=0.1051$).

Conclusions: In this preliminary matched cohort, point estimates favored trial enrollment for both PFS and OS, but neither time-to-event endpoint reached statistical significance. These findings support expansion of the cohort to improve precision and further evaluate associations between trial enrollment and survival outcomes across gynecologic malignancies.