

Limited information was available linking disease severity to QoL. **CONCLUSIONS:** In studies of patients receiving treatment for recurrent or metastatic SCCHN, median OS did not differ systematically among populations receiving regimens containing cetuximab, docetaxel, methotrexate, or paclitaxel. Among platinum-refractory patients, no treatment was identified as having demonstrated significant improvements in QoL.

PCN26

LIPEGILGRASTIM FOR REDUCTION OF CHEMOTHERAPY-INDUCED NEUTROPENIA RELATED EVENTS: A META-ANALYSIS

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OBJECTIVES: The purpose of the current meta-analysis was to compare the efficacy of lipegilgrastim (LIP) to pegfilgrastim (PEG) and filgrastim (FIL). **METHODS:** EMBASE was searched for head-to-head trials examining the efficacy of LIP, PEG, or FIL. Outcomes included incidence of febrile neutropenia (FN), incidence of severe neutropenia (SN), duration of SN (DSN), and time to recovery of absolute neutrophil count (ANC). Direct comparisons of SN/FN between LIP and PEG were made using random-effects models estimating relative risk (RR). No trials directly compared LIP and FIL; indirect comparisons were made with PEG or placebo/no treatment (PLA) as the common comparator. For DSN/ANC recovery, generic inverse variance methods were employed. **RESULTS:** Sixty-five studies were identified and 24 were included after full-text review and quality assessment via PRISMA criteria. Over all treatment cycles, LIP was non-inferior to PEG for risk of FN (RR 0.34, 95% CI: 0.05, 2.14). The indirect estimate of FN for LIP versus FIL was also non-significant (RR 0.22, 95% CI: 0.03, 1.51). For SN during cycle 1, LIP had a RR of 0.80 (95% CI: 0.63, 1.03) versus PEG and 0.79 (95% CI: 0.61, 1.03) versus FIL. For subsequent cycles, the RR was 0.53 (95% CI: 0.35, 0.79) LIP versus PEG and 0.45 (95% CI: 0.27, 0.75) versus FIL. Time to ANC recovery was significant: -1.75 days (95% CI: -2.61, -0.90) for LIP versus PEG and -1.88 days (95% CI: -2.82, -0.95) for LIP versus FIL. No comparisons were significant for DSN. **CONCLUSIONS:** LIP showed non-inferiority to PEG for risk of at least one FN episode and SN in cycle 1. LIP was more effective than both PEG and FIL for prevention of SN in cycles 2-4 and reduced ANC recovery time. However for DSN differences were not significant. These results suggest that LIP is a possibly more effective treatment.

PCN27

COMPARATIVE EFFECTIVENESS OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSF) FOR REDUCING INCIDENCE OF FEBRILE NEUTROPENIA (FN)-RELATED HOSPITALIZATION: A RETROSPECTIVE COHORT STUDY USING GERMAN CLAIMS DATA

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OBJECTIVES: Effectiveness of daily G-CSF prophylaxis can be decreased when given in short courses. The objective was to determine the difference in odds of FN-related hospitalizations with once per cycle G-CSF (pegfilgrastim) prophylaxis compared to daily G-CSF (filgrastim/lenograstim) prophylaxis for patients receiving high/intermediate FN-risk chemotherapy for breast cancer or Non-Hodgkin lymphoma (NHL). **METHODS:** This retrospective cohort study used claims data from the Health Research Institute research database with <4 million insured individuals in Germany. Patients receiving first-line, high/intermediate FN-risk chemotherapy for breast cancer or NHL from January 1, 2009 to December 31, 2013 were included and those cycles with G-CSF administration initiated ≤ 5 days following chemotherapy were assessed. G-CSF types were identified by ATC codes and FN-related hospitalizations within each cycle were identified by ICD-10-GM codes with a primary/secondary diagnosis of neutropenia (D70.1*, D70.7). Odds ratios (OR) for FN-related hospitalization and 95% confidence intervals (CI) were estimated with generalized estimating equation models and adjusted for age, gender, tumour type, metastatic status, cycle number, chemotherapy FN-risk and history of anaemia and surgery. **RESULTS:** In total, 2,278 patients representing 7,918 cycles (6316 pegfilgrastim, 1602 daily G-CSF) were included in the analysis; 2,037 (89%) patients had breast cancer and 241 (11%) had NHL. More than half of patients receiving pegfilgrastim prophylaxis initiated it in cycle 1, primary prophylaxis, (56%) whereas 37% of patients receiving daily G-CSF prophylaxis initiated it in cycle 1. Three-quarters of patients receiving daily G-CSF were prescribed 5 or less doses in at least one cycle. Cycles with prophylactic daily G-CSF were associated with an increased risk of FN-related hospitalizations (adjusted OR=2.19, 95% CI: 1.41-3.39; p-value < .001) in comparison to cycles with prophylactic pegfilgrastim. **CONCLUSIONS:** This comparative effectiveness analysis showed a significantly higher likelihood of FN-related hospitalizations in cycles with daily G-CSF prophylaxis versus those with pegfilgrastim prophylaxis.

