1035 POSTER*

Magnetic resonance imaging (MRI) of pulmonary lesions with single shot fast and ultra-fast gradient echo imaging

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The purpose of our study was to evaluate the the clinical applications of subsecond MRI of thoracic lesions in direct correlation to intraoperative findings. The studies were performed on a 1.5 tesla MR-system/Magnetom SP 4000, Siemens) using a whole body resonator. We used three sequences: T1w-TurboFLASH (T1wTF), FLASH and T2w-TurboFLASH (T2wTF). Images were acquired in the coronal, transversal and sagittal plane. 20 patients with pathological findings in conventional radiography and computed tomography (CT) were studied with MRI prior resection.

For the detection of a lesion, the combination of the FLASH and the T2wTF showed the highest diagnostic gain. Due to the different, reproducible signal intensity of vascular and malignant lesions in the FLASH and T2wTF images, a clear identification was obtained without contrast media. Lesion detection as well as classification of extend was excellent in all pts. The total examination time was less than 30 minutes. A combination of single shot FLASH with a single shot T2wTurboFLASH sequence enables subsecond imaging of pulmonary lesions. All important vascular structures were reliably visualized without contrast media. While MRI does not currently have any diagnostic advantage overover CT in the detection of thoracic lesions, the excellent differentiation of parenchymal lesions and vascular structures without the use of contrast media and the variability of imaging planes are significant methodological advantages.

1036 POSTER*

Interim results of a phase II study of docetaxel (Taxotere®) in unresectable non-small cell lung cancer (NSCLC) on 204 chemotherapy naive or pretreated patients

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Taxotere® has already produced promising responses as a single agent in locally advanced and/or metastatic NSCLC. Therefore, a phase II study was started with Taxotere at a dose of 100 mg/m² every 3 weeks with a 5 day oral corticosteroid premedication. Evaluation of efficacy was performed every 2–3 cycles. Patients (pts) received 6 to 9 cycles according to response. Histologically confirmed NSCLC, KPS ≥ 60%, no brain involvement and signed informed consent were the main eligibility criteria. 29 centers in 4 countries accrued 204 pts with measurable or evaluable lesions. To date 127 pts have been assessed. The characteristics of the pts were: male: 81%; median age: 59 years (19–78); median KPS: 80% (60–100); chemotherapy pretreated pts: 31%; metastatic: 77%. Pts received a mean of 4.3 cycles (1–17). 91 pts were evaluable for response: 24 PR (26% of evaluable pts-20% of ITT pts) and 29 NC (32%) were observed and confirmed by an independent panel. Median time to progression was 2.6 months and median duration of response was 8.6 months. Median survival was 8.4 months and one year survival was 36%. Main toxicities were neutropenia: G4: 57%, G3: 14%; febrile neutropenia: 6%; infection: 30%; severe asthenia: 10%; severe fluid retention: 2%; neurosensory G-3: 2%; 2 deaths due to neutropenic infection. The results of this interim analysis confirm the published results of Taxotere® in chemotherapy naive pts as well as in pretreated pts.

1037 POSTER*

Gemcitabine (GEM) – Cisplatin (CDDP) – Vinorelbine (VNR) combination in advanced non-small-cell lung cancer (NSCLC). A phase II randomized study

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Purpose: To define the activity and toxicity of the GEM-CDDP-VNR combination in advanced NSCLC.

Methods: Chemo-naive pts. with stage IIIB–IV, age ≤70 and PS 0–1 were randomized to receive GEM (1,000 mg/m²), CDDP (50 mg/m²) and VNR (25 mg/m²) (all drugs were given on d 1 & 8 of an every 3-week cycle) or CDDP (80 mg/m² d 1), epiDX (80 mg/m² d 1), VDS (3 mg/m² d 1) every 4 weeks, plus ionidamine (150 mg × 3 daily, orally) as standard treatment.

Results: On December 1996 we stopped the randomization since we had already reached the target number of 31 responses required by our study design in the experimental arm. We decided, however, to continue the accrual in this arm until the planned sample size (81). To date, 127 eligible pts. have been accrued, 73 in the experimental and 54 in the standard arm. Both treatments have been associated with a manageable toxicity. 53 and 41 pts. are evaluable for response respectively. Objective responses are 32/53 (60%; 95% CI = 46–73) and 15/41 (37%; 95% CI = 22–53). At a median follow-up of 8 months, median survival is >14 months in the experimental and 8 month in the standard group.

Conclusion: The GEM-CDDP-VNR combination is a highly active treatment for advanced NSCLC patients.

1038 POSTER*

Topotecan (Hycamtin™) in small cell lung cancer (SCLC) after failure of first line therapy: Multicentre phase II study

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Purpose: This phase II study was conducted to confirm the documented activity of topotecan (TPT), a selective topoisomerase-I inhibitor in 2nd-line SCLC.

Methods: 95 males and 24 females with measurable SCLC classified as refractory (R; i.e. progressed on first-line treatment or within 3 m of stopping (n = 48)) or sensitive (S; i.e. progressed >3 m after stopping first-line treatment (n = 71)) received TPT 1.5 mg/m²/day as a 30 min infusion daily for 5 d, q 21 d. All responses were independently verified.

Results: 98 pts were fully evaluable for response (41 R; S 57). Responses were seen in 9 pts (8S; 1R). In S pts one patient had a CR. 11 pts had objective stable disease. For the intent-to-treat population, median survival was 21.6 wks overall (25.7 wks S, 16.3 wks R), and time to progression was 8.1 wks. In 9 pts with brain metastases, there were, within the CNS, 4 PRs and 3 SDs plus 1 CR in a patient who received concurrent RT. Toxicities were mainly haematologic, consistent with the profile of the drug.

Conclusion: Ardizzoni, ESMO, 1996, reported a response rate of 23% in pts demographically similar to ours, but with fewer S pts (48% v 60%), and who received twice as much TPT therapy; (median 4 cyc v 2 cyc). Of the 11 SD in our study, none had evidence of PD or intolerable side effect at withdrawal, 9 were S, and 9 are known to have received subsequent chemo; 6 were both S and received subsequent chemo. This study shows that TPT has activity in 2nd-line SCLC pts, achieving an overall median survival of 21.6 wks. TPT appears to induce, besides clinical responses, slow tumour regression or arrest of tumour growth. This, together with the activity observed in those pts with cerebral secondaries, suggests a potential role of TPT in 1st-line therapies, either as a cranial prophylaxis or as a maintenance agent. These studies are being planned.

1039 POSTER*

High dose-density chemotherapy for small cell lung cancer (SCLC)

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Purpose: To explore the feasibility of administration of a high-density chemotherapy regimen in small cell lung cancer and to assess the impact in survival.

Methods: We treated 45 patients (pts) with SCLC with a sequential treatment consisting of 4 cycles of VEC (Vincristine 1.4 mg/m², Epidoxorubicin 110 mg/m², Cyclophosphamide 1 g/m² IV d 1) followed by 2 cycles of PE (Cisplatin 120 mg/m² IV d1, Etoposide 200 mg/m² IV d1–3 or 1–2). Cycles were administered every two weeks and G-CSF (filgrastim) 300 μgr SC qd was administered during the interval. Complete responders with limited stage disease received prophylactic cranial irradiation and thoracic radiotherapy at the end of chemotherapy. 43 pts were male and 2 female. Median age was 59 years (36–75). 93% of pts had ECOG 0–1. 26 pts had limited stage (LS) and 19 extensive stage (ES).