2011). In ROC the efficacy of chemotherapy is broadly accepted to be highly correlated with the PFI. Patients with PFI ⩾ 6 months (mo) are considered as platinum sensitive (PS). Within this subset, a PFI of 6–12 mo implies partially platinum-sensitive (PPS) disease. Thus, the PFI represents an important factor to interpret the results in this setting. Kaplan–Meier survival estimates according to stratification categories are widely used for plotting time-to-event curves (e.g. <6 *vs.* ⩾6 mo) but it may not account for imbalance within strata. (i.e. a patient with PFI=12 mo may have higher risk of death than one with PFI=36 mo). Allmer and Sargent (SUGI-2003) proposed a method to plotting survival estimates at a specified point in time, adjusted by a continuous explanatory variable.
Methods: Adjusted estimates of OS by continuous PFI at fixed timepoints (12, 18, 24 and 36 mo) according to Allmer and Sargent method have been considered.
Results: A Cox regression model using treatment group and continuous PFI as covariates was performed in the overall population, resulting both variables statistically significant ($p = 0.0029$ and $p < 0.0001$, respectively). After adjustment by PFI, the plots representing the OS rate prediction at 12, 18, 24 and 36 mo showed a significant difference along PFI axis favoring the combination of trabectedin and PLD. The PS and PPS subgroups showed consistency in the main effect model, enhanced for the combination (adjusted HR = 0.72 and 0.62, respectively; $p = 0.0036$, $p = 0.0018$).
Conclusions. The outcome of chemotherapy in ROC is strongly influenced by the PFI. Therefore, it is important to adjust for it in the analysis of OS. In accordance with previously published estimates for OS, the new approach for presenting predicted survival data based on the continuous PFI showed an improved OS in patients treated with the combination of trabectedin and PLD.

8032 POSTER

Catumaxomab Administered as a 3-hour Infusion – Results From a Newly Integrated Safety Analysis Comprising 7 Clinical Studies

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Background: Catumaxomab (anti-EpCAM x anti-CD3) is approved in the EU for the intraperitoneal treatment of malignant ascites with an infusion time of 6 hours (h), as used in the pivotal phase II/III clinical study. Experience with a 3-h infusion has grown substantially as all studies conducted thereafter used a reduced 3-h infusion time. The exiting database was enlarged by data from 2 clinical studies (additional 42 patients).
Methods: A newly integrated safety analysis (ISA) comprising 7 completed studies of patients with ovarian or gastric cancer primarily without malignant ascites treated with a 3-h catumaxomab infusion was conducted. In 4 of 7 studies, catumaxomab was administered in a perioperative setting. This 3-h database (ISA-3 h, N = 224) was compared with the reference database of the 6-h catumaxomab infusion (ISA-6 h, N = 293), which mainly includes patients with malignant ascites. Symptomatic adverse drug reactions (ADRs) of intensity grade ⩾3 occurring in ⩾1% of patients were used to describe the safety profiles derived from two databases.
Results: The nature of these ADRs and their intensity on System Organ Class level was comparable between both databases. The frequency of ADRs of intensity grade 3 or 4 was comparable for reactions such as abdominal pain, pyrexia and vomiting. Increased occurrence rates were observed for specific ADRs of intensity 3 or 4 with the 3-h vs the 6-h infusion, e.g. diarrhea (4.0% vs 1.4% of patients) and nausea (5.4% vs 2.4% of patients). In contrast, Ileus of severity grade 3 or 4 was reported more frequently in patients receiving catumaxomab as 6h infusion (0.4% vs 2.4%). For ADRs of lower intensity grade 1 or 2, a higher occurrence rate was observed in the ISA-3 h data set for a few ADRs, e.g. chills, hypotension, fatigue and diarrhea. The observed ADRs are well-known and partly expected due to catumaxomab's mechanism of action. All ADRs reported with a higher occurrence rate can be well controlled with pre- and/or concomitant medication.
Conclusions: The available safety data support the reduction of the catumaxomab infusion time from 6 h to 3 h. The reduction of the infusion time represents a significant advance in terms of the time spent at a healthcare facility. A variation of the EU product information in this regard was submitted.

