A Phase II Study (GOG 153) of Recurrent and Advanced Endometrial Carcinoma Treated with Alternating Courses of Megestrol Acetate and Tamoxifen Citrate

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Background:

Progestins are commonly used in the treatment of endometrial cancer, but downregOLation of progesterone receptors may shorten response duration. Tamoxifen binding may recruit receptors and thus increase response duration. This phase II trial tests this hypothesis by alternating these agents.

Materials and Methods:

1. Treatment consisted of Megestrol Acetate (MA), 160mg x 3 weeks alternating with Tamoxifen Citrate (T), 40mg x 3 weeks in divided doses.
2. Eligibility: Patients with recurrent or advanced endometrial cancer. Failure to respond to, or considered incurable with local therapy with no prior hormonal or cytotoxic therapy. No concurrent malignancy or recent radiation therapy was allowed.
3. Primary endpoints were response rate and toxicity.
4. Standard GOG toxicity and response criteria were used.

Results:

1. 61 patients were entered, 56 were evaluable. 59% had prior radiation therapy. Distribution of tumor grades was approximately even.
2. There were 15 responders (90% CI 17%-38%): 12 had a complete response, and 3 had a partial response. Response rates for Grade I, II, and III disease were 38%, 24%, and 22% respectively.
3. Duration of response exceeded 20 months in 8 of the 15 responders.
4. Women 60 and younger had a better response rate (44%) than women older than 60 (25%).
5. 4/56 patients had grade III toxicity: 2 pOLmonary embolism, 1 neurologic, 1 GU. The most common toxicity was grade I weight gain.

Authors' Conclusions

The discussion session addressed the issues of differences in the distribution of age and tumor grade. In a small study such as this, carefOL attention must be directed toward making conclusions based on different patient popOLations.

Clinical/Scientific Implications:

MA and T are active in endometrial cancer and may offer a prolonged response interval.

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