Clinical pharmacy and clinical trials

unit. For each patient, we detected potentially inappropriate medication (overuse, misuse and underuse) depending on the chronic conditions and suggested drug modifications to the general practitioner (GP). Three months after discharge, we phoned the GPs to find out if the pharmaceutical interventions had been accepted or not, and if patients had fallen again.

Results 96 patients (65% of women; median age 85 years) were admitted for falls due to medicines. 86% of the patients were living at home. Medicines involved with the risk of falling were essentially diuretics, benzodiazepines, calcium inhibitors, antiarrhythmics, sar-tans, anticholinesterases. The modifications usually suggested related to diuretics, benzodiazepines, anticholinergics, vitamin-calcium supplements, osteoporosis treatment and the use of stockings. Among patients called three months later, 75% of the suggestions were still respected, but 29% of the patients had fallen again. There was no difference in the number of falls for patients for whom the modifications had been respected and those for whom they had not been.

Conclusions This study suggested that falls were more frequent among patients living at home; work needs to be done to secure elderly people’s houses. The importance of inappropriate prescriptions on fall events was also underlined. Falls occurred because of multifactorial mechanisms: inappropriate home fittings, sarcopenia, neurodegenerative diseases and inappropriate medicines. One way of reducing the risk of falling in elderly people is to improve the medication.

No conflict of interest.

IMPOR TANCE OF RESIDU AL INVESTIGATIONAL MEDICINAL PRODUCT COUNT  

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Background Good Clinical Practice specifies the role of the pharmacist in clinical trials. For each prescription dispensed for a named patient, the pharmacist is responsible for educating the patient on the treatment, counting any residual Investigational Medicinal Product (IMP), and thus for evaluating the compliance.

Purpose To assess the importance of pharmaceutical vigilance about IMPs.

Materials and Methods This prospective study took three months. For each named-patient prescription dispensed, a count of returned treatment (RT) by the patient from the previously dispensed medicines was performed to assess compliance.

Results 117 RTs were analysed. 43 additional RTs from 1 clinical trial were not included in this study due to the impossibility of evaluating compliance (posology changes not notified to the pharmacy and unsuitable secondary packaging). The non-conformity rate was 20% (23 RT). 39% (n = 9) of the non-conformities (NC) were due to allowing empty boxes not to be returned. In 61% (n = 14) of NC there was a discrepancy between the expected count of returned IMPs and the one actually made, showing poor compliance.

Average counting time was 12 minutes (5–30 min).

An exact count of returned IMP was operated during dispensing for 34% of returns and after dispensing for 66%. In all cases, a global analysis was performed before the prescription was dispensed.

Conclusions This study points out the major role of the pharmacist in the education of the patient enrolled in clinical trials, about the return of all experimental medicines and the therapeutic schedule. It appeared very important to evaluate compliance while the pharmacist was dispensing the next prescription, independently of the time consumed, in order to correct possible errors in taking the medicines at that time.

No conflict of interest.
(18 patients). The average follow up was 4 months. Most of the patients were treated with capectabine-oxaliplatin, followed by those treated with capectabine monotherapy and other minority schemes (cyclophosphamide or bevacizumab). The median starting dose of capectabine was 3300 mg.

32% of patients required a dose adjustment (delay and/or dose reduction) during the follow-up period. The treatment of 26% of patients was delayed by an average of 16 days (2 of the patients had to delay 2 cycles). The initial dose was reduced in 24% of patients (twice in three of the patients).

Toxicity in any grade was reported by 30% of the patients. Severe toxicities (grade 3 of CTC-AE) were sickness and neutropenia. Most frequent toxicities were gastrointestinal side effects (6 patients) and grade 2 hand-foot syndrome (4 patients), followed by mucositis, skin side effects, hyperbilirubinemia and thrombopenia.

Toxicity and dose adjustment were not statistically related to the treatment regimen, ECOG, gender or age.

**Conclusions**

The toxicity profile was consistent with the trials. 81% of patients who had a dose adjustment didn’t need a further dose reduction.

No conflict of interest.

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**CPC-072** INCLUSION OF PHARMACOGENETICS STUDIES, PATIENT-REPORTED OUTCOMES AND COST MEASURES IN CLINICAL TRIALS; VARIABLES ADDED IN RECENT YEARS

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**Background** Pharmacogenetic studies analyse the variability of drug response; patient-reported outcome (PRO) measures complement traditional measures. Pharmacoeconomic studies tell us the efficiency of different therapeutic alternatives.

**Purpose** To evaluate the use of PRO measures, including health-related quality of life questionnaires (HRQoLQ), and the frequency of inclusion of pharmacogenetics studies and economic variables in the design of clinical trials (CT) and observational studies (ST). For CT, the quality of the study design was also measured.

**Materials and Methods** Observational study of CT and ST approved by a Clinical Research Ethics Committee (active between January/2008–May/2012). Information recorded: medical specialty, pathalogy, methodological quality ( Jadad scale: 0–5), inclusion of PRO, HRQoLQ, pharmacogenetics studies (collection or not of human biological samples) and economic variables (use of healthcare resources and/or indirect costs defined as the number of days lost due to sick leave of patients and caregivers).

