SALVAGE CHEMOTHERAPY IN RECURRENT OVARIAN CANCER: A COMBINATION OF GEMCITABINE AND TREOSULFAN IS EQUALLY ACTIVE IN PLATINUM-RESISTANT AND PLATINUM-SENSITIVE DISEASE

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Aim: The prognosis of heavily pretreated patients (pts) with epithelial ovarian carcinoma (EOC) and related malignancies having failed multiple chemotherapy (CTx) regimens is poor, irrespectively of the individual platinum-resistance status. In preceding studies, the combination of treosulfan and prolonged low-dose gemcitabine (GeT) has shown promising activity in platinum-resistant EOC. This non-interventional study has been set up in order to obtain more detailed informations regarding the clinical value of GeT given under routine conditions.

Methods: 59 pts with recurrent EOC (n = 54), fallopian tube cancer (FTC; n = 2), peritoneal papillary-serous carcinoma (PPSC; n = 2), and type II endometrial carcinoma (EC-II; n = 1) who did not qualify for recruitment into a controlled clinical trial were included in this study. Pts had failed a median of 3 (range 1-11) prior CTx. 37 were platinum-resistant (group R) and 22 were sensitive (group S). GeT was administered for 1-11 q2w cycles with treosulfan at 1 g/m² PO on days 1-4 and gemcitabine at 450 mg/m² IV (3 h infusion) on day 1. Adverse effects were scored according to CTCAE 4.0. responses were classified according to the integrated GCIG criteria. PFS and OS were calculated from the start of GeT until progression or death from any reason or loss to follow up.

Results: GeT was generally well tolerated. Hematological side-effects were frequent but manageable with G3-4 neutropenia seen in 6, G3-4 anemia in 8, G3 fever in 3 and G3 infection in 1 pt. Non-hematological side effects exceeded G2 in only 4 pts. In 1 pt, GeT was prematurely stopped due to toxicity (allergic exanthema). A total of 8 CR and 19 PR accounted for an ORR of 45.8%. Adding 16 pts with SD, the clinical benefit rate (CBR) was 72.9%. PFS was 17.3 weeks (wks) and OS was 67.6 wks. No significant differences between groups R and S were found in regard to ORR (40.5% vs 54.5%), CBR (70.3% vs 77.3%), PFS (17.0 vs 18.4 wks), and OS (63.0 vs 72.6 wks). Moreover, prior CTx with one of the single agents did not lower the likelihood to benefit from GeT.

Conclusions: GeT given under routine conditions is well-tolerated and efficacious in heavily pretreated pts with recurrent EOC, FTC, PPSC, and EC-II by exhibiting chemomodulatory properties. Its particularly promising activity in platinum-resistant disease should be further explored in large-scaled prospective clinical trials.

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