PCN10

A RETROSPECTIVE CLAIMS DATABASE COMPARISON OF SORAFENIB AND SUNITINIB DOZING PATTERNS IN PATIENTS WITH RENAL CELL CARCINOMA (RCC)

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OBJECTIVES: To compare dose-reduction patterns in patients with RCC treated with FDA-approved tyrosine kinase inhibitors (TKIs) sorafenib and sunitinib.

METHODS: A retrospective analysis was conducted using data from a claims-based database (MedStar MedStat) covering 218 million lives from 2002-2008 in the US and Canada, including patients with RCC from specified census regions. Patients with 22 claims for RCC (ICD9 189.0 or 198.0), continuous health care coverage, >180 days coverage before RCC diagnosis, and no claim for sorafenib or sunitinib before RCC diagnosis, who received a standard RCC initial daily dose of 400 mg or sunitinib 50 mg and >2 consecutive dispensions, were included. Initial episode was defined as time from date of first drug-dispensing to first of switch to another TKI, health care coverage end, treatment end, or March 31, 2008. Both patient and patient-time level analyses for dose reductions between treatments were conducted.

RESULTS: Baseline demographics between patients were similar (sorafenib, n = 189, sunitinib, n = 304) except for a higher incidence of stroke (7.9% vs. 3.6%, P = 0.037) and other cancer site (93.7% vs. 87.8%, P = 0.016) in the sunitinib group. Significantly more patients receiving sunitinib required dose reductions compared with sorafenib (first 3 months: 23.0% vs 4.2%; complete initial episode: 35.5% vs 16.9%; P < 0.001 for both). For all episodes, mean time to dose reduction was significantly longer for sunitinib than sorafenib (162 days vs 104 days, P = 0.003). Significantly more dose reductions occurred within the first 3 months with sunitinib than with sorafenib (2–6 times greater, P < 0.001).

CONCLUSIONS: This retrospective US claims analysis showed that for patients receiving TKI doses, nearly all patients treated with sunitinib were required in patients who initially received sunitinib than in those who received sorafenib.

PCN11

INFLUENCE OF AGE ON COMORBIDITIES AND TREATMENT IN PATIENTS WITH RENAL CELL CARCINOMA (RCC)—A RETROSPECTIVE CLAIMS DATABASE ANALYSIS

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OBJECTIVES: To analyze baseline symptoms, comorbidities, and treatments in newly diagnosed RCC patients by age group. METHODS: Retrospective claims-based analysis was conducted using MarketScan MedStat, a database covering all US census regions, including 218 million lives for years 2002-2008. Patients with initial RCC diagnosis in 2005-2007, 2nd outpatient or 21st inpatient RCC claims (ICD9 189.0 or 198.0), continuous health care coverage, and >180 days coverage before diagnosis were included. Patients were followed from diagnosis until health care coverage end or June 30, 2008. Conditions, symptoms, and individual Charlson comorbidities were assessed. Treatment was analyzed using prevalence and time to initiation in patients < and ≥65 years old. RESULTS: Of 12,253 patients identified, 61.8% were male (mean age, 63 years old and 51.0% were ≥65 years old. Overall, pain (39.6%), hypertension (15.3%), and diabetes (12.6%) were the most common comorbidities reported. Most comorbidities were prevalent in 265 years old than ≥65 years old; notably, cerebrovascular disease (8.7% vs. 3%; P < 0.001), acute myocardial infarction (2% vs. 0.7%; P < 0.001), and chronic renal failure (9.3% vs. 6%, P < 0.001). In <65 and ≥65 groups, most commonly used treatments were nephrectomy (53.4% vs. 40.4%; P < 0.001), intravenous chemotherapy (11.7% vs. 13.3%; P = 0.0079) and oral chemotherapy (10.5% vs. 13.3%; P = 0.0001), although less than 4% of patients in either group received FDA-approved oral agents sorafenib or sunitinib. For <65 and ≥65 groups, respectively, mean time from RCC diagnosis to nephrectomy, 25 and 31 days; radiotherapy, 170 and 177 days; intravenous chemotherapy, 154 and 181 days; sorafenib, 220 and 247 days; sunitinib, 221 and 205 days. CONCLUSIONS: Baseline comorbidities and symptoms were more common in RCC patients ≥65 years old than those <65 years old. Nephrectomy was used more frequently in patients <65, probably because of comorbidity differences in older patients. In contrast, systemic treatment was similar in both groups.

