PCN15

CHRONIC MYELOID LEUKEMIA TREATED WITH IMATINIB IN FRANCE: EFFICACY IN REAL LIFE

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OBJECTIVES: Chronic Myeloid Leukemia (CML) is a rare tumor. In France, the incidence is estimated to be $1/10^5$ inhabitants/years. Imatinib has been approved to treat CML since 2002 but information on routine use, safety and efficacy in unselected "real life" setting is lacking. An observational cohort (LMC) in France was designed to provide data on survival, safety, treatment patterns and quality of life. **METHODS:** LMC is nationwide, multicenter, observational study on CML patients treated with Imatinib between the availability on the French Market and the end of the 2008. Centers were randomly selected in national files of oncologists, hematologists and internists. The planned follow-up duration was five years. A case report form had to be completed at inclusion and during each follow-up visits. Quality of life was assessed using QLQ-C30 and SF36 questionnaires. **RESULTS:** Thrity-nine on 55 selected centers enrolled at least one patient and 387 patients were included (as of June 2009). The median age of disease onset was 59 years. At diagnosis 94% of patients were in a chronic phase and had a low or intermediate Sokal (74%). Before Imatinib, 49% of patients received hydroxuyrea and 16% received interferon. Imatinib initiation was SPC conform: 400 mg per day for 95% of patients. Median treatment duration at inclusion was 25 months. 11% of patients with a follow-up of 1 year iin the study had a modification of te Imatinib dose. Rate of complete molecular response was 37%. With a median follow-up of 3.6 years, 2 years overall survival from first treatment with Imatinib was 96.2% (IC95%: [94.1%–98.4%]). Quality of life of patients was stable. **CONCLUSIONS:** LMC study is still on ongoing. Current results confirm previous published data on survival in CML treated with Imatinib in an unselected cohort of patients outside a clinical trial.

PCN16

EVALUATION OF THE EFFICACY OF THE POPULATION-BASED CERVICAL CANCER SCREENING IN HUNGARY

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OBJECTIVES: The occurrence of cervical cancer in the Western Trans-Danubian region of Hungary is outstandingly high. Cervical screening upon individual invitation was launched within the frameworks of a National Program in Hungary in 2003. In the course of our study we have sought an answer to the question why women do not take the opportunity offered, why they fail to appear on screening examinations. **METHODS:** The sample population of the cross-section survey involved women between the age of 18–65 from the city of Zalaegerszeg with a convenient sampling method. In addition to a motivational scale of 21 variables, our questionnaire included demographical aspects, the subjective judgment of health status and one group of the questions were related to the factors of appearing on a gynecological screening examination. **RESULTS:** A total of 51.3% of the women appear on the annual screenings regularly from among the 520 women assessed. In the course of assessment of the primary component, the 21 variables of our motivational scale were grouped around six theoretical sub-concepts. Cronbach Alfa coefficiency was 0.8257. Non-appearance on the examinations due to fear has shown a significant relationship with age, marital status and level of education ($p < 0.05$). **CONCLUSIONS:** In order to further decrease national mortality rates an adequately motivated, continuous performance of cancer screening remains essential. For cervical cancer check-ups a separate concept and infrastructure is provided on behalf of our health administration. The weakness of this system however is connected to the low rate of appearance of the population, which in accordance with the above results is also supported by statistical data, is influenced by fear, the injury of the personal intimacy the sense of an uncomfortable examination and long waiting times as well. At the same time we must note that a majority of women feeling responsible for their own health conditions do appear on screening examinations.

PCN17

SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY OF IMIQUIMOD 5% CREAM FOR THE TREATMENT OF SUPERFICIAL BASAL CELL CARCINOMA

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OBJECTIVES: The aim of the review was to evaluate the efficacy and safety of imiquimod 5% cream compared with vehicle for treating superficial basal cell carcinoma. **METHODS:** The analysis was performed in accordance with the rules of systematic review, based on the Cochrane Collaboration (Cochrane Reviewer's Handbook) guidelines and the Health Technology Assessment Agency in Poland (AOTM) recommendations. **RESULTS:** Two multicenter, vehicle-controlled, randomized clinical trials of high quality were identified according to predefined selection criteria. Treatment with imiquimod 5% cream once a day, 3 times per week resulted in significantly greater complete response rate than vehicle in the period of 6 as well as 12 weeks. Probability of achieving the complete response rate (no histological evidence of superficial basal cell carcinoma in the excised post–treatment target tumor tissue) was significantly greater for imiquimod 5% cream than vehicle and amounted to 18.2 (95% CI: 4.19; 84.84) and 146.14 (95% CI: 69.3; 323.75) respectively at 12 and 6 weeks after treatment. The incidence of adverse events during the treatment period such as application site reaction including itching, pain and tenderness at the target tumor site and local skin reaction such as erythema, scabbing, were more frequently recorded in the group of subjects who received imiquimod 5% cream in comparison with the vehicle group. **CONCLUSIONS:** Imiquimod 5% cream appears to be effective in the treatment of superficial basal cell carcinoma. A 3 times a week dosing demonstrates high efficacy results with acceptable safety profile, during the 6 as well as 12-week period.

