

Poster Session

Lung cancer

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POSTER

Efficacy of oral UFT for adjuvant chemotherapy after complete resection of non-small cell lung cancer: Meta-analysis of six randomized trials in 2003 patients

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Background: Clinical trials assessing the response of non-small-cell lung cancer to postoperative adjuvant chemotherapy should use survival as the primary endpoint. Response should be evaluated by means of randomized controlled studies using surgical therapy alone as control. Single studies usually do not provide clear-cut conclusions because of limited sample size. We therefore performed a meta-analysis of all properly randomized clinical trials comparing long-term adjuvant chemotherapy with UFT, an oral fluorinated pyrimidine derivative, with surgery alone in patients with completely resected non-small-cell lung cancer.

Material and methods: Six such trials were identified.

- 1) The Japan Lung Cancer Research Group
- 2) The West Japan Study Group for Lung Cancer Surgery(II)
- 3) The West Japan Study Group for Lung Cancer Surgery(IV)
- 4) North-east Japan Study Group for Lung Cancer Surgery
- 5) Osaka Lung Cancer Study Group
- 6) Adjuvant Chemotherapy for Lung Cancer Study Group

The analysis was based on individual patient data provided by the principal investigator of each trial. Data from 2003 eligible patients were analyzed on an intention-to-treat basis. The endpoint of interest was overall survival at 5 years after surgery. Major prognostic factors were well balanced between the UFT group and surgery alone group. Most patients had early-stage non-small-cell lung cancer, pT1(65%) and pT2(34%).

Results: The results of meta-analysis demonstrated that adjuvant chemotherapy with UFT improved overall survival (hazard ratio, 0.77; 95%CI, 0.63-0.94; $p=0.011$). The difference in the 5-year survival rate between the UFT arm (81.8%) and surgery alone arm (77.2%) was 4.6%. Heterogeneity of effect among the six studies was not significant ($p=0.76$).

Conclusion: On the basis of our meta-analysis, we conclude that postoperative adjuvant chemotherapy with UFT has a beneficial effect on outcome in patients with curatively resected non-small-cell lung cancer.

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Reducing health care burden for the treatment of toxicity associated with pemetrexed or docetaxel in patients with advanced non-small cell lung cancer who previously received chemotherapy: application to the UK setting

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Introduction: Management of toxicities associated with cytotoxic chemotherapy contributes to the burden of the UK National Health Service (NHS) of providing health care to patients (pts) with advanced non-small cell lung cancer (NSCLC). This preliminary analysis summarises incidence and costs of some of the most expensive toxicity-related supportive care for two treatments for NSCLC.

Methods: This economic assessment was based on resource utilisation data collected prospectively in a multinational, phase III randomised study comparing pemetrexed (pem) with docetaxel (doc) in pts with NSCLC who had previously received chemotherapy. We evaluated the direct medical costs of key investigator-determined drug-related adverse events (AEs) reported for these two treatment groups. Data included in this initial analysis were hospitalisations (both admissions and days), transfusions, erythropoietin, granulocyte colony-stimulating factors (GCSFs) and parenteral antibiotics. Unit costs were sourced from UK NHS casemix data (published in 2002) and UK national drug prices. Costs were calculated as mean cost per pt.

Results: Baseline pt and disease characteristics from the 541 pts who received treatment were well balanced. Results of the trial demonstrated similar median survival time and tumour response rates for both arms (approximately 8 months and 9%, respectively). The mean number of cycles administered was 4.4 on the pem arm and 3.9 on the doc arm. Drug-related serious AEs were significantly higher for doc compared with pem (24% vs 10%). CTC grade 3/4 neutropenia and neutropenic fever were significantly higher in the doc arm (40% vs 5%, 13% vs 2%, respectively). Most other grade 3/4 toxicities, including nausea/vomiting, thrombocytopenia and anemia, were similar between treatment arms and occurred at low rates ($\leq 5\%$). Although more pts on the doc arm received erythropoietin, more pts on the pem arm received red blood cell transfusions. Pts on the pem arm received fewer courses of parenteral antibiotics (106 vs 151) and GCSF (10 vs 100) and required fewer hospital admissions (21 vs 72) and days (160 vs 346). The most common reason for drug-related hospitalisation for both arms was febrile neutropenia (4 admissions in the pem arm vs 43 in the doc arm). Cost results (mean cost per pt) were as follows:

	Pemetrexed (N=265)	Docetaxel (N=276)
Total hospitalisations	£154	£408
Outpatient transfusions	£2	£0
Erythropoietin	£61	£70
GCSF	£13	£128
Parenteral antibiotics	£9	£12
Total	£239	£618

Conclusions: For patients with advanced NSCLC who have previously received chemotherapy, pemetrexed offers similar survival and response rates with a more favourable toxicity profile relative to docetaxel. In the management of chemotherapy-related adverse events, pemetrexed is less expensive and requires fewer unscheduled supportive care interventions, thus reducing the NHS health care burden.

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Final results of phase II trial of s-1 plus cisplatin (CDDP) in patients with non-small-cell lung cancer (NSCLC)

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Background: 5-Fluorouracil (5-FU) is one of the widely used therapeutic agents for solid tumors. However, its usefulness is limited by dihydropyrimidine dehydrogenase (DPD), which rapidly inactivates 5-FU. To enhance therapeutic activity, two new oral 5-FU derivatives combined with DPD inhibitors, UFT and S-1, have been developed. UFT consists of 1 M tegafur (a prodrug of 5-FU) and 4 M uracil (a DPD inhibitor) and has been approved in 60 countries. UFT plus CDDP is effective against NSCLC with a response rate (RR) of 29.1%. S-1 consists of 1 M tegafur, 0.4 M gimeracil (a potent DPD inhibitor), and 1 M potassium oxonate, which selectively decreases gastrointestinal toxicity. S-1 is now widely used for the management of