8028 POSTER

Safety analysis of trabectedin in combination with pegylated liposomal doxorubicin (PLD) vs PLD alone in ovarian cancer patients 65 years of age and older

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Study ET743-OVA-301 was a randomised Phase III trial comparing the combination of trabectedin, 1.1 mg/m^2 + pegylated liposomal doxorubicin (PLD), 30 mg/m^2 once every 3 weeks vs standard single-agent PLD 50 mg/m^2 every 4 weeks in 672 women with advanced ovarian cancer after failure of an initial platinum-based regimen. Significantly superior progression-free survival was achieved with the trabectedin+PLD combination assessed by independent radiology (HR 0.79, p = 0.019), independent oncology (HR 0.72, p = 0.0008) and investigator assessment (HR 0.72, p = 0.0002) with significantly superior response rate and a favourable trend in the interim analysis of overall survival (HR 0.85) presented at ESMO meeting 2008. 663 patients received at least one dose of study drug and are included in the current post-hoc analysis of safety profiles by age group, <65 vs. ⩾65 years. Selected AEs are displayed below.

Adverse Event	Age <65			Age ⩾65		
	Any	Grade 3	Grade 4	Any	Grade 3	Grade 4
PLD (n = 330)	**(n = 227)**			**(n = 103)**		
Neutrophils*	74%	16%	9%	73%	28%	11%
Febrile neutropenia	2%	2%	0	3%	2%	1%
Platelets*	25%	3%	2%	34%	2%	2%
ALT increased*	43%	3%	0	21%	1%	0
Vomiting	29%	5%	0	31%	3%	0
Fatigue	34%	5%	0	42%	6%	1%
Mucositis	18%	5%	0	23%	7%	0
Stomatitis	34%	5%	<1%	30%	5%	0
Hand-foot syndrome	52%	15%	1%	58%	25%	1%
Trabectedin/PLD (n = 333)	**(n = 254)**			**(n = 79)**		
Neutrophils*	92%	29%	42%	91%	32%	43%
Febrile neutropenia	9%	6%	3%	5%	4%	1%
Platelets*	63%	13%	10%	65%	11%	13%
ALT increased*	97%	48%	4%	94%	37%	5%
Vomiting	56%	13%	0	53%	8%	1%
Fatigue	43%	6%	<1%	56%	14%	0
Mucositis	11%	2%	0	15%	4%	0
Stomatitis	20%	1%	0	20%	0	0
Hand-foot syndrome	24%	3%	0	25%	6%	0

* Based on laboratory data

As previously reported, trabectedin + PLD resulted in more common transient neutropenia, thrombocytopenia, nausea/vomiting and fatigue, and less mucositis/stomatitis and hand-foot syndrome than single-agent PLD. In patients aged ⩾65 treated with single-agent PLD there was more grade 3–4 neutropenia and hand-foot syndrome than in younger patients. There were no marked differences by age in the safety profile/tolerability of trabectedin + PLD, except for more fatigue in the older subset compared with younger patients.

Conclusion: the safety profile of trabectedin + PLD is virtually identical by age group. This effective novel non-platinum combination is reasonably well tolerated and can be administered safely to women with relapsed ovarian cancer of 65 years of age and older.

8029 POSTER

The expression of CASA in ascites correlates with the overall survival and clinical outcome in patients with ovarian cancer

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The main scope of our study was to analyze the expression of CA 125 and CASA in ascites and serum in patients with primary and recurrent ovarian cancer, and the prognostic value of these tumor markers.

Methods: In our study 91 patients with ovarian cancer (54 primary and 37 recurrent ovarian cancer) and 66 patients with benign diseases were included. Patients were treated in our clinic from November 1997 until December 2000, the last follow up being performed in September 2007. The tumor markers expression was determined using ELISA technique. For the study we analyzed following cut-off values for the tumor markers: CA-125 35; 65; 500; 1000 U/ml and for CASA 4; 8; 35; 65 U/ml.

Results: The concentrations of both tumor markers were significantly higher in ascites and serum of the patients with ovarian cancer, compared with patients having benign diseases. Our study revealed a statistically significant association between the ascites volume and circulating levels of CA 125 (p = 0.018) and CASA (p = 0.004) in patients with primary and recurrent ovarian cancer. The cut-off values of 500 U/ml and 8 U/ml for CA-125 and CASA, respectively, showed better results for the differential diagnosis between malign and benign diseases. The highest sensitivity (95%) was reached with the CA-125 cut-off value of 35 U/ml. The most sensitive prognostic parameter for the overall survival was for the primary and recurrent ovarian cancer group the expression of CASA in ascites (p = 0.030 and p = 0.024, respectively). In order to approximate the risk of the patient to develop recurrence in the next 5 years from initial diagnosis, the CASA cut-off value in serum of 4 U/ml provide the best results (p = 0.074). For recurrent disease, the circulating CASA cut-off value of 65 U/ml was the most sensitive method (p = 0.018) for determining the risk of new progression. For the overall survival, the residual tumor load and the expression of CASA in ascites (cut-off values of 35 U/ml and 65 U/ml) were the only independent prognostic factors.

Conclusions: The results of the current study showed that the expression of CASA in ascites has a prognostic role in patients with primary and recurrent ovarian cancer. The 5 year overall survival is decreased in patients with higher ascitic levels of CASA.

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Prospective validation of a predictive score for complete tumor resection in recurrent ovarian cancer (ROC): an intergroup study of AGO kommission OVAR, AGO-OVAR, AGO Austria, MITO and NOGGO

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Background: In the multicenter DESKTOP I study patients only benefited from surgery for ROC if complete resection was achieved. Good performance status, complete resection at 1st surgery and absence of ascites were identified as the only indepedent predictors for complete resection. If all three factors were positive the AGO score was classified as positive. This score was now prospectively validated in a prospective multicenter trial. Furthermore postoperative complications were analyzed descriptively.

Method: Prospective validation of the AGO-score for surgery for platinum-sensitive ROC in a multicentre study. The statistical assumption was that 75% of the patients should be confirmed with 95% probability for a correct prediction of complete resection in >2 out of 3 patients. Therefore a total of 122 score-positive operated patients have to be enrolled.

Results: Between 08/06 and 03/08 412 patients with first relapse and 105 with 2nd relapse of a platinum-sensitive ROC were screened. 193 (47%) of the patients were deemed eligible for surgery. 127 of these 193 pts (66%) underwent surgery and had a positive score. Complete resection was achieved in 76% (95% CI: 69–84%) The rate of relaparotomies caused by complications was 8.7%. Two patients (1.6%) died within 60 days after surgery.

Conclusion: The AGO score is a reliable tool to predict complete resection. Based on these data a prospective randomized trial is planned to define the definitive role of complete resection in ROC.