PCN18

OUTCOMES RESEARCH OF BORTEZOMIB INDICATED FOR MULTIPLE MYELOMA IN THE CONTEXT OF THE DUTCH REIMBURSEMENT POLICY FOR EXPENSIVE MEDICINES: THREATS TO THE INTERNAL VALIDITY OF THE INCREMENTAL EFFECTIVENESS ESTIMATE

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OBJECTIVES: In The Netherlands, additional funding of expensive hospital drugs requires an assessment of real-world cost-effectiveness. We explored the extent to which real-world data for bortezomib in relapsed or refractory multiple myeloma (MM) patients provides a valid estimate of its real-world incremental effectiveness. **METHODS:** A retrospective study was conducted by collecting data from medical records of Dutch MM patients. Validity of the real-world incremental effectiveness estimate was assessed by comparing real-world bortezomib patients (N = 72) first to bortezomib patients in the APEX trial (N = 333) in relation to baseline prognostic factors and treatment outcomes, and secondly to real-world patients not receiving bortezomib (N = 67) in relation to baseline prognostic factors. **RESULTS:** Comparisons between all groups in relation to the baseline prognostic factors serum β2-microglobulin, c-reactive protein, creatinine clearance and performance status were restricted due to frequent missing values. Real-world bortezomib patients did not differ from trial-based patients in previous treatment profile and some treatment outcomes such as time-to-progression (7 vs. 6 months), complete or partial response (39% vs. 38%) and minor response (13% vs. 8%). However, real-world bortezomib patients differed from trial-based patients in the frequency of treatment responses stable (3% vs. 43%) and progressive disease (19% vs. 7%), and less often received bortezomib monotherapy. At baseline, median time-to-first-progression was significantly longer in real-world bortezomib patients (28 vs. 23 months) compared to real-world patients never receiving bortezomib, possibly due to being more likely to have received prior maintenance therapy (55% vs. 39%). **CONCLUSIONS:** Preliminary results suggest that the real-world effectiveness of bortezomib for MM may not differ greatly from trial-based efficacy, but that a valid incremental estimate may be difficult to obtain. The challenge of obtaining relevant comparator groups and limited data available in patient charts compromise the ability to obtain a valid real-world estimate, underscoring the need for an alternative study design.

PCN19

A LITERATURE REVIEW ON THE CLINICAL AND ECONOMIC OUTCOMES ATTRIBUTABLE TO FIRST-LINE TREATMENT FOR CHRONIC MYELOID LEUKAEMIA (CML) WITH IMATINIB MESYLATE AND BONE MARROW TRANSPLANTATION (BMT)

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OBJECTIVES: While BMT is the only potentially curative treatment for CML, patient eligibility is limited and morbidity risks are common. Imatinib (IM) is the current treatment of choice for many patients with CML. This literature review compared the clinical and economic outcomes attributable to first-line treatment for chronic phase CML with IM and BMT. **METHODS:** A systematic review of published literature was undertaken using Medline. The search terms focused on IM and BMT as well as epidemiology, morbidity, mortality, quality of life and cost-effectiveness. The search of English language papers was undertaken from 1997 to the present. A manual literature search was also undertaken, identifying further articles from citations in published papers. **RESULTS:** Twenty-nine relevant publications were identified providing data on at least 4,931 IM-treated patients and 1,699 patients who received BMT (sample size was omitted in some instances). The probability of mortality in year 1 was estimated to be ~28% and 0% among those who received BMT and IM respectively. Use of IM relative to BMT in chronic phase CML is also expected to lead to increased rates of complete haematologic and cytogenetic response, higher short-term overall survival and event-free survival. Moreover, IM is associated with fewer haematological complications such as chronic and acute graft versus host disease and a greater proportion of IM-treated patients are expected to be free from disease progression. IM treatment compared with transplant resulted in an incremental cost saving of $5000 per surviving patient after approximately 2–4 years of follow-up. **CONCLUSIONS:** Published evidence supports the use of IM in patients eligible for transplant. In the short-term, imatinib appears to be a clinically more effective, better tolerated, cost-effective treatment compared to BMT in the management of chronic CML. However, longer-term published data are lacking.