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Abstract

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A Pooled Analysis of the SOLAR and SATURN Clinical Trials Comparing the Progression of de Novo versus Recurrent PSMA-Defined Oligo-M1 Prostate Cancer Following Systemic Therapy and Tumor-Directed Therapy

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Abstract

Objectives:

Therapeutic strategies for oligometastatic castration sensitive prostate cancer (omCSPC) combining treatment of the primary and metastases with short-term intensified systemic therapy aim to improve survival and local control while minimizing toxicity from indefinite systemic therapy. This post-hoc analysis of the SOLAR (NCT03298087) and SATURN (NCT03902951) trials, which evaluated systemic and tumor-directed therapy in PSMA-PET defined oligo-M1 (≤ 5 metastases) de novo and recurrent omCSPC, respectively, aims to draw inferences on biology and oncologic outcome.

Methods:

This is a pooled analysis of individual patient data from 50 PCa patients enrolled in two phase 2 clinical trials. All patients were treated with 6 months of systemic therapy: leuprolide, abiraterone acetate with prednisone, and apalutamide in conjunction with SBRT to oligometastatic sites. SOLAR patients were treatment naïve and underwent either radical prostatectomy (RP) with lymph node dissection followed by post-operative radiotherapy for high-risk features, or definitive radiotherapy (dRT). SATURN patients all had recurrent disease after RP with or without postoperative radiotherapy and may have also had prior hormone or metastasis-directed therapy. The primary endpoint (response rate) was the percentage of patient with an undetectable PSA (< 0.05 ng/mL) for post-RP patients, or a PSA < 2 ng/mL for post-dRT patients, six months after recovery of testosterone to > 150 ng/dl. Secondary endpoints included progression-free survival (PFS) and eugonadal PFS starting from time of testosterone recovery. Kaplan-Meier assessed differences in time-to-event endpoints from initiation of systemic therapy. Fischer's Exact Test compared proportional outcomes.

Results:

Analysis included data from 24 SOLAR and 26 SATURN patients. Overall, median follow-up was 32 months (interquartile range 28.25-36.75 months). The average number of M1 metastases were both two for de novo and oligorecurrent patients. Response rates were higher for de novo versus oligorecurrent patients (20/24 [83%] versus 13/26 [50%], $p=0.018$). PFS and eugonadal PFS were also significantly longer (median not reached versus 17 months and median not reached versus 13 months, respectively, $p < 0.05$). PFS was shorter for oligorecurrent patients with prior exposure to hormone therapy (median 10 months versus not reached, $p < 0.05$). There was no PFS difference comparing patients treated in the de novo setting versus the recurrent setting who were naïve to hormonal therapy ($p=0.23$).

Conclusion(s):

Patients with recurrent omCSPC PSMA-PET defined M1 disease had a worse response rate and shorter PFS following intensified systemic and metastasis-directed SBRT than those with de novo omCSPC. The

difference was driven by recurrent patients with prior exposure to hormonal therapy, suggesting a continuum of treatment resistances over repeated courses of hormonal therapy. The majority of patients with de novo omCSPC remain in remission after gonadal recovery.