Clinical pharmacy and clinical trials

Materials and Methods XAMOS was a phase IV, non-interventional, open-label cohort study in patients undergoing major orthopaedic surgery in daily clinical practice. The choice of rivaroxaban or standard of care (SOC) for VTE prophylaxis was at the discretion of the attending physicians. All adverse events, including symptomatic thromboembolic and bleeding events, and pre-trial and concomitant use of medicines were reported.

Results XAMOS enrolled 17,701 patients; the safety population included 17,413 patients, of whom 8778 received rivaroxaban and 8635 received SOC (81.7% low molecular weight heparin). Baseline patient demographics and use of cytochrome P450 (CYP) 3A4 inhibitors or inducers and platelet aggregate inhibitors (PAIs) before surgery were similar between groups; these drugs were used less frequently after surgery. There was a significant reduction in the incidence of symptomatic thromboembolic events in the rivaroxaban group compared with the SOC group, with numerically but not statistically higher incidence of major bleeding events. Concomitant use of PAIs was associated with higher incidences of symptomatic thromboembolic and any bleeding events compared with non-use in both the rivaroxaban and the SOC groups (Table).

Conclusions XAMOS confirmed the results of the RECORD studies. CYP3A4 inhibitors or inducers and PAIs were used less frequently after surgery compared with before surgery. The benefit–risk profile of rivaroxaban compared with SOC was maintained in routine clinical practice in patients undergoing major orthopaedic surgery; including patients with concomitant use of PAIs.

Abstract CPC-124 Table 1

<table>
<thead>
<tr>
<th>Pre-trial and concomitant use of drugs and clinical outcomes in the XAMOS study*</th>
<th>Rivaroxaban (%)</th>
<th>SOC (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-trial use (&lt;7 days before surgery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP3A4 inhibitors</td>
<td>2.3</td>
<td>3.0</td>
</tr>
<tr>
<td>CYP3A4 inducers</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>PAIs</td>
<td>6.8</td>
<td>8.2</td>
</tr>
<tr>
<td>Concomitant use during the study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP3A4 inhibitors</td>
<td>0.5</td>
<td>1.0</td>
</tr>
<tr>
<td>CYP3A4 inducers</td>
<td>0.4</td>
<td>0.7</td>
</tr>
<tr>
<td>PAIs</td>
<td>2.8</td>
<td>3.7</td>
</tr>
<tr>
<td>Incidence of any symptomatic thromboembolic events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant use of PAIs</td>
<td>2.4</td>
<td>4.0</td>
</tr>
<tr>
<td>No concomitant use of PAIs</td>
<td>0.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Incidence of any treatment-emergent bleeding events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant use of PAIs</td>
<td>8.4</td>
<td>8.1</td>
</tr>
<tr>
<td>No concomitant use of PAIs</td>
<td>4.6</td>
<td>3.0</td>
</tr>
</tbody>
</table>

*Unadjusted data as crude estimates for comparison between groups (covariate-adjusted and propensity score-adjusted results will be presented elsewhere upon completion of the final data analysis).

No conflict of interest.

CPC-126 SECOND-LINE CHEMOTHERAPY WITH NAB-PACLITAXEL IN PATIENTS WITH PANCREAS CANCER

doi:10.1136/ehjpharm-2013-000276.583


Background Pancreatic cancer is one of the most deadly forms of cancer. Standard treatment in metastatic disease is the chemotherapy with gemcitabine, but there is not a standard therapy for gemcitabine-refractory patients.

Purpose Assess the off-label efficacy of nab-paclitaxel, in patients who progressed on gemcitabine-based therapy, in our hospital.

Materials and Methods Observational retrospective study of pancreatic cancer patients treated with nab-paclitaxel who progressed on gemcitabine-based therapy from June 2011 to April 2012. Data were collected from clinical history, Oncofarm® and Omega-3ML® programmes. We determined: Progression free survival (PFS) and Overall Survival (OS). 12 patients (100% male) were treated with nab-paclitaxel. Eleven of them presented metastatic disease. The patients were treated with two therapies:

- nab-paclitaxel 100 mg/m2 (1.8,15/28d): 5 patients received this treatment. Median age was 79.4 years (sd = 11.8 years)
- Gemcitabine 1000 mg/m2 plus nab-paclitaxel 100 mg/m2 (1.8,15/28d): 7 patients received this treatment; Median age was 65.5 years (sd = 6.9 years).

Results Median PFS was 2.8 months (95% CI, 1.5 to 4.1 months) with single agent, and 5.3 months (95% CI, 4.0 to 6.5 months) with gemcitabine plus nab-paclitaxel. The PFS in the study was 20% and 83% respectively. The OS couldn’t be determine in the nab-paclitaxel group, because there wasn’t any event during the study period. The OS with gemcitabine plus nab-paclitaxel was 66.7%.

CPC-125 SATISFACTION SURVEY WITH PHARMACEUTICAL CARE IN AMBULATORY CANCER PATIENTS ON TREATMENT WITH ORAL ANTHEOPLASTIC AGENTS

doi:10.1136/ehjpharm-2013-000276.582

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Background In recent years, many oral antineoplastic agents (OAA) have appeared providing patient convenience. According to law, in the Autonomous Community of Región de Murcia (Spain), these drugs are dispensed at hospital pharmacies in the outpatient setting.