The information was systematically collected by 2 reviewers and checked by a third if discrepancies arose.

**Results** Ninety-four protocols (79CTs, 15ST) were analysed; 51 included PRO measures (54.5%), 44 CT (58 had HRQoLQ) and 7 ST (6 had HRQoLQ). Analysis by area showed PRO measures were most commonly studied in: endocrinology, neurology, digestive diseases and cardiology. The average quality score was 3.04. 31 studies incorporated pharmacogenetics studies, which were less frequent before 2010 than after (45.3% versus 65.4%). In 50% of the pharmacogenetics studies the storage of collected human biological material in biobanks was planned with the objective of conducting studies about drugs responses according to the genetic endowment. Twenty (25%) CTs and two (18.2%) STs included economic variables.

**Conclusions** The evaluation of economic measures in CTs and STs was low. More than half of the protocols included PRO measures, reflecting the importance of these parameters. Increasing knowledge of pharmacogenetics has resulted in a higher inclusion of these studies in more recent CTs. The average quality for the CT exceeded the value 5, indicating that studies analysed were of reasonable quality.

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**CPC-073** INFLUENCE OF FIRST-LINE EGFR THERAPY ON SURVIVAL AND MORTALITY RATES IN NON-SMALL CELL LUNG CANCER

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**Background** The efficacy of chemotherapy has reached a plateau for advanced non-small cell lung cancer (NSCLC). Increasing evidence has demonstrated that patients with sensitising mutations in the epidermal growth factor receptor (EGFR) are associated with sensitivity to reversible EGFR tyrosine kinase inhibitors (TKIs). Numerous studies have demonstrated improvement of progression-free survival compared to conventional chemotherapy as first-line treatment for advanced NSCLC with EGFR mutations.

**Purpose** To evaluate mortality and overall survival (OS) in NSCLC patients treated with EGFR-TKIs or chemotherapy according to their EGFR status.

**Materials and Methods** Retrospective study. Sixty-one patients diagnosed with NSCLC and available EGFR status during 2008–2012 were included. Socio-demographic, clinical and pharmacologic characteristics of patients were collected. Comparison of medians by Mann-Whitney-Wilcoxon Test for numerical variables and Chi-Square Test for categorical variables was performed.

**Results** Mean age was 62±12years; 52.8% (32/61) male; 70.5% (43/61) smokers/ex-smokers; 60.7% (37/61) stage IV; 42.6% (23/54) mutant EGFR. Minimum follow-up of 6 months was accomplished in 54 patients.

An EGFR-TKI was prescribed as first-line treatment in 65.2% (15/23) EGFR-positive patients, 80.0% (12/15) stage IV, with an OS of 12.40±[11.30–23.33] months and 53.3% (8/15) deaths. Two patients required second-line chemotherapy (2/15; 13.3%).

Chemotherapy as first-line treatment was prescribed in 75% patients (46/61), 17% EGFR-Positive (8/46), 50.0% (4/8) stage IV, with 29% (2/7) deaths. EGFR-TKIs were used as second-line treatment in 87.5% (7/8) patients and third-line in 12.5% (1/8). OS was 17.97±[8.23–60.84] months.

EGFR was native in 67.4% (31/46) patients, 58.1% (18/31) stage IV, and 61.3% (19/31) deaths. EGFR-TKIs as second-line treatment were prescribed in 61.3%. (19/31) patients, third-line in 35.5% (11/31) and fourth-line in 3.2% (1/31).

Seven patients had unknown EGFR status (7/61; 11.5%), 57.1% (4/7) stage IV, and 42.8% (3/7) deaths. EGFR-TKI as second-line treatment was prescribed in 85.7% (6/7) patients and fourth-line treatment in 14.3% (1/7).

OS and mortality were not statistically different between EGFR-positive patients treated with EGFR-TKIs/chemotherapy as first-line treatment (F=0.836; p=0.105). Mortality was not associated with stage or EGFR status (F=0.086; p=1.000).

**Conclusions** Mortality and OS are not associated with EGFR status or stage in this NSCLC population. EGFR-positive patients present similar OS and mortality rates regardless of first-line treatment.

No conflict of interest.

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**CPC-074** INTENSIVE MONITORING OF ADVERSE REACTIONS IN ONCOHEMATOLOGY: PROJECT FARMAREL

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**Background** For advanced non-small cell lung cancer (NSCLC), numerous studies have demonstrated a 25% improvement in progression-free survival compared to conventional chemotherapy as first-line treatment for advanced NSCLC with EGFR mutations.
CPC-071 Incidence and Causes of Capecitabine Dose Adjustment in Colon Cancer Patients
C Gonzalez-Perez, E Márquez Fernández, B Ruiz Pérez, B Solano Hernández and JM Fernández Ovies

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