Adding docetaxel-based chemotherapy to standard treatment for high-risk prostate cancer

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According to the American Cancer Society, prostate cancer is the second most common cause of cancer-related death among men in the United States in 2018. Currently, the standard of care treatment for high-risk, localized prostate cancer is a combination of radiotherapy (RT) and long-term (24-36 month) androgen suppression (AS). Researchers theorized that adding adjuvant docetaxel, a cytotoxic chemotherapy drug, to the standard of care RT and long-term AS treatment could potentially improve overall survival and clinical outcomes for men with localized, high-risk prostate cancer.

Docetaxel-based chemotherapy has improved overall survival among men with castration-resistant and castration-sensitive prostate cancers, is typically well-tolerated by patients, and may be able to target hormonally resistant cells, thus complimenting the abilities of AS to target hormonally sensitive cells. Therefore, the NRG Oncology clinical trial NRG-RTOG 0521 was designed to compare the standard of care with and without docetaxel-based chemotherapy and to determine if the addition of docetaxel improved OS, disease-free survival (DFS) and rates of distant metastasis (DM) for men with high-risk non-metastatic prostate cancer. The results of this study were recently published in the *Journal of Clinical Oncology*.

The multicenter, Phase III trial NRG-RTOG 0521 randomly assigned men to one of two possible treatment arms. Both treatment arms received eight weeks of AS followed by RT with concurrent AS and then adjuvant AS treatment for 24 months. The standard of care plus chemotherapy arm received an additional six cycles of docetaxel and prednisone given concurrently with AS beginning 28 days after their completion of RT.

"The addition of cytotoxic chemotherapy to androgen suppression and radiotherapy improved overall survival from 89% to 93% at 4 years following randomization. There was also improvement in disease-free survival and reduced rates of distant metastases," stated Seth A. Rosenthal, MD, FACR, FASTRO, of Sutter Medical Group and Sutter Cancer Centers, Sacramento, California, and corresponding author for

NRG-RTOG 0521. "These are promising results. The trial results suggest that the addition of docetaxel chemotherapy to standard treatment with long-term androgen suppression therapy and RT, is a viable treatment option for men with high-risk non-metastatic prostate cancer. Physicians should be considering the discussion of this option with selected patients who are fit for chemotherapy"

Of the 563 evaluable patients on NRG-RTOG 0521, there were no unexpected toxicity signals during the conduct of the trial and treatment was well-tolerated on both arms. 4-year OS rates were 89% [95% CI: 84-92%] for AS and RT treatment arm and 93% [95% CI: 90-96%] for AS and RT plus chemotherapy treatment arm (one-sided p= 0.034, HR=0.69 [90% CI: 0.49, 0.97]). 6-year rate of DM were 14% for AS and RT treatment arm and 9.1% for AS and RT plus chemotherapy treatment arm (two-sided p=0.044, HR=0.60 [95% CI: 0.37, 0.99]) and 6-year disease-free survival (DFS) rates were 55% for AS and RT treatment arm and 65% for AS and RT plus chemotherapy treatment arm, (two-sided p=0.043, HR=0.76 [95% CI: 0.58, 0.99]).

More information: Seth A. Rosenthal et al, Effect of Chemotherapy With Docetaxel With Androgen Suppression and Radiotherapy for Localized High-Risk Prostate Cancer: The Randomized Phase III NRG Oncology RTOG 0521 Trial, *Journal of Clinical Oncology* (2019). DOI: 10.1200/JCO.18.02158

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