Abstract CPC-122 Table 1

Risk factors	Patients	CR (N, %)	Non-CR (N, %)	Risk reduction CR vs. Non-CR	Statistical difference (SD) or Non-significant difference (NSD)
Age (n = 30)	3	3 (100%)	0	100%	SD between all subgroups.
Age >75	21	16(76.2%)	5(23.8%)	52.4%	
Age 51–74	6	2 (33.3%)	4(66.7%)	33.3%	
Age 31–50					
Sex (n = 30)	14	8 (57.1%)	6(42.9%)	14.2%	NSD
Female	16	13(81.2%)	3(18.8%)	62.4%	
Male					
History of motion sickness	4	3 (75%)	1 (25%)	50%	
Pregnancy-induced vomiting	4	3 (75%)	1 (25%)	50%	
Radiotherapy	3	2 (66.7%)	1(33.3%)	33.3%	
Anxiety/depression	6	3 (50%)	3 (50%)	–	
Alcohol intake history (n = 30)					SD between zero and mild consumption vs.
None	19	12(63.2%)	7(36.8%)	26.4%	moderate and high.
Mild (1–5)	9	6 (66.7%)	3(33.3%)	33.4%	
Moderate (6–14)	1	1 (100%)	0	100%	
High (>14)	1	1 (100%)	0	100%	

CINV was investigated. CR was defined as no emetic episodes during the overall 5-day study period. Patients' risk factors were recorded before chemotherapy infusion. All patients received intravenous 5HT3-receptor antagonists before chemotherapy infusion and a two-drug combination (metoclopramide and dexamethasone) on the following four days. Patients kept a diary to report CINV during the 5-day period. Univariate analyses were performed to determine the risk factors significantly associated with emesis after the first cycle of chemotherapy. Risk reduction between CR and non-CR results were calculated. The statistical significance among risk-factor subgroups was also evaluated in order to assess the extent of influence of each one.

Results A total of 30 patients were evaluated. The incidence of emesis is summarised in the table.

Conclusions The younger the patient the less emetic control there was. Although the risk was higher in women, this difference was not significant. None or minor consumption of alcohol had significantly higher risk of emesis than moderate or high. A multivariable analysis may be performed to confirm the relationship between risk factors and CINV.

No conflict of interest.

CPC-123 RISPERIDONE AND SUSPECTED ANGIONEUROTIC OEDEMA: CONTRIBUTION OF MULTIDISCIPLINARY CARE

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Background Psychotropic drugs may cause cutaneous eruptions with various degrees of severity ranging from urticaria to 'angioedema' (AE). Respiratory tract obstruction needs emergency care.

Purpose To report on a patient who developed facial AE following treatment with risperidone.

Materials and Methods An 85-year-old woman was admitted to the emergency department (ED) for acute respiratory failure 24 hours after risperidone was introduced.

Results She presented macroglossia, dyspnoea and oedema of the soft palate, unresolved with antihistamines and steroids. In the ED, risperidone was reintroduced for agitation. It was immediately followed by severe dyspnoea, oedema of the tongue and uvula requiring admission to the intensive care unit. Risperidone imputability was suspected after a review of the literature. The Regional Reference Centre for Bradykinin AE (BAE) was consulted. Allergic oedema caused by risperidone but not BAE was concluded (delay of occurrence, absence of real BAE case with risperidone). Risperidone was stopped, the patient was monitored and treated with the optimal dose of steroids and antihistamines. Oedema resolved in 48 hours and patient went back home without sequelae. Naranjo evaluation scored 9, so it was highly probable that oedema was linked to the drug.

Conclusions AE can result in laryngeal oedema and fatal airway obstruction. When differential diagnoses are eliminated, AE is classified into allergic/pseudo-allergic or bradykinin-related (hereditary or acquired with angiotensin-converting enzyme inhibitors and sartans). The mechanism of drug-induced BAE seems to be mediated by increased plasma bradykinin levels, because these drugs reduce its breakdown.

AE has been reported to occur with antipsychotics like risperidone, but these drugs probably produce histaminergic AE, not BAE. In our case, this hypothesis must be ruled out with cutaneous allergology prick tests with risperidone.

Diagnosis of BAE can be difficult. Clinical signs and oedema resistant to conventional treatments have led to suspicion of BAE. French Reference Centres can improve and optimise detection and treatment of these orphan diseases and limit use of expensive drugs (*e.g.* icatibant: 6,300 US dollars per patient).

No conflict of interest.

CPC-124 RIVAROXABAN OR CONVENTIONAL THROMBOPROPHYLAXIS AFTER MAJOR ORTHOPAEDIC SURGERY IN ROUTINE PRACTISE: INFLUENCE OF CO-MEDICATIONS ON OUTCOMES IN THE XAMOS STUDY

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Background Rivaroxaban, a direct Factor Xa inhibitor, has been shown to be more effective in preventing venous thromboembolism than enoxaparin regimens, with a similar safety profile, in patients undergoing hip or knee arthroplasty (the phase III RECORD studies). Rivaroxaban is approved for this indication worldwide.

Purpose To examine the effectiveness and safety of rivaroxaban for thromboprophylaxis in routine clinical practise and the impact of selected co-medication use on outcomes.

Materials and Methods XAMOS was a phase IV, non-interventional, open-label cohort study in patients undergoing major orthopaedic surgery in daily clinical practise. 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 aggregation 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 practise in patients undergoing major orthopaedic surgery, including patients with concomitant use of PAIs.

Abstract CPC-124 Table 1

Pre-trial and concomitant use of drugs and clinical outcomes in the XAMOS study*

	Rivaroxaban (%)	SOC (%)
Pretrial use (≤7 days before surgery)		
CYP3A4 inhibitors	2.3	3.0
CYP3A4 inducers	0.8	0.8
PAIs	6.8	8.2
Concomitant use during the study		
CYP3A4 inhibitors	0.5	1.0
CYP3A4 inducers	0.4	0.7
PAIs	2.8	3.7
Incidence of any symptomatic thromboembolic events		
Concomitant use of PAIs	2.4	4.0
No concomitant use of PAIs	0.6	0.9
Incidence of any treatment-emergent bleeding events		
Concomitant use of PAIs	8.4	8.1
No concomitant use of PAIs	4.6	3.0

*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 analyses).

No conflict of interest.

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

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Background In recent years, many oral antineoplastic agents (OAAs) 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: demographical 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; 53% 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 88.33%. 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.

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

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Background Pancreatic cancer is one of the most deadly forms of cancer. Standard treatment in metastatic disease is the quemotherapy 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-3MIL® 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 desease. The patients were treated with two therapies:

- nab-paclitaxel 100 mg/m^2 (1.8,15/28d). 5 patients received this treatment. Median age was 79.4 years (sd = 4.2 years)
- Gemcitabine 1000 mg/m^2 plus nab-paclitaxel 100 mg/m^2 (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%.