PCN3

ERLOTINIB PLUS GEMCITABINE COMPARED WITH GEMCITABINE MONOTHERAPY IN PATIENTS WITH PANCREATIC CANCER: A REAL-WORLD ANALYSIS OF KOREAN NATIONAL-WIDE DATABASE

Shin S1, Park C2, Kwon H3, Suh J4, Cho B5, Shin M6
1National Evidence-based Health-care Collaborating Agency, Seoul, South Korea
2National Evidence-based Health-care Collaborating Agency, Seoul, South Korea
3National Evidence-based Health-care Collaborating Agency, Seoul, South Korea

OBJECTIVES: This national population-based retrospective study aimed to evaluate the real-world effectiveness of adding erlotinib to gemcitabine chemotherapy in patients with locally advanced or metastatic pancreatic cancer compared to gemcitabine in real clinical practice. METHODS: Patients were identified retrospectively using Korean National Health Insurance claims database. Survival analysis was performed using the Cox proportional hazards model. RESULTS: Median overall survival (OS) was 7.06 months for gemcitabine (n=766) and 8.43 months for gemcitabine plus erlotinib (n=503). One-year survival rate was also not significantly different (27.0% vs. 27.3%; p=0.958). Based on this relative effectiveness, incremental cost per life year gained over gemcitabine was estimated at USD 70,843.64 for gemcitabine plus erlotinib. CONCLUSIONS: Combination of gemcitabine/erlotinib of advanced pancreatic cancer is not more effective than gemcitabine monotherapy in a real-world setting. It does not provide reasonable cost-effectiveness over gemcitabine alone, and reimbursement strategies for pancreatic cancer in Korea could be reconsidered.

PCN4

THE RELATIVE EFFICACY AND SAFETY OF TREATMENTS IN SECOND-LINE MANAGEMENT OF CHRONIC MYOLOGID LEUKAEMIA: SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS FEASIBILITY STUDY

Kreis J1, Winkler-Schunder A2, Zagorski J3, Major A4
1Abacus International, Bristol, UK; 2Zedzehed Consulting, Wokingham, UK; 3Bristol Myers Squibb, Rueil Malmaison, France; 4Instituto Portugues de Oncologia de Lisboa, Lisbon, Portugal

OBJECTIVES: To assess relative efficacy and safety of second-line treatments in chronic myeloid leukaemia (CML). Methods: A systematic review (SR) and network meta-analysis (NMA) feasibility study were conducted. METHODS: A SR was conducted in January 2015 (Embase, MEDLINE, Cochrane Library, Clinicaltrials.gov and conferences) to identify comparative trials evaluating treatment outcomes in patients with CML previously treated with tyrosine kinase inhibitors. Eligible studies were examined to assess NMA feasibility. RESULTS: Twenty-three publications relating to six randomised controlled trials (RCTs) on second-line treatment met the eligibility criteria. Included trials compared either nilotinib (n=3) or imatinib (n=1) vs nilotinib (n=4). Improvements in response were seen in patients treated dasatinib at alternative doses (n=2). No comparative bosutinib or ponatinib studies were identified. Efficacy outcomes were reported using various definitions and different time points. Compared with nilotinib, significantly fewer imatinib-treated patients with complete cytogenetic response (CCyR) at baseline, achieved complete molecular response (CMR) (23% vs 11%, p=0.02) by 12 months and in patients without major molecular response (MMR) by 12 months. MMR by 12 months was 16% vs 36%, p=0.006 and 24 (83.3% vs 53.6%, p=0.0324) months. Compared with imatinib, significantly more dasatinib-treated patients achieved CMR (16% vs 40%, p=0.004; 18% vs 44%, p=0.0025), MMR (4% vs 16%, p=0.038; 12% vs 26%, p=0.0092) and complete haematologic response (82% vs 93%, p=0.034; 82% vs 93%, p=0.0341) at 15 and 24 months, respectively. Interpretation of survival data was inconclusive due to its limited availability and treatment exposure. CONCLUSIONS: Differences in results among these NMA analyses may have been due to missing network links, significant differences between trial populations, and varying follow-up times. The study was designed as a retrospective chart review. Patients were identified through treating oncologists and urologists. Eligible mCRPC patients were aged ≥70 years, previously treated with docetaxel and naive to prior AA treatment. Baseline characteristics were described using summary statistics. Kaplan-Meier survival analysis was performed for AA treatment duration, overall survival (OS) and time to prostate-specific antigen (PSA) progression endpoints. RESULTS: A total of 68 patients (France and the Netherlands) reported data on 269 mCRPC patients treated with AA. Median PSA (ng/mL) of patients from France and the Netherlands at baseline was 56.0 (interquartile range [IQR]: 28.0–120.0) and 174.5 (IQR: 69.5–371.5), respectively. Mean time to progression (TTP) between AA was 10.6 months (IQR: 7.0–27.2) in France and 18.3 (IQR: 9.0–63.0) in the Netherlands. Median (months) AA treatment duration, median OS and median time to PSA progression in France was 11.3% (95% confidence interval [95%CI]: 8.3–13.7), 21.6 (95%CI: 14.5–) and 13.8 (95% CI:11.4–) respectively. In the Netherlands, it was 4.9 (95% CI: 3.6–4.6), 11.0 (95% CI: 7.3–13.0) and 4.9 (95% CI: 3.0–7.3), respectively. CONCLUSIONS: Here we describe the real-world treatment of mCRPC patients receiving AA in the post-chemotheraphy setting in two EU countries. This study suggests that initiating AA earlier in the post chemotherapy mCRPC setting may result in better health outcomes.

