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POSTER

Surgical resection for Pancoast tumours after neoadjuvant chemoradiotherapy?

I. Kappers¹, J.S.A. Belderbos², J.A. Burgers², J.W. van Sandick¹, N. van Zandwijk³, H.M. Klomp¹. ¹The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Surgical Oncology, Amsterdam, The Netherlands; ²The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Radiotherapy, Amsterdam, The Netherlands; ³The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Thoracic Oncology, Amsterdam, The Netherlands

Background: Superior sulcus tumors (SST) or Pancoast tumors are preferably treated with neoadjuvant concurrent chemoradiotherapy (CRT) and surgical resection. Induction CRT increases the probability of a complete resection and local control. However, it is associated with an increased complication rate. Resections generally involve the upper lobe with contiguous thoracic wall including apical ribs (and T1 plexus root /partial vertebra if necessary). We evaluated the role of surgery as part of multimodality treatment in our institute.

Methods: From registration databases all patients with SST referred to our institute from 1995 to 2006 were identified. The preferred treatment, if feasible, was CRT (66 Gy in fractions of 2.75 Gy with daily cisplatin 6 mg/m²) followed by resection. Performance status, clinical and pathological tumor stage, (response to) treatment, and survival were reviewed retrospectively. Survival analysis was performed using the Kaplan-Meier method.

Results: 85 patients with SST, 57 men and 28 women, were identified. The median follow-up was 15 months (2–123). Mean age was 57 years (32–82). After further evaluation 21 patients were diagnosed with stage IV disease; 42 patients were rejected for resection due to comorbidity/inoperability (n=25), irresectability or poor response to induction treatment. Of 64 patients with stage II or III disease, 22 underwent surgery. The 2- and 5-year overall survival (OS) was 70% and 37%. All resections were complete and local recurrences were not observed. In 13 patients a pathologic complete response (pCR) was found. pCR was a significant prognostic factor for survival (5 yr OS 50% vs. 17%). Radiological restaging imaging (CT or MRI) did not identify these responses. There were no fatal toxicities or treatment-related mortalities.

Forty-two patients (rejected for resection) received either concurrent CRT (n=19, 2- and 5-yr OS 39% and 15%) or RT and CT sequentially (n=23, 2- and 5-yr OS 18% and 5%). Local recurrence/progression occurred in 13 out of 42 patients, 6 of these patients also had distant metastases.

Conclusions: Surgical resection following induction CRT is associated with excellent local control and acceptable long-term survival. Surgery however may not have additional value for patients with pCR. Unfortunately, pCR could not be sufficiently recognized with conventional imaging.

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Clinical and economic impact of febrile neutropenia management of lung cancer patients in clinical practice in Spain

N. Viñolas¹, A. Gúrpide², A. Frau³, J.L. González Larriba⁴, M.J. Lamas⁵, F. Alvarez⁶, M. Layola⁷, J.A. Gasquet⁸. On behalf of the ENIA Study Group. ¹H. Clínica i Provincial, Oncology, Barcelona, Spain; ²H. Clínica Universitaria de Navarra, Oncology, Pamplona, Spain; ³H. Provincial de Castellón, Oncology, Castellón, Spain; ⁴H. Clínico San Carlos, Oncology, Madrid, Spain; ⁵H. Clínico de Santiago, Oncology, Santiago de Compostela, Spain; ⁶H. Infanta Cristina, Oncology, Badajoz, Spain; ⁷IMS Health, Medical, Barcelona, Spain; ⁸Amgen S.A., Medical, Barcelona, Spain

Background: Despite the significant impact of chemotherapy-induced febrile neutropenia (FN) on patients (pts) with lung cancer and its implications for health care costs, there are no data on economic costs of FN in clinical practice in Spain. FN impact on planned chemotherapy (CT) dose and/or schedule in the same setting is also unclear.

Methods: This is a sub-analysis of lung cancer pts included in a multicentre, retrospective, chart review of adult pts from 16 Spanish hospitals who suffered from at least one FN episode related to cytotoxic chemotherapy (CT). Resource use and subsequent costs including days of hospitalization, number of transfusions, number and type of complementary tests, use of colony-stimulating factors (CSFs), and use of antibiotics and other drugs to manage FN were assessed for each episode. The impact of FN on planned CT was also analysed in terms of dose delays (DD) and/or reductions (DR).

