

Trial reaffirms carboplatin and paclitaxel chemotherapy alone should remain standard treatment for endometrial cancer

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The *New England Journal of Medicine* recently published the primary endpoint of the NRG Oncology clinical trial NRG-GOG 0258, which showed that carboplatin and paclitaxel chemotherapy preceded by radiotherapy with concurrent cisplatin, or combined modality therapy, did not significantly increase recurrence-free survival for women with stage 3-4A endometrial cancer when compared to chemotherapy with carboplatin and paclitaxel alone. These results were also presented in abstract form at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

"This combined modality approach to locally advanced endometrial carcinoma has been previously studied, however, earlier trials never compared the regimen to chemotherapy given alone. The results of NRG-GOG 0258 indicate that the combined modality regimen did not result in an improvement in recurrence-free survival, and that chemotherapy alone remains the standard of care for stage III uterine cancer. Our data are compatible with findings from prior studies that the completion of chemotherapy is key to preventing distant relapse," stated Daniela Matei, MD, of the Division of Gynecologic Oncology at Northwestern University and the lead author of the NRG-GOG 0258 manuscript.

The phase 3 trial randomly assigned 736 eligible patients to one of two possible treatment study arms. 346 women received the combined modality treatment, which included cisplatin and volume-directed



radiation followed by 4 cycles of carboplatin and paclitaxel, over a median of 21 weeks, whereas 361 women received chemotherapy alone in 6 cycles over a median of 17 weeks. While the primary endpoint was to determine if the combined modality arm increased recurrence-free survival, patients were also observed for secondary endpoints that included overall survival, acute and chronic toxicities, and quality of life. At this time, the <u>overall survival</u> data are not mature and this secondary endpoint will be reported at a later date.

At 60 months, 59% (95% CI 53%-65%) and 58% (95% CI 53%-64%) of patients were alive, recurrence-free on combined modality and chemotherapy only arms, respectively (hazard ratio was 0.9; 90% CI 0.74 to 1.10). Combined modality treatment reduced the 5-year incidence of vaginal (2% vs. 7%, HR = 0.36, 95% CI 0.16 to 0.82), pelvic and para-aortic lymph node recurrences compared to chemotherapy alone (11% vs. 20%, HR=0.43, 95% CI 0.28 to 0.66), but distant recurrences were more common with combined modality treatment (27% vs. 21%, HR 1.36, 95% CI 1 to 1.86). Grade 3-5 adverse events were reported in 202 (58%) and 227 (63%) patients in the combined modality and chemotherapy alone arm, respectively.

More information: Daniela Matei et al, Adjuvant Chemotherapy plus Radiation for Locally Advanced Endometrial Cancer, *New England Journal of Medicine* (2019). DOI: 10.1056/NEJMoa1813181

Provided by NRG Oncology

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