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## Can concomitant diseases predict the compliance with cisplatin plus RT in patients with LA SCCHN? An exploratory endpoint analysis of the COMPLY trial

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**Background:** International guidelines recommend the use of high-dose platinum chemoradiotherapy (CRT) (3 x 100 mg/m<sup>2</sup>, q3w) for the treatment of LA SCCHN. The clinical benefit of CRT decreases with lower cumulative dosage. Dose reductions to  $\leq 200$  mg/m<sup>2</sup> lead to a significantly lowered OS. Predictive factors would help to select patients who are suitable for an optimal cumulative dose of cisplatin.

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**Methods:** The COMPLY trial included patients with LA SCCHN from Germany and Switzerland. Eligible patients were treated in 2013/2014. The planned target dose of cisplatin had to be > 200 mg/m<sup>2</sup>. Compliance was defined as an administration of > 200 mg/m<sup>2</sup> cisplatin. R/M SCCHN, nasopharyngeal carcinomas, adjuvant treatment or participation in other clinical trials were excluded. The exploratory objective was to identify a predictive score for therapy compliance with platinum-based CRT. A multiple logistic regression analysis was performed to identify independent explanatory variables associated with compliance with cisplatin. Only independent variables with a p-value <0.15 in the univariate analysis.

**Results:** 184 patients in 9 sites were included. Median age was 61.0 years, 82.6% were male, 167 patients (90.8%) were ECOG 0-1. A significant difference in treatment compliance with cisplatin was shown for patients with concomitant musculoskletal/connective tissue disorders (odds ratio for absence of disease vs. presence: 9.43; 95% CI: 1.20, 74.02; p = 0.03) and respiratory, thoracic and mediastinal disorders (odds ratio for absence of disease vs. presence: 6.59; 95% CI: 1.47, 29.48; p = 0.01) by system organ class. The probability of treatment compliance with cisplatin, being an estimate from a scoring system developed for the study, was 43.4% in subjects with absence of both disorders while the treatment compliance was 8.9% in subjects who presented with either one of the disorders and 1.2% in subjects with both disorders.

**Conclusions:** These exploratory results indicate that subjects without musculoskeletal/ connective tissue and respiratory, thoracic and mediastinal disorders as concomitant diseases were more likely to have received cisplatin >200 mg/m<sup>2</sup>.

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