The Outcome of Patients with Platinum-Resistant/Refractory Ovarian Cancer Treated with the Combination of Pegylated Liposomal Doxorubicin and Gemcitabine

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Objective

To evaluate the efficacy, toxicity and survival of patients with platinum-resistant/refractory ovarian cancer treated with the combination of pegylated liposomal doxorubicin (PLD) and gemcitabine.

Background

- An optimal treatment regimen for recurrent and platinum resistant ovarian cancer has not been defined.
- The combination of pegylated liposomal doxorubicin (PLD) and gemcitabine has been previously shown to have some activity against recurrent disease in two prospective studies in Europe and Australia.
- There are no published studies evaluating this combination in the United States.

Patients and Methods

- Retrospective chart review of 39 patients treated with PLD gemcitabine between 2006 and 2009 at the Lehigh Valley Health Network in Allentown, PA.
- All patients were initially treated with cytoreductive surgery and platinum/taxane chemotherapy.
- Patients were treated with PLD 30 mg/m² on day one and gemcitabine 650 mg/m² on days one and eight of a 21 or a 28-day cycle. Pegfilgrastim was administered as part of this protocol. Patients receiving more than one cycle were included as part of this protocol.
- All patients were included in the toxicity analysis (39 patients). Patients receiving more than one cycle were included in the outcomes analysis (37 patients).
- All patients were included in the toxicity analysis (39 patients).
- Response rates were measured using Rustin’s criteria for CA125 levels or RECIST criteria for tare lesions. The overall survival was calculated according to the method of Kaplan and Meier. Toxicities were scored according to the CTCAE Version 3.0 criteria.

Results

- Patient characteristics are summarized in Table 1.
- Two hundred (median = 5, range: 1–12) cycles were administered, with 37 patients receiving more than one cycle.
- The overall response rate was 30% (partial response rate = 24.3%, n = 9/37, complete response rate = 5.4%, n = 2/37). Four patients (11%) had stable disease (figure 1).
- The median progression-free interval for patients with either a complete or partial response was five months (range: 1–12 months).
- The two-year overall survival was 75%.
- Of the 11 patients who completely or partially responded, six received the regimen as a second-line treatment and five were heavily pretreated with more than two previous regimens prior to initiating PLD-gemcitabine (figure 2).
- One patient (2.6%) experienced grade 3/4 anemia and four (10%) had grade 3/4 thrombocytopenia. There were no cases of grade 3/4 neutropenia, however there was one case of febrile neutropenia. There were only two cases of grade 3/4 nausea/vomiting, one case of grade 3/4 mucositis/stomatitis and no cases of grade 3/4 plantar palmar erythrodysesthesia (figure 3).
- Grade 3/4 toxicities were minimal.
- The combined response rate was nearly 30%.
- The overall tolerability of this regimen allows for its use beyond the customary six cycles in responding patients.

Conclusions

- The combination of PLD and gemcitabine was an effective and well-tolerated regimen in patients with platinum-resistant/refractory ovarian cancer at our center.
- The combined response rate was nearly 30%.
- Grade 3/4 toxicities were minimal.
- The overall tolerability of this regimen allows for its use beyond the customary six cycles in responding patients.
- Larger prospective studies are needed to confirm the findings of the present preliminary study.