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Altretamine (Hexalen) Consolidation for Patients with Stage III Epithelial Ovarian Cancer in Clinical Complete Remission: A Southwest Oncology Group Trial (S9326).

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Objective:

This multicenter Phase II trial was designed to evaluate the 2-year survival rate (2-yr OS) and tolerability of consolidation chemotherapy (chemoRx) for women with Stage III ovarian cancer in clinical complete remission (cCR) following completion of front-line therapy.

Methods:

Pts were documented to be in cCR by physical examination, CT or MRI, and CA-125. Pts must have received their last cycle of platinum-based induction chemoRx within 28-56 days of enrollment. Treatment consisted of altretamine (Hexalen) 260 mg/m²/day po divided into 4 doses taken after meals and at bedtime for 14 of 28 days for 6 cycles. With a targeted sample size of 93 pts, this study had a power of 0.90 if the true 2-yr OS was 65% and a type I error rate of .05 if the true 2-yr OS was 50%. These figures were based on 2-yr OS (as measured from the end of platinum-based front-line chemoRx) of 70% and 45% in pts with optimal and suboptimal disease (dz), respectively, in 2 prior SWOG studies.

Results:

From 9/1/93 and 7/1/97, 112 pts were registered and 97 were fully

evaluable. The majority of pts had optimally-debulked (≤ 1 cm: 63%), high-grade (Grade 3: 82%) carcinomas. Eighty-four percent of pts had received paclitaxel as part of front-line platinum-based therapy. Two-year OS from the time of enrollment was 75% (95% CI: 66-84%). For those pts with optimal dz, the 2-yr OS was 82% (95% CI: 72-92%) while for those with suboptimal dz, it was 64% (95% CI: 48-79%). Four pts (4%) experienced Grade 4 and 21 pts (22%) experienced Grade 3 toxicities consisting primarily of nausea/vomiting, neutropenia, fatigue, anxiety, and paresthesias. Limiting total daily dose to ≤ 400 mg and the scheduled use of oral antiemetics improved the tolerability of treatment.

Conclusions:

The 2-yr OS rate for women in cCR treated with consolidation altretamine exceeds that attained in previous Southwest Oncology Group trials. A randomized, controlled trial of consolidation altretamine in women with ov ca in cCR is necessary to confirm this result and to determine what effect, if any, the use of front-line paclitaxel could have had on this result.