

Non-small cell lung cancer(NSCLC) remains the leading cause of cancer related death and 5-year survival rate is approximately 10-15%. Platinum-based chemotherapy has been demonstrated to improve survival in advanced NSCLC. Platinum-based paclitaxel and gemcitabine combination therapy considered moderately active regimen in patients with advanced NSCLC and warrants comparison with existing platinum-based regimen in randomized trial. The aim of this study was to evaluate toxicity and efficacy of platinum-based paclitaxel and gemcitabine combination therapy.

The medical charts of fifty-six patients with NSCLC, who met selection criteria from January 2000 to March 2001, were reviewed retrospectively. They received one of three regimens greater than 2 cycles up to 7 cycles, paclitaxel (140mg/m²) and cisplatin (60mg/m²), paclitaxel (120mg/m²) and carboplatin (300mg/m²), gemcitabine (1000mg/m²) and cisplatin (60mg/m²). Data collection and analysis included baseline characteristics, hematologic and non-hematologic toxicity profiles according to WHO toxicity criteria and overall response according to clinician's opinion on basis of clinical results.

As results, WHO grade above 2 hematologic toxicity occurred high in gemcitabine/cisplatin arm(9.6%) compared with other two arms (paclitaxel/cisplatin 2.8% vs. paclitaxel/carboplatin 5.8%). WHO grade above 2 non-hematologic GI toxicity occurred high in paclitaxel/carboplatin arm(5.2%) compared with other two arms (paclitaxel/cisplatin 3.4% vs. gemcitabine/cisplatin 2.5%). WHO grade above 2 non-hematologic excluding GI toxicity occurred high in paclitaxel/cisplatin arm(8.8%) compared with other two arms (paclitaxel/carboplatin 7.9% vs. gemcitabine/cisplatin 2.6%). Common side effects included nausea/vomiting, peripheral neuropathy and alopecia. Comparing toxicity profiles for the three regimens revealed no significant difference. Overall response rate was 22% for paclitaxel/cisplatin arm, 31% for paclitaxel/carboplatin arm, and 15% for gemcitabine/cisplatin arm. Comparing response rate for the three arms revealed no significant difference. The median survival period was 12.2 months for paclitaxel/cisplatin arm, 18.3 months for paclitaxel/carboplatin arm, and 8.3 months for gemcitabine/cisplatin arm. Comparing survival for the three arms revealed no significant difference. There were several limitations of this study, uncontrolled baseline disease, baseline toxicity, number of patient and number of effective cycles for the treatment group. Further well-designed study is required and pharmacist's role in ADR monitoring should be emphasized.

[PA2-5] [10/18/2001 (Thr) 14:00 - 17:00 / Hall D]

A Comparison of Lovastatin and Simvastatin in Treatment of Hyperlipidemia

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Hypercholesterolemia is one of main causes of coronary heart disease(CHD). Clinical trials demonstrated that lowering serum cholesterol levels would reduce incidence of new cardiovascular events and mortality by primary or secondary preventions. The objective of this retrospective study was to compare efficacy and side effects of lovastatin and simvastatin in treatment of hypercholesterolemia. In Boramae Hospital, patients were included when they have taken lovastatin 20mg or simvastatin 10mg for 52 weeks with laboratory monitoring for cholesterol at baseline, 3, 6 and 12 month period. As results, total 128 outpatients were included with their total cholesterol level ≥ 240 mg/dL and triglyceride level < 400 mg/dL at baseline. Total cholesterol and LDL cholesterol of lovastatin group(n=60) and simvastatin group(n=68) were significantly reduced from baseline(p=0.001). Lovastatin maximally reduced total cholesterol by 23.9%, triglyceride by 12.3%, LDL cholesterol by 36.1% and increased HDL cholesterol by 7.8% and simvastatin reduced by 24.1%, 20.5%, 34.3% respectively and HDL increased by 11.2%. There were no significant differences between lovastatin and simvastatin in mean percent change of lipid levels at 12, 24 and 52 weeks from baseline. Cumulative percentage of patients reaching the target LDL cholesterol concentration by 24 weeks was 61.7% in lovastatin and 64.7% in simvastatin. Average time to reach the target LDL goal was 100.1 days in lovastatin and 99.8 days in simvastatin. Both lovastatin and simvastatin also significantly reduced total cholesterol and LDL cholesterol in all three subgroups (diabetes mellitus group, hypertension group, and coronary heart disease group), but there was no significant difference in efficacy between lovastatin and simvastatin. In this study, treatment efficacy in patients with coronary heart disease was lower than other patients. Considering clinical importance of secondary prevention, more intensive treatment is necessary to decrease LDL cholesterol level of 100mg/dL or lower in patients with coronary heart disease or other clinical

