demographics, comorbidities, therapy type, treatment initiator, and concomitant medications were assessed across the EU-5 and by individual country. RESULTS: A total of 64,932 patients from Germany (24,577), France (12,574), Italy (11,676), UK (8,427), and Spain (7,698) were included. The majority were male (64%, except Germany was 50%), 56 years (70%), and had chem-radiation (91%). Concomitant medications across countries, except COPD (5%, whereas Spain was 19%) and Cardiac Dysfunction (4%, whereas Germany was 21%). Except in the UK, temozolomide was used, on average, for 82% of front-line patients with treatment being initiated by a radiologist (58%) or medical oncologist (23%). In the UK, temozolomide was used for 65% of front-line patients and was initiated by a radiologist 90% of the time. Surgical procedures including Excision of Lesion, Craniootomy, and Lobectomy were performed, on average, in 67% of patients, except in France (44%). However, French patients were more likely to have a Burr Hole Biopsy (43%) versus the other countries (average of 40%). Frequently used concomitant medications were corticosteroids (3-fold variation across EU-5), anti-emetics (5-fold variation), and targeted anticancer treatments (on average 15% of front-line treatments). The most commonly used front-line treatment for glioblastoma was found to be surgery followed by temozolomide chemotherapy, consistent with guidelines. However, there was some variation across countries with regards to the type of surgery, comorbidities, chemotherapy regimens, and supportive care. Further study is needed to comprehensively characterize glioblastoma treatment patterns in the EU-5.

PCN355

BONE PAIN AND BONE TARGETING AGENT (BTA) TREATMENT PATTERNS IN PATIENTS WITH BONE METASTASES (BMS) FROM BREAST CANCER (BC) IN REAL WORLD SETTING IN EUROPE

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OBJECTIVES: To examine bone pain and BTA treatment patterns in patients with BMs from BC in real-world setting in Europe. METHODS: The study was conducted using the Adelphi Breast Cancer Disease-Specific Programme (DSP) 2015 database, a multi-country cross-sectional survey of 385 oncologists from 6 European countries (UK, Germany, France, Italy, Spain, and Belgium). Each physician completed a patient survey for at least 3 patients being treated for BC that captured the following information: presence of BMs, current pain state, current analgesic use, BTA treatment, and reasons behind BTA treatment decisions. RESULTS: A total of 1337 patients with BM from BC were identified. At the time of survey (an average of 13 months after diagnosis of BMs), 47% of the patients experienced mild pain; 20% had moderate/severe pain. The majority of the patients (96%) with pain took analgesic drugs to manage pain, which included 28% (n = 260) patients treated with non-steroidal anti-inflammatory drugs (e.g. morphine and non-steroidal anti-inflammatory drugs), and 35% of BM patients and still experienced moderate/severe bone pain. Among the patients with BMs, 88% (n = 1192) were treated with a BTA. Of them, 81% (n = 979) received treatment within 3 months of BMs diagnosis. Reasons for BTA treatment initiation within 3 months of BMs were “bone pain” (34%), “high risk of bone complications” (31%), “number of BMs” (13%), “location of BMs” (8%) and “prior history of bone complications” (7%). Reasons for not treating patients with BMs were “recent diagnosis” (40%), “low bone complication risk” (17%), “focus on treating primary tumor” (10%), and “short life expectancy” (10%). CONCLUSIONS: Bone pain is the main symptom encountered by patients with BMs from BC. Most of these patients treated with strong opioids still still experienced moderate/severe bone pain. The majority of patients with BMs received BTAs; primary treatment goals were reductions of bone pain and risk of bone complications.

PCN356

BONE PAIN AND BONE TARGETING AGENT (BTA) TREATMENT PATTERNS IN PATIENTS WITH BONE METASTASES (BMS) FROM PROSTATE CANCER (PC) IN REAL WORLD SETTING IN EUROPE