8033 POSTER

Metastatic Endometrial Cancer at Diagnosis – Survival Patterns

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Introduction: Endometrial carcinoma is the most common gynecologic malignancy in industrialized countries. The majority of cases with endometrial carcinoma are found at an early stage, with disease apparently confined to the uterus. Distant metastasis at diagnosis are uncommon and usually involves lung and/or liver. Systemic treatment represents the cornerstone of endometrial cancer management in advanced, relapsed and metastatic disease, which is still characterized by poor prognosis. Caboplatin and paclitaxel is an increasingly used regimen for advanced/metastatic or recurrent endometrial cancer, the response rate is about 40%, and median overall survival is about 13 months. The aim of this study was to characterize patients with metastatic endometrial cancer at diagnosis, describe treatment options and evaluate overall survival (OS) patterns.
Material and Methods: A retrospective review of medical records of 34 women with metastatic endometrial cancer treated with palliative chemotherapy with carboplatin and paclitaxel, and some of them with radiotherapy in Cancer Centre in Porto, between January 2005 and December 2010 was performed.
Results: A total of 34 patients were in stage IV disease at the diagnosis and underwent chemotherapy with carboplatin and paclitaxel. The median age was 65 years old (min: 46 max: 77). Endometrioide carcinoma of endometrium was the predominant (70%). Most of patients presented with peritoneal carcinomatosis and lung metastasis. There were 21 (61%) patients undergoing only palliative chemotherapy and 13 patients (38%) did palliative chemotherapy and radiotherapy. The median number of cycles of chemotherapy was 6. The median of progreesion-free interval was 6 months (min:5 months, max: 42 months). The median of OS was 21 months (min: 1month, max: 64 months).
Conclusion: Aggressive treatment including systemic chemotherapy prolongs survival of patients with metastatic endometrial carcinoma at diagnosis. In our study 61% of patients had overall survival beyond 2 years, of which 14% had higher overall survival at 4 years.

8034 POSTER

Capecitabine as Second- and Third-line Chemotherapy in the Treatment of Platinum-refractory Epithelial Ovarian Cancer

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Background: The aim of the study is to evaluate the value of Capecitabine (Xeloda) in the treatment of epithelial ovarian cancer, after failure of initial chemotherapy. Response rates to first-line chemotherapy in women with ovarian cancer are high but most patients relapse and need further treatment. Recurrent disease is incurable, however, many patients can obtain good palliation from further treatment.
Material and Methods: The study included 20 patients with epithelial ovarian cancer treated initially with cytoreductive surgery and followed by chemotherapy treatment: 14 patients received platinum/paclitaxel therapy and 6 patients received platinum/cyclophosphamide therapy. Progression of disease was manifested with hepatic metastases in 11 patients (55%), lung metastases in 2 (10%), carcinosis peritonei in 2 (10%) and an increase in serum CA125 in 5 patients (25%). Comparison of the value of serum CA125 before and after treatment was taken as an indicator of response to chemotherapy. The treatment schedule consisted of oral capecitabine 1250 mg/m^2 administered twice daily for 14 days, followed by a 7-day rest period. Treatment was administered orally within 30 min of breakfast and dinner, and swallowed with approximately 200 ml of water. The cycle was repeated every 21 days.
Results: 16 patients (80%) received 6 courses chemotherapy with Capecitabine, 4 (20%) did not achieve the planned 6 courses of chemotherapy due to the deterioration of their general condition. In 10 patients (50%) decreased value of serum CA125 was observed, in 8 (40%) value was unchanged, and in 2 (10%) an increase in serum CA125 was noted. All 20 patients were evaluable for safety. Capecitabine was very well tolerated, with the most common clinical adverse events being nausea and diarrhoea, neither of which occurred with grade 3 or 4 intensity.
Conclusions: Capecitabine has demonstrated promising activity and a favourable safety profile in the treatment of platinum-refractory epithelial ovarian cancer. The safety and convenience advantages afforded to patients over current i.v. options make capecitabine an ideal agent for administration in the outpatient setting, potentially freeing them from the burden of i.v. therapy.