PCN28

ANALYSIS OF ERIBULIN MESYLATE DOSING MODIFICATIONS IMPACT ON ADMINISTRATION PERSISTENCE IN PATIENTS WITH METASTATIC BREAST CANCER (MBC)

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OBJECTIVES: Eribulin mesylate is a microtubule inhibitor FDA approved for patients with MBC after treatment with at least two prior chemotherapeutic regimens. The recommended dose of eribulin is 1.4 mg/m² administered on Days 1 and 8 of a 21-day cycle with options for dose modification (dose reduction/dose delay) based on severity and duration of specific toxicities. Recent studies, limited to the clinical trial setting, have shown dose modifications lead to greater treatment persistence and improved patient outcomes. This study utilized real-world

claims data to evaluate the relationship between dose modifications and persistence among patients that receive 5 or more administrations. **METHODS:** Using data from the Cardinal Health Specialty Solutions Revenue Cycle Management medical claims database, 267 patients who received 5 or more eribulin administrations and completed therapy between May 2014 and April 2015 were included in the analyses. The Relative Dose Intensity (RDI) methodology compared the intensity of dose received per day of treatment against expected dose (recommended dose) intensity. RDI values and total number of eribulin administrations were calculated for each patient based on the presence or absence of either dose reduction and/or dose delay. Data was analyzed using an independent samples t-test. **RESULTS:** An analysis of patient distribution revealed the mean number of eribulin administrations was 13.4 with a mean RDI of 85%. Persistence was statistically higher in patients that had eribulin therapy managed through dose delay and dose reduction strategies. Patients with no modification (100% RDI) received an average of 8.1 eribulin administrations. Patients with dose modification (81% RDI) received an average of 14.5 eribulin administrations (p < 0.001). **CONCLUSIONS:** Management of eribulin therapy in patients with MBC via dose delay and/or reduction resulted in a statistically significant increase in persistence among responding patients.

PCN29

A SYSTEMATIC LITERATURE REVIEW TO IDENTIFY AND COMPARE CLINICAL TRIALS EVALUATING NOVEL THERAPEUTIC AGENTS IN POST-GEMCITABINE ADVANCED PANCREATIC CANCER

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OBJECTIVES: There is currently no standard of care for patients with advanced pancreatic cancer (APC), including locally advanced and metastatic disease, who progressed following first-line therapy. Available treatment options have been limited by a lack of therapeutic breakthroughs, and primarily utilize different combinations and dosing schedules of established chemotherapeutic agents. The current review assesses the relative efficacy of new therapeutic agents tested, alone or in combination, since 2003 in patients with APC who progressed following gemcitabine-based therapy. **METHODS:** A systematic literature review was performed in PubMed/MEDLINE, EMBASE and ASCO meeting abstracts between January 2003 and June 2015. This review identified randomized controlled trials (RCTs) and single-arm trials evaluating new post-gemcitabine regimens in patients with APC. **RESULTS:** A total of 34 trials, evaluating 1263 patients, were identified. New agents that have been tested include small molecules (24 trials), antibodies (3 trials), nanotherapeutics (4 trials), and immunotherapies (3 trials). The majority of studies were small, single-arm trials (n=27). RCTs (n=7, enrolling 835 patients) were further investigated as they represent the standard for demonstrating therapeutic efficacy. At the time of analysis, the only Phase 3 RCT to evaluate a new therapeutic agent in post-gemcitabine APC was the NAPOLI-1 trial (nanoliposomal irinotecan (MM-398, nal-IRI) + 5-fluorouracil and leucovorin (5FU/LV) versus 5FU/LV), which was a large, global study that demonstrated a statistically significant improvement in overall survival in patients with metastatic disease, including heavily-pretreated patients. **CONCLUSIONS:** The present review highlights the limited number of RCTs evaluating new therapeutic agents in patients with APC who previously received gemcitabine. Most new agents fail to be evaluated beyond small, uncontrolled trials of APC. Despite much research in this difficult-to-treat patient population with high unmet medical need, only one Phase 3 RCT of a new agent (nal-IRI) + 5FU/LV demonstrated significant improvement in overall survival in patients with APC who had progressed following gemcitabine-based therapy.

PCN30

A REAL-WORLD ANALYSIS OF KOREAN NATION-WIDE DATABASE: PATTERN, ADHERENCE, AND ASSOCIATED HEALTHCARE COSTS OF IMATINIB AMONG PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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OBJECTIVES: This study aimed to determine the demographic features, treatment pattern, medication adherence, survival rates and associated healthcare costs in patients with newly diagnosed Ph+ CML from Korean National health Insurance (NHI) claims database. **METHODS:** We conducted a longitudinal analysis of patients with newly diagnosed Ph+ CML (ICD-10: C92.1) and started treatment with imatinib in 2005 enrolled in the Korean NHI program. Patients were excluded if they had ≥ 1 claim with a diagnosis of other cancer within one year before diagnosis of CML. All data were retrieved from the NHI Database provided by National Health Insurance Corporation in Korea. **RESULTS:** In the study, a total of 8,986 patients with a diagnosis of Ph+ CML between January 1, 2004 and December 31, 2013 were identified. Among them, our study population consisted 268 patients (mean age: 46.4 \pm 14.7 years, male: 57.4%) with the diagnosis of CML in 2005. The majority of patients (75.9%) initiated imatinib therapy at a starting dose was 400mg/day. With over 7 years of follow-up data, based on the 180-day gap definition of discontinuation, 33 (11.7%) patient was discontinued and discontinuation period was 395.4 \pm 137.2 days (range: 189-1,023). Overall, 44.3% (n=125) of patients were defined as Good Medication Possession Ratio (MPR) ($\geq 90\%$) and 19.2% (n=54) were as Poor MPR (<70%). During follow-up period, 69 patients (24.5%) were deceased and the time to death for them was 3.18 years (1,159.5 \pm 845.1 days) after initiation of imatinib. Patients with Good MPR had significantly higher survival compared to patients with Poor MPR (p<0.001). **CONCLUSIONS:** In a retrospective assessment of a large cohort of patients with CP-CML treated with imatinib, we have shown that nonadherence to therapy is important factor for survival. Adherence to therapy must be included as an important evaluation parameter in all future studies of CML.