Results: Medical charts from 194 pts were reviewed, 44 (23%) of whom had lung cancer (50% non-small cell, 50% small cell), which accounted for 52 documented FN episodes included in this analysis. The median (range) age of patients was 63.5 (34–89) years, 93% males, 59% stage IIIB/IV, and 96% were treated with platinum-based CT. FN appeared during first

CT cycle in 61% of the pts. Hospitalization was required in 98.1% of the episodes and the median length of hospital stay due to FN was 7 days (p25:5-p75:10). During an FN episode 23% of episodes required ≥1 transfusion, 92% needed a blood test and 73% a blood culture. Microbiologically documented infection appeared in 21% of FN episodes. All episodes were treated with antibiotics (65.4% with cephalosporins) and CSFs were used in 76.9% of the episodes. In 67% of episodes, FN impacted on planned CT dose and/or schedule: DR were observed in 51% of pts, DD in 29% and CT withdrawal in 10%.

Healthcare costs per FN episode

FN episode	Cost, € [mean (SD)]
Hospitalizations	2619.54 (1531.96)
Transfusions	18.11 (34.27)
Complementary tests	94.27 (43.60)
CSFs	211.47 (181.36)
Antibiotics and other drugs	367.46 (266.48)
Total	3310.85 (1818.39)

Conclusions: In current clinical practice, FN in pts with lung cancer incurs substantial healthcare resource use with associated costs. The main drivers of FN cost are hospitalization and antibiotic treatment. In addition, FN can negatively impact on planned CT dose and/or schedule, with potential consequences for treatment outcome.

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Phase II trial of the novel epothilone ZK-EPO as second-line therapy in patients with stage IIIB or stage IV non-small-cell lung cancer

U. Gatzemeier¹, J. von Pawel², C. Eschbach³, A. Brune⁴, A. Wagner⁵, M. Giurescu⁵, M. Reck¹. ¹Krankenhaus Großhansdorf, Zentrum für Pneumologie und Thoraxchirurgie, Großhansdorf, Germany; ²Asklepios Fachkliniken München-Gauting, Zentrum für Pneumologie und Thoraxchirurgie, Gauting, Germany; ³Thoraxzentrum Hamburg, Allgemeines Krankenhaus, Hamburg, Germany; ⁴Bayer Schering Pharma AG, Global Clinical Operations, Berlin, Germany; ⁵Bayer Schering Pharma AG, Global Clinical Development, Berlin, Germany

Background: The novel epothilone ZK-EPO has demonstrated significant activity against non-small-cell lung cancer (NSCLC) cell lines. The results of the first completed Phase I study (one 30-minute infusion q3w) demonstrated that ZK-EPO was well tolerated, with peripheral neuropathy being the most common toxicity. Signs of activity, including objective responses, were observed. A Phase II trial was performed to determine the efficacy and safety of ZK-EPO as second-line therapy in patients with stage IIIB and IV NSCLC.

Methods: Eligible patients had relapsed after one previous platinum-based chemotherapy regimen, and had measurable disease according to RECIST. Patients received a maximum of six 3-hour infusions of ZK-EPO 16 mg/m² q3w. A fixed sample design with 38 patients was used ($\alpha=0.10$ [one sided], $p_0=0.20$, power = 0.80 at $p_1=0.08$). If ≥5 responses were observed in the first 38 evaluable patients, the drug would be considered efficacious.

Results: A total of 44 patients have entered the study (accrual completed in May 2006). Two patients were excluded from the efficacy analysis as per protocol due to termination for reasons other than progression before the first efficacy evaluation. Preliminary data are available on all patients. A total of 113 infusions were administered. Responses were seen in 4 of the first 38 evaluable patients (response rate=10.5%; 80% CI=4.7%, 19.9%). The most common drug-related toxicity was peripheral sensory neuropathy (less than grade 3 in 45% of patients; grade 3 in 14%). Seven patients discontinued treatment due to neuropathy. Other drug-related toxicities (all grades >10%) were myalgia (23%), alopecia (18%), nausea (16%), fatigue (16%) and vomiting (14%).

Conclusion: ZK-EPO, administered as a 3-hour infusion at a dose of 16 mg/m², showed activity as second-line treatment in NSCLC. The only noteworthy toxicity currently appears to be peripheral neuropathy. The study has been amended to investigate 22 mg/m² q3w, and recruitment is ongoing.