atherosclerotic disease. There were no serious side effects during the study period. Digestive side effects were most frequently reported (lovastatin 8.3% vs simvastatin 8.8%). In conclusion, both lovastatin and simvastatin were similar in lipid lowering effects and there was no difference in incidence of side effects.

[PA2-6] [10/18/2001 (Thr) 14:00 – 17:00 / Hall D]

Gabapentin and Tramadol for the Management of Chronic Low Back Pain

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Background : Gabapentin and tramadol had demonstrated its usefulness in treatment of neuropathic pain. These drugs are very safe with minimal side effects. Chronic intractable low back pain is very difficult to be relieved and has some limitation with use of conventional drugs because of side effects. Gabapentin is advisable to start with low doses with a slow increase to reach full dosage for several weeks, which emphasize on improvement of compliance by patient education.

Objective : We conducted this study to evaluate the effect of the combination therapy of gabapentin and tramadol on chronic low back pain.

Methods : Medical charts were reviewed retrospectively for patients who received gabapentin and tramadol for the treatment of chronic low back pain for the year of 2000. Gabapentin was administered initially 300 mg up to 1800 mg and tramadol, 50 – 150 mg. We studied of relieving the pain score in patients who received the drugs for more than 4 weeks and for less than 4 weeks. Data were collected for sex, age, dosage and duration of treatment, causes and duration of the chronic low back pain. Then we called patients and asked about the pain score, side effects, causes of withdrawal of the drugs and alternative treatments after withdrawal. We analyzed the pain score before the combination therapy and after the therapy in the subgroups with duration of treatment(<4 weeks, ≥4 weeks).

Result : Among patients with low back pain, 9% of them suffered from chronic low back pain. Most of these patients were nonspecific origin. A significant decrease of the pain score in patients who received study drugs more than 4 weeks was noted(pre-treatment, 5.5 ± 1.1 , post-treatment, 4.2 ± 1.6 , $n=17$, $p=0.001$). In patients who received the drugs less than 4 weeks, however, no significant decrease was observed(pre-treatment, 5.9 ± 1.0 , post-treatment, 5.5 ± 1.3 , $n=10$, $p=0.104$). The difference of the post-treatment between two groups was significant($p=0.007$). There were several mild side effects and three of patients should withdraw the regimen.

Conclusions : The combination therapy of gabapentin and tramadol may be the alternative for the treatment of intractable chronic low back pain. But patient education for the regimen which should be increased slowly may be necessary for better outcome of pain control.

[PA2-7] [10/18/2001 (Thr) 14:00 – 17:00 / Hall D]

Bleeding Complications and Analysis of Risk factors in Patients on Warfarin after Mechanical Heart Valve Replacement

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Warfarin is an anticoagulant for preventing thromboembolic disorder. Patients on warfarin should be monitored closely because of narrow therapeutic range. Bleeding is a common, potentially lethal complication of warfarin therapy. This retrospective study was to evaluate the incidence and risk factors of bleeding in patients on warfarin after mechanical valve replacement. Patients were included if they were on Anticoagulation Consult Service (ACS) after mechanical valve replacement. Exclusion criteria were an active peptic ulcer and bleeding disorders other than warfarin related risk. Data were collected for patient characteristics, comorbid diseases, bleeding sites and frequency. Bleeding complications