PCN5

REAL-WORLD ANALYSIS OF TYROSIN KINASE INHIBITOR TREATMENT PATTERNS IN PATIENTS WITH CHRONIC MYOLOGID LEUKOYIA IN KOREA

Shin S1, Lee J2, Kim J3, Shin M4, Park J2, Kwon H2
1National Evidence-based Health-care Collaborating Agency, Seoul, South Korea

OBJECTIVES: To compare adherence, persistence and switching pattern of tyrosine kinase inhibitor (TKI) treatment profiles, and survival outcomes in patients with newly diagnosed Ph+ CML from Korean national health insurance (NHI) claims database. METHODS: Patients with newly diagnosed Ph+ CML (ICD-10: C41.2) in Korea between January 1, 2013 and December 31, 2013 were identified from NHI claims database. Treatment switching was defined as patients who had claims for both second-line agents during the 70-day window. This study aimed to evaluate AA treatment duration in routine clinical practice in mCRPC patients receiving AA in the post-chemotherapy setting in two EU countries. Treatment sequencing and survival data were assessed to place the treatment duration into context. Results for France and the Netherlands are reported. METHODS: The study was designed as a retrospective chart review. Patients were identified through treating oncologists and urologists. Eligible mCRPC patients were aged ≥70 years, previously treated with docetaxel and naive to prior AA treatment. Baseline characteristics were described using summary statistics. Kaplan-Meier survival analyses were performed for AA treatment duration, overall survival (OS) and time to prostate-specific antigen (PSA) progression endpoints. RESULTS: A total of 68 patients (France and the Netherlands) reported data on 269 mCRPC patients treated with AA. Median PSA (ng/mL) of patients from France and the Netherlands at baseline was 56.0 (interquartile range [IQR]: 28.0–120.0) and 174.5 (IQR: 69.5–371.5), respectively. Mean time to progression (TTP) between AA was 10.6 months (IQR: 7.0–27.2) in France and 18.3 (IQR: 9.0–63.0) in the Netherlands. Median (months) AA treatment duration, median OS and median time to PSA progression in France was 11.3% (95% confidence interval [95%CI]: 8.3–13.7), 21.6 (95%CI: 14.5–) and 13.8 (95% CI:11.4–) respectively. In the Netherlands, it was 4.9 (95% CI: 3.6–4.6), 11.0 (95% CI: 7.3–13.0) and 4.9 (95% CI: 3.0–7.3), respectively. CONCLUSIONS: Here we describe the real-world treatment of mCRPC patients receiving AA in the post-chemotheraphy setting in two EU countries. This study suggests that initiating AA earlier in the post chemotherapy mCRPC setting may result in better health outcomes.

PCN6

NEW DRUGS IN ADVANCED MELANOMA: DISPARITIES IN REQUIREMENTS FOR POST-TRAUNCH REAL-WORD EVIDENCE IN EUROPE

Mol C1, Ford D2, Puntier C3
1Evidence-Based Health-care Collaborating Agency, Seoul, South Korea
2Post-Market EA Ltd, London, UK

OBJECTIVES: To determine country-specific requirements for real-world evidence (RWE) in melanoma, to support ongoing access for new drugs in melanoma. General perceptions suggest that RWE is crucial for demonstrating long-term value of innovative products. However, it is unclear how these perceptions correlate with absolute requirements of reimbursement agencies. METHODS: We performed an assessment of health technology assessment (HTA) and reimbursement agency websites for feasible data sources for melanoma RWE generation and guidance on collecting RWE in Europe. We also performed a pragmatic review of peer-reviewed literature to identify examples of published RWE in melanoma, and sought views of market access specialists from a global pharmaceutical com