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OBJECTIVES: To examine bone pain and BTA treatment patterns in patients with BMs from PC in real-world setting in Europe. METHODS: The study was conducted using the Adelphi Prostate Cancer Disease-Specific Programme (DSP) 2015 database, a multi-country cross-sectional survey of 385 oncologists from 6 European countries (UK, Germany, France, Italy, Spain, and Belgium). Each physician completed a patient survey for at least 3 patients being treated for BC that captured the following information: presence of BMs, current pain state, current analgesic use, BTA treatment, and reasons behind BTA treatment decisions. RESULTS: A total of 1376 patients with BM from PC were identified. At the time of survey (an average of 15.2 months from BMs diagnosis), 41% of patients experienced mild pain; and 29% had moderate/severe pain. Reason for not treating patients with BMs were “bone pain” (34%), “high risk of bone complications” (31%), “number of BMs” (8%) and “prior history of bone complications” (5%). Reasons for not treating patients with BMs were “recent diagnosis” (40%), “low bone complication risk” (17%), “focus on treating primary tumor” (10%), and “short life expectancy” (10%). CONCLUSIONS: Bone pain is the main symptom encountered by patients with BMs from PC. The majority of these patients treated with strong opioids still still experienced moderate/severe bone pain. Approximately three quarters of patients with BMs received BTAs; primary treatment goals were reductions of the risk of bone complications and associated bone pain.

PF31

TORSADE DE POINTES AND QT PROLONGATION COULD RESULT FROM DESLORATADINE ALLERGY-TREATMENT TREATMENT

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OBJECTIVES: This signal detection pharmacovigilance activity aims to determine if treatment with desloratadine is associated with more than expected reporting of torsade de pointes and QT prolongation in real-world settings. METHODS: Adverse event reporting system were used (cumulative to June 2014), and Multi-registry data were reviewed over the period of June 2010 to June 2014 to calculate Empirical Bayes Geometric Mean (EBGM) and corresponding 95%CI as association metrics. Desloratadine was defined by generic name, and ventricular tachycardia events were defined as structured MedDRA queries of Preferred Terms defined as torsade de pointes and QT prolongation. DISCUSSION: Desloratadine was not associated with QT prolongation or torsade de pointes. In contrast, patient reports for desloratadine were more likely to report all serious adverse drug reactions, most commonly anaphylaxis, cardiovascular, respiratory, and dermatological events.
For loratadine, a total of 147 TQP reports were submitted, corresponding to 61% male users (mean age 51 years), and 8% and 36% of TQP events were fatal respectively. For terfenadine were associated with significant signals of TQP (EBGM = 3.65; 95%CI=3.18-4.17). Astemizole and terfenadine were associated with significant signals of TQP (EBGM = 20.1; 95%CI=17.3-23.3 and EBGM =15.0; 95%CI=13.6-16.4, respectively). CONCLUSIONS: Anti-allergy treatment with desloratadine might be associated with TQP. A non-arrhythmogenic antihistamine might be an alternative therapy in patients at risk of ventricular tachycardias. Cardiac conduction monitoring might be recommended in desloratadine users.

OBJECTIVES: To estimate the prevalence of ADRs including serious/fatal ADRs and clinical manifestations. 2 To analyze cost of treatment for serious and fatal ADRs. METHODS: The prevalence of ADRs: A cross-sectional descriptive study. Data was collected from electronic database in Vajira Hospital during 1 January 2012-31 December 2013 from inpatient and outpatient departments. Those patients who had experienced with those ADRs from other hospitals or been diagnosed at Vajira Hospital and clinical manifestations at the time of ADR occurrence were included. Costs of treatment for serious and fatal ADRs (baht per event) were direct medical costs. Costs included drug costs which were obtained from the median price from the Drug and Medical Supply Information Center, Ministry of Public Health. Costs of admissions to hospital and laboratory cost, which were obtained from the unit cost of the standard cost for HTA. The Costs were evaluated from the resources being used in admission, medications, respiratory therapy, and finally the cost for hospital stay (TAL). A total of 737 identified ADRs events which consisted of ADRs type A (42events%,6%) and ADRs Type B (695 events, 94%). Amlodipine was responsible for the most common ADRs type A (n=71,17%) for swollen feet while antimicrobial agents, ceftriaxone, and clindamycin were responsible for the most common causes (ceftriaxone n= 4) followed by NSAIDs (ibuprofen n =3) and anticonvulsants (Phenytoin n=4). Direct medical cost for the treatment of Serious and Fatal ADRs was about 41,000 baht per visit. CONCLUSIONS: This study provided information to develop the medical service to the patient by identifying whether some drugs were safe for severe allergic reactions. To increase patient safety and reduce costs arising from the treatment of those severe allergic reactions, the pharmacists should counsel and educate patients to the level that those patients can be able to observe themselves.

OBJECTIVES: It is well known that the patients treated with fixed combination of inhaled corticosteroid/long acting beta-2 agonist (ICS/LABA) show pneumonia as an adverse effect. The purpose of this study was to compare the risk of pneumonia associated with the use of combination therapy, based on propensity-score matched analysis of patients who were treated with different ICS/LABA substanc.