PCN12

OFF-LABEL USE OF ONCOLOGY DRUGS IN A COMMUNITY ONCOLOGY EMR DATABASE

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OBJECTIVES: The objective of this study was to examine the utilization patterns of cancer medications beyond their labeled indications approved by the FDA in community oncology practices.

METHODS: Drug prescription information from a community oncology data warehouse was used for two separate analyses. Patients were categorized according to whether they had an ICD-9 diagnosis code for one of four cancer types including lung, breast, bladder or gastric, and having no other malignancy. The frequency of use of various oncology drugs was examined for each of these groups, against a set of medications that were FDA-approved for these indications or were recommended by NCCN guidelines. In the second analysis, patients with a single malignancy, who received any of the five oncology drugs (paclitaxel, vinorelbine, rituximab, bevacizumab) and gemicitabine, were counted. Comparisons were then made against the cancer indications for which these agents were approved by the FDA.

RESULTS: Seventy-eight percent of breast and 95% of lung cancer patients received medications approved for these indications, while 68% and 75% also received drugs that were not approved by the FDA for those conditions. More than 99.7% of these patients received agents recommended on NCCN guidelines. None of the bladder cancer patients and only 5% of gastric cancer patients received drugs approved for these indications, while 97% and 95% of them received guideline-recommended drugs. Only half of the patients given paclitaxel or bevacizumab received these for an FDA-approved indication. In the case of vinorelbine and gemicitabine, the proportion was lower at 30% and 40% respectively, while it was higher for rituximab at 60%.

CONCLUSIONS: Oncologists’ choice of drugs is driven by evidence-based guidelines, independent of FDA approval. There is a high and varying proportion of off-label use across oncology medications and cancer types.

GASTROINTESTINAL DISEASES – Clinical Outcome Studies

PGII

A SYSTEMATIC REVIEW ON KUSHENIN VERSUS WESTERN MEDICINES FOR PATIENTS WITH CHRONIC HEPATITIS B

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OBJECTIVES: Hepatitis B virus (HBV) infection affects over 2 billion people worldwide, and 350 million suffering from chronic HBV infection. The prevalence of chronic HBV infection is high in Asia and most of Africa. Kushenin injection as a new traditional Chinese medicine is now widely used for chronic HBV treatment in China. The objective of this review was to compare the effectiveness between Kushenin and western medicines on patients with chronic HBV. METHODS: Based on a pilot study of patient interview at one hospital setting, we identified key outcome measurements of effectiveness related to Kushenin and western medicine, including ALT recovery rate and negative conversion rate of HBeAg. Consequently, we performed a systematic literature review using computer-based search-engines such as MEDLINE (1966 to 2007), EMBASE (1966 to 2006), OVID (1965 to 2006), the Chinese Biomedical Database (CMB) (1978 to 2006) and CNKI (China National Knowledge Infrastructure) (1994 to 2007). From available data, both interferon and lamivudine were selected as western medicines to compare with Kushenin regimen. A Meta-analysis was performed using a software program of Reviewman® 4.2. RESULTS: A total of 15 published clinical studies involving 1396 patients met inclusion criteria for the meta-analysis. Comparing to interferon alone regimen, Kushenin showed no significant differences in terms of ALT recovery rate [relative risk, RR = 0.96, 95% confidence interval (CI),0.86-1.09] and negative conversion rate of HBeAg [RR = 0.85, 95% CI, 0.69-1.05]. Meanwhile, kushenin combined with lamivudine showed better effectiveness in terms of ALT recovery rate [RR = 1.77, 95% CI,1.38-2.26] and negative conversion rate of HBeAg [RR = 2.39, 95% CI, 1.81-3.88] compared with lamivudine alone. CONCLUSION: Integrated Kushenin plus lamivudine showed better clinical outcomes in ALT recovery rate and HBeAg negative conversion rate. Further evidence-based analysis is required due to low quality of randomization procedure in clinical trials and insufficient study patients for treating chronic HBV with kushenin.