Hospital pharmacists, because of their frequent contact with cancer patients on treatment with OAA, play a pivotal role in improving adherence and ensuring that medicines are taken correctly through oral and written information.

Purpose To know patient satisfaction with pharmaceutical care (PC) through a survey in ambulatory cancer patients who take OAA.

Materials and Methods A Likert-type scale on patient satisfaction with PC was designed and run on every other week for six weeks. The survey was completed by patients in an anonymous and voluntary manner. It included 17 questions in 5 groups: demographic data, PC request, opinion about the information provided to them, consultation with the pharmacist and global satisfaction degree with PC. Only these 2 latest question groups were considered for the analysis, including 5 items: pharmacist accessibility, courtesy, professional competence, patient opinion about pharmacist utility and global satisfaction degree with PC. Survey internal consistency was measured with Cronbach’s alpha coefficient.

Results This survey was completed by 57 patients (71.25% of the total; 55% men; 47% women). Answers to questions were graded with 5 points. For the items pharmacist accessibility, courtesy, professional competence, patient opinion about pharmacist utility and global satisfaction degree with PC, the mean plus/minus standard deviation values achieved were 4.53 ± 0.49, 4.53 ± 0.49, 4.29 ± 0.53, 4.29 ± 0.53 and 4.46 ± 0.53, respectively. Overall satisfaction extent was 83.33%. In this survey, Cronbach’s alpha coefficient was 0.85, so we can say that this scale is trustworthy.

Conclusions In this patient group, the degree of overall satisfaction with pharmaceutical care was satisfactory. Future surveys will be needed to cheque and improve our service.

No conflict of interest.
Conclusions

- It showed better clinical outcomes in the gemcitabine plus nab-paclitaxel group in PFS.
- The nab-paclitaxel can be an effective second-line chemotherapy in gemcitabine resistant patients.

No conflict of interest.

CPC-127  SEVERAL TYPES OF PROTEINURIA AND ASSOCIATED FACTORS AMONG HIV-INFECTED ADULTS IN THE HAART ERA

doi:10.1136/ejhpharm-2013-000276.584

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Background

HIV-infected individuals have an increased risk of chronic kidney disease.

Purpose

To evaluate the prevalence of different types of proteinuria and associated factors in a HIV-infected population with a high percentage (92%) of Caucasian origin.

Materials and Methods

Cross-sectional study of all HIV-infected adults seen at the Montpellier University Hospital HIV outpatients unit over 6 months. Demographics, treatment history, co-morbidities and laboratory data were collected from an electronic database and manual review chart. Spot urine protein to creatinine (uPCR) and albumin to creatinine (uACR) ratios, estimated glomerular filtration rate using the MDRD equation (eGFR) were assessed. Three types of proteinuria were defined: tubular proteinuria (uPCR > 200 mg/g and albuminuria/proteinuria < 0.5), glomerular proteinuria (uPCR > 200 mg/g and albuminuria/proteinuria > 0.5), microalbuminuria (uPCR < 200 mg/g and uACR 30–300 mg/g). Multivariate logistic regression was used to identify independent factors of proteinuria for patients with eGFR > 60 mL/min/1.73 m².

Results

Characteristics for 1210 patients were: median age 48 years, 26% women, 71% black, 93% on HAART, 54% on tenofovir, median CD4 cell count 488 cell/μl, 73% with HIV viral load <20 copies/mL, 78.8% hypertensive, 3.4% diabetic, 18.2% HCV positive, 2.1% with history of kidney disease. eGFR was >90 for 59.3%, 60 to 90 for 36% and <60 for 4.5%. Of 1156 patients with eGFR > 60 mL/min/1.73 m², proteinuria was observed in 159 patients (13.7%). Tubular: [tubular: 124 (10.7%), glomerular: 35 (3.2%) and microalbuminuria for 51 patients (4.4%)]. Factors associated with tubular proteinuria were: current regimen with tenofovir (OR 2.70), diabetes (OR 2.54), HCV+ (OR 1.62), AIDS stage (OR 1.54), older age (OR 1.46/10-year increment). Diabetes (OR 5.15) and hypertension (OR 3.74) were associated with glomerular proteinuria.

Conclusions

The prevalence of proteinuria or microalbuminuria was 18.1% in this predominantly white, cART (current antiretroviral therapy)-experienced cohort. Measuring uPCR and albuminuria may assist in the diagnosis of early renal disease.

Abstract CPC-127 Table 1

<table>
<thead>
<tr>
<th>1210 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>uPCR &lt; 200 mg/g</td>
</tr>
<tr>
<td>uPCR &gt; 200 mg/g</td>
</tr>
<tr>
<td>Tubular proteinuria alb/prot</td>
</tr>
<tr>
<td>Glomerular proteinuria alb/prot</td>
</tr>
</tbody>
</table>

No conflict of interest.
CPC-126 Second-Line Chemotherapy with Nab-Paclitaxel in Patients with Pancreas Cancer

S Alonso Castellanos, RM Romero Jimenez, M Ubeira Iglesias, E Briones Cuesta, A Pedrosa Naudín, B Oca Luis, A López Insua, S Barbadillo Villanueva, R Martínez de Arriba and M Güemes García

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