Conclusion: This novel treatment is well tolerated and highly active in limited SCLC.

1006 POSTER

The role of TC-99m tetrofosmin (T) SPECT in primary lung cancer (LC) detection

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Purpose: The aim of the study was to further evaluate the usefulness of Tetrofosmin-SPECT in identifying primary lung cancer.

Methods: After T injection, SPECT images of the chest were acquired in 122 pts with suspect pulmonary lesions at conventional imaging procedures. Scan data were analized qualitatively and semiquantitatively, the latter by calculating the Tumor/Background ratio (T/B) in the coronal slices, and were then related to histology.

Results: T-SPECT was true positive in 105/105 LC pts (sens. 100%) and true negative in 13/17 pts with benign pulmonary lesions (spec. 76.5%). T/B value was higher in malignant lung lesions than in benign ones (2.37 ± 0.84 vs 1.42 ± 0.24; $p < 0.05$). Considering a T/B cut-off value of 1.4, T-SPECT specificity increased to 88.2%.

Conclusion: T-SPECT appears a highly sensitive method in primary lung cancer detection since there was no false negative result in our cases. Moreover, the additional use of T/B seems to give more useful information in differentiating malignant from benign pulmonary lesions.

1007 POSTER

Chemoradiotherapy for advanced non-small cell lung carcinoma (NSCLC). Qualitative and quantitative evaluation of the literature

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Purpose: The treatment of unresectable stage III NSCLC by chest irradiation with or without chemotherapy remains controversial. In order to clarify the role of each therapeutic modality, we performed a systematic review of randomised trials on this field.

Methods: We assessed the selected studies for their quantitative therapeutic results. A qualitative overview was carried out using two scales: the Chalmers and the ELCWP (Lung Cancer 19:141;1998) scores. The ELCWP score includes 15 groups of items, 7 on internal validity and 8 on external validity (maximal theoretical score of 110 points).

Results: Ten studies were eligible for our analysis, including 1749 eligible patients. Five were significantly in favour of combined treatment. Overall median ELCWP and Chalmers scores were respectively 63.2% (range: 36% to 85%) and 49.2% (range: 29.3% to 71.6%). However, no statistically significant difference in methodology was found between negative ($p > 0.05$ on survival curves) and positive trials ($p \leq 0.05$ on survival curves) as well for the ELCWP or the Chalmers scores. No difference could be detected according to the number of eligible patients, the date of first registration or publication.

Conclusions: These methodological similarities allows to aggregate the results of the tested treatments.

1008 POSTER

Extensive clinical experience with Taxotere® (T) in 1st and 2nd line treatment at 100 mg/m² in locally advanced or metastatic NSCLC

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100 centers from Europe, Middle East, Asia and South America participated in NSCLC study with broad inclusion criteria (1st + 2nd line) to establish the toxicity and efficacy profile of docetaxel at 100 mg/m² in worldwide clinical practice. 754 patients (pts) have been treated, 585M/169F. 3023 cycles have been administered, median: 3 (1–12). Median age was 59 yrs (25–83), median WHO PS: 1 (0–3), Median number of organs involved: 2 (1–6). Adenocarcinoma: 313 pts, squamous cell: 235 pts, large cell: 35 pts, other: 171 pts.

Results: To date 536 patients are evaluable for reponse, the overall response rate in first line is 27.9% (95% CI [17.5–29.8]). Safety profile: neutropenia gr. 3/4: 55% of pts, non hematologic toxicities gr 3/4: infection 5%, diarrhea 4%, pulmonary 3%, skin 2%, stomatitis 2%, neurosensory 3%

Conclusion: The safety and efficacy reported in more limited studies is maintained in a broad population.

1009 POSTER

Bendamustin in untreated small cell lung cancer (SCLC): Efficacy and toxicity

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Purpose: High response rates can be induced in patients (pts) with SCLC by different cytostatic treatment regimens. Durable remissions, however, are rare, even after aggressive and toxic combinations. Therefore, at least equally effective but less toxic first line treatments are warranted.

Methods: Twenty-six pts with extensive disease (ED) SCLC and no prior treatment received Bendamustin 120 mg/m² as an one-hour infusion on two consecutive days. The treatment was repeated every three weeks. If a complete (CR) or partial (PR) remission was achieved, six treatment cycles were given. In case of "no change" (ND) therapy was terminated after 4 cycles. It was immediately stopped, if disease progression (PD) could be demonstrated at regular tumor evaluations prior to every new treatment cycle.

Results: So far, 22 pts are evaluable for response and toxicity. Two pts (9%) showed CR, 8 pts (36%) PR and 4 pts (19%) NC. Another 8 pts (36%) had PD. The median remission duration is 3+ months (range, 1+–5). The median survival time is not achieved. Side effects (preferably WHO grade 1 and seldom 2) restricted to myelosuppression and gastrointestinal toxicities.

Conclusion: Bendamustin is a very effective and well-tolerated agent in ED SCLC. Remission durations are comparable to more aggressive and toxic cytostatic combinations.

1010 POSTER

Unresectable non-small cell lung cancer (NSCLC) as a target for clinical trials of AG3340, a selective inhibitor of matrix metalloproteases (MMPs), in combination with standard chemotherapies

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While treatment of newly diagnosed, advanced stage NSCLC with combination chemotherapy commonly results in patient benefit, therapies that enhance outcome are needed. MMPs are a family of enzymes that degrade the matrix between cells. Several of these enzymes have been shown to facilitate tumor angiogenesis, invasion, and metastasis. AG3340 is a potent and selective inhibitor of MMPs designed using X-ray crystallography. AG3340 inhibits MMP-2, -9 and -14 with Ki values of 30–330 pM, but is less potent against the enzyme believed to be responsible for maintaining function in the joints (MMP-1, Ki 8300 pM). Preclinical experiments conducted in xenograft tumor models demonstrated antitumor effects of single agent AG3340 and enhanced efficacy of chemotherapy and radiation therapy when administered in combination with AG3340. The pharmacokinetics of AG3340 in volunteers and patients are similar and linear, the free fraction in plasma is high (31%), and the minimum effective concentration identified in preclinical models is easily exceeded with well-tolerated doses of AG3340 administered twice daily. Two randomized, double-blind, placebo-controlled Phase III studies in patients having newly diagnosed Stage IIIB/IV or recurrent NSCLC are underway in North America, Europe and Australia. AG3340 or placebo is administered beginning on Day 1 of the study in combination with standard doses and regimens of gemcitabine/cisplatin or paclitaxel/carboplatin. Because AG3340 might be expected to slow the rate of tumor growth beyond an arbitrary definition of progression, patients may continue treatment with study tablets (AG3340 or placebo) in combination with the investigator's choice of subsequent therapies, in hopes of providing additional survival benefit. As of March, 1999, 400 patients have been accrued at over 50 participating institutions. Therapies used subsequent to first-line therapy and in combination with study tablets have