6.

Randomized phase II study of adjuvant cisplatin/docetaxel (Cis-Doc) or cisplatin/vinorelbine (Cis-VRB) in patients (pts) with resected stage IB-II NSCLC: interim analysis

P. Germonpré, P. Driesen, M. Lambrechts, L. Bosquée, F. Bustin, D. Verresen, D. Galdermans (Anwerpen, Liège, Belgium)

Background: Several randomized phase III trials in early-stage NSCLC, showed that Cis-VRB adjuvant chemotherapy (CT) improves survival; however, compliance with adjuvant CT remains problematic .
A recent meta-analysis in pts with advanced NSCLC found a significant survival benefit for docetaxel-based CT compared to vinca alkaloid-based CT

Methods: Pts with completely resected stage pIB-II NSCLC, good performance status and planned start of chemotherapy within 60 d of resection were included. Pts were randomized (2:1) to adjuvant CT with Cis-Doc (Cis and Doc both 75 mg/m2 on day 1) or Cis-VRB (Cis 80 mg/m2 on day 1; VRB 25 mg/m2 on days 1 and 8) every 3 weeks for 4 cycles. Primary endpoint was success of treatment delivery (defined as ≥3 cycles of chemo with a relative dose intensity (RDI) of ≥80%). A two-staged design with pre-planned interim analysis was used (total sample size 99 pts).

Results: From 12/2005 to 09/2007, 45 pts (33 males, 12 females) were randomized (Cis-Doc 35/ Cis-VRB 10). Pathological stages included stage IB (n=32), stage IIA (n=6), stage IIB (n=7). Resection consisted of segmentectomy (n=1), (bi-)lobectomy (n=34), sleeve lobectomy (n=2) and pneumonectomy (n=8).
In arm Cis-Doc 25 and 23 pts and in arm Cis-VRB 15 and 9 pts completed 3 and 4 cycles resp. Dose intensity (mg/m2.wk) was: Cis 24.4 and Doc 24.5 in Cis-Doc arm and Cis 23.7 and VRB 15.0 in Cis-VRB arm. RDI was Cis-Doc 98%/98% and Cis-VRB 89%/90%. No treatment-related deaths were observed.

Conclusions: Adjuvant CT with 3-weekly shedules of Cis-Doc or Cis-VRB results in a good CT compliance and dose intensity