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Abstract CT002: Circulating tumor DNA status to direct adjuvant immunotherapy for mismatch repair deficient tumors FREE

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Abstract

Background:

Patients with early-stage solid tumors who harbor minimal residual disease (MRD) following surgical resection as detected by circulating tumor DNA (ctDNA), have a high risk of recurrence. It remains uncertain whether therapeutic intervention of MRD in this context reduces cancer recurrence. We evaluated the efficacy of PD-1 blockade in resected early-stage mismatch repair deficient (MMRd) tumors with ctDNA-detected MRD, given high sensitivity of MMRd tumors to immune checkpoint blockade.

Methods:

We conducted a prospective clinical study assessing PD-1 blockade with pembrolizumab in patients with resected MMRd solid tumors treated with surgery and standard of care adjuvant therapy. Treatment with PD-1 blockade was guided by ctDNA status, measured 6-10 weeks after curative intent surgery and standard of care adjuvant therapy. Study arms included, Arm A (Interventional) comprised of ctDNA-positive patients treated with pembrolizumab for 6 months, and Arm B (Observational) comprised of ctDNA-negative patients. The primary endpoint was ctDNA clearance at 6 months in 40% of study patients. Recurrence-free survival (RFS) and overall survival (OS) were included as exploratory endpoints.

Results:

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Three-hundred and three patients with resected MMRd solid tumors were screened and ctDNA status was measured in 174 of these patients in 16 different tumor types. Twenty-two patients (12.6%) were ctDNA positive and enrolled in Arm A (Interventional). Of these 22, 13 ctDNA-positive patients received six months of PD-1 blockade and 9 did not because of radiographically detected disease recurrence prior to initiation of therapy. Fifty-two ctDNA-negative patients were enrolled in Arm B (Observational) and observed. The median follow-up time for all patients was 32.1 months. The study met the primary endpoint; 85% (11/13) of patients in Arm A (Interventional) achieved ctDNA clearance at 6 months, the median RFS was not reached, and the recurrence rate was 38% (5/13). In those that were ctDNA positive that did not receive PD-1 blockade the median RFS was 0.8 months (95% CI 0.3-1.3) and the recurrence rate was 100% (9/9). In Arm B (Observational) the median RFS was not reached, and the recurrence rate was 5.9% (9/152). Overall survival at 2 years was 92% (95%CI: 79-100%) in ctDNA positive patients who received PD-1 blockade and 78% (95%CI: 55%-100%) in patients that did not receive PD-1 blockade. In ctDNA negative patients, the OS at 2 years was 98% (95%CI: 96%-100%).

Conclusion:

Adjuvant PD-1 blockade directed by ctDNA status post-resection early-stage MMRd malignancies may provide clinical benefit in a agnostic of tumor type.

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