OBJECTIVES: A retrospective cohort study was conducted using 2013 HIRA-NPS(National Patients Sample of Health Insurance Review and Assessment Service) database of Korea. The cohort consisted of the patients who were prescribed DDP (Dried Powder Inhaled) form of fluticasone/salmeterol and budesonide/formoterol at least once as an initial user from Feb 2013 to Dec 2013. The patients who were enrolled to the cohort was observed until the first hospitalization due to pneumonia(12-18 IC-D-10 code) occurrence. The incidence rate of pneumonia were estimated and crude and adjusted hazard ratio of pneumonia associated with ICS/LABA use with 95% confidence intervals were estimated by Cox proportional hazard model. RESULTS: The cohort included 5,939 patients of which 4,531 patients(76.3%) treated with fluticasone/salmeterol and 1,408 patients(23.7%) treated with budesonide/formoterol. The pneumonia incidence rate was higher with fluticasone/salmeterol which was 8.50 per 100 person-year while the pneumonia incidence rate of budesonide/formoterol was 5.14 per 100 person-year. Compared with budesonide/formoterol, the pneumonia risk was higher in patients treated with fluticasone/salmeterol(hazard ratio: 1.53; 95% CI = 0.66-2.06). The results were similar in sensitivity analysis which was performed by matching different covariates.

OBJECTIVES: To assess the comparative efficacy and safety of monocular antibodies and a tyroside-kinase inhibitor for severe or uncontrolled asthma, using a Bayesian network meta-analysis. METHODS: A systematic literature review was conducted according to NICE guidelines. Outcomes of interest included asthma control questionnaires (ACQ score), asthma exacerbations and discontinuations due to adverse events (AE). Identified studies assessed mepolizumab, lebrikizumab, omalizumab and mepolizumab. Networks of evidence were based on treatment- and dose-specific nodes except for mepolizumab (results were only reported for pooled doses). Interpretation of results was based on absolute differences/ratios and Bayesian probabilities for treatments to perform better than others (P), where P=15% indicated a smaller effect and P=85% a larger effect. Vague prior distributions were used. RESULTS: 8/6/3 studies reported results at 16/26/52 weeks respectively. Analyses indicated that active treatments and placebo had comparable ACQ score reductions (D) at 16 weeks; at 52 weeks, omalizumab performed better than placebo (D = 0.18; 95% CI = 0.11–0.25), and was comparable to mepolizumab 250mg (D = 0.13, P=0.75). All active treatments performed better than placebo. In terms of asthma exacerbations, at 16 weeks, mepolizumab performed better than placebo (D = 0.60, P=0.76). At 26 weeks, omalizumab performed better than placebo. At 16 and 26 weeks, active treatments and placebo had comparable discontinuations due to AE rates. At 26 weeks, omalizumab reduced 70% of GLN/IND doses rates than mepolizumab 75mg, and was comparable to other treatments. Omalizumab, mepolizumab 250mg, 750mg and placebo were comparable.

OBJECTIVES: To estimate the efficacy and safety of glycopirronium-indacaterol combination therapy compared to other first-line treatments, through a systematic review and meta-analysis. METHODS: A detailed search was performed in eight electronic databases (MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Randomized Controlled Trials, WHO International Clinical Trials Registry Platform, ClinicalTrials.gov) searching for clinical trials that compared efficacy and safety of glycopirronium-indacaterol to other GLN/IND combination drugs for severe COPD. Seven functional and quality of life outcomes were collected. An expert panel supported and validated the methodology. Finally, a meta-analysis was performed when the homogeneity of the information permitted. RESULTS: 14.349 references were originally identified, 13.239 were left after eliminating duplicates, and were reviewed by two researchers; 112 full-text articles were retrieved, and finally 13 provided useful information and were included in the analysis. A network comparison was performed (TIoG) with GLN/IND, to identify significant differences in efficacy or safety. Studies comparing GLN/IND against TIoG, showed statistically significant results, favoring GLN/IND, for “trouch FEV1” (a functional indicator), as well as for, both quality of life scales (Transition Dyspnea Index and St George’s Respiratory Questionnaire SGtR) with respect to safety, GLN/IND and all first drugs have a similar profile. CONCLUSIONS: We conclude that GLN/IND is more effective than other first-line treatment in the management of moderate to severe COPD, with a similar safety profile.