

enhanced the amount of itraconazole absorbed. When six healthy male received single 100 mg dose of itraconazole, both the mean maximum concentration of itraconazole in plasma and AUCinf after the standard meal (bread meal with milk and bacon) were approximately a three-fold increase compared with that after the fasting. As the kinds of food for Asian are mainly non-fat carbohydrates and different from fatty western food, the pharmacokinetics of itraconazole was studied with healthy Korean volunteers. In a cross-over study, single itraconazole capsule (100 mg) was administered with and without Korean standardized breakfast (rice meal with vegetable soup and vegetable side dish) after an overnight fast. Plasma samples were obtained up to 72 hr after intake of each drug. Measurement of itraconazole plasma concentrations was performed by HPLC. In results, non-fat rice meal appeared to decrease the absorption rate and extend of itraconazole significantly, tmax being doubled from about 3 hr to 6 hr and Cmax decreased to half. The corresponding AUCinf also decreased to half with rice meal. The rate of elimination was not affected (terminal half-life, approximately 19 hr). These results indicate that the kinds of food influence the absorption of itraconazole significantly by increasing the absorption with fatty meal and rather decreasing the absorption of itraconazole with non-fat carbohydrates meal. Therefore, it shows that the indication of itraconazole in Asian countries should be reconsidered.

[PF1-2] [10/19/2001 (Fri) 14:00 – 17:00 / Hall D]

Nested case-control study on the association between histamine-2-receptor antagonist and gastric cancer in the Korean elderly.

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Gastric cancer is the most common cancer in the Korean elderly. Some epidemiological studies suggested that histamine-2-receptor antagonist (H₂-RA) increase the risk of gastric cancer. But little has been known about the association between H₂-RA and gastric cancer in the elderly. The goal of this study was to estimate whether H₂-RA increases the risk of gastric cancer in the elderly. The study population were members of the Korean Elderly Pharmacoepidemiology Cohort (KEPEC:n=23,649), aged 65 years or more. The information on drug exposure including H₂-RA was collected from the claims data of hospitals between 1993 and 1994. The information on the potential gastric cancer cases was collected from the claims data between 1993 and 1998. The hospital survey was conducted to confirm the final diagnoses of the potential cases. The information on confounders was collected by questionnaire survey. Every gastric cancer patient was matched with 4 non-gastric cancer controls of the same age and gender in the KEPEC. Conditional logistic regression model was used to evaluate the risk of gastric cancer after controlling for potential confounders. 52 cases were identified as the final gastric cancer. 208 controls were selected. 8 cases (15.4%) and 9 controls (4.3%) were exposed to H₂-RA. The crude odds ratio was 4.0 (95% CI: 1.47-11.00). After adjusting for existence of heart burn, body shape, total smoking dose, insomnia and medication history, adjusted OR was 5.1 (95% CI=1.72-14.99). The use of H₂-RA might increase the risk of gastric cancer in the Korean elderly. This finding supports the hypothesis that achlorhydria induced by H₂-RA increases the risk of gastric cancer.

[PF1-3] [10/19/2001 (Fri) 14:00 – 17:00 / Hall D]

Drug Utilization Review for the Antiulcerative Agents in the Elderly Inpatients

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Background

Antiulcerative agents are one of the most commonly prescribed drugs in Korea and worldwide. This study aimed to review the drug utilization pattern of antiulcerative agents for the elderly people in Korea.

Method

The study population were geriatric inpatients of community hospitals between 1993–1994, aged 65 years or over, beneficiaries of the Korea Medical Insurance Corporation(KMIC) and residing in Pusan city. The information on the drug exposure was collected from the claims data of hospital where the cohort members received medical care between 1993 and 1994. The information included personal identifier, age, gender, diagnosis for prescribing, dosage, data of prescription and name of medical institutions where the study population were prescribed.

Results

The number of patients prescribed antiulcerative agents between 1993 and 1994 was 1,051(64.9%) male and 1,724(65.5%) female. Antacid and composite agents were most frequently prescribed antiulcerative agent(70.8%), and the second most frequently prescribed antiulcerative agent was H2 antagonist(16.0%). The antiulcerative indicated diagnosis categorized in ICD-9 in whom antiulcerative agents were prescribed at least once during any of inpatient period was only 29.6% for all antiulcerative agents.

Discussion

The study result could be used as a fundamental data for further drug utilization review for antiulcerative agents.

[PF1-4] [10/19/2001 (Fri) 14:00 ~ 17:00 / Hall D]

Effect of Joins, a New Herbal Anti-Arthritic Agent, in Patients with Osteoarthritis of the Knee: a Double-Blind Placebo Controlled Phase 2 Study

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Joins (SKI 306X) is a purified extract from a mixture of three oriental herbal medicines (*Clematis mandshurica*, *Trichosanthes kirilowii* and *Prunella vulgaris*) that have been widely used for the treatment of inflammatory diseases such as lymphadenitis and arthritis in far East Asia.

A double-blind, controlled phase 2 study of Joins was performed in patients with osteoarthritis (OA) to evaluate the efficacy and safety of Joins with placebo in 96 patients with classical osteoarthritis of the knee. Patients were randomized to four treatment groups: placebo, 200 mg, 400 mg and 600 mg of Joins *t.i.d.*. Clinical efficacy and safety were evaluated for 4 weeks continuous treatment. Joins demonstrated its clinical efficacy, as assessed by 100mm visual analogue scale (VAS), Lequesne index and patients' and investigators' opinion of the therapeutic effect compared with placebo. ($p < 0.01$) Result from this study indicated that Joins had a similar good efficacy profile when administered 200, 400 and 600 mg. No significant adverse events were observed in patients treated with Joins. Considering the pharmaco-economical aspect of Joins, the dosage of 200 mg *t.i.d.* will be most suitable. This study demonstrated that Joins, a new herbal anti-arthritic agent provided clinical efficacy in patients with osteoarthritis.

[PF1-5] [10/19/2001 (Fri) 14:00 ~ 17:00 / Hall D]

Randomized Double-blind trial of the Efficacy and Safety of Joins, a New Herbal Anti-Arthritic Agent vs. Diclofenac in Patients with Osteoarthritis of the Knee

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