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Table 1: Cases of ONJ with ibandronate

Case	Age (years)	Ibandronate dose	ONJ site	Dental extraction/ prosthesis	Time to onset	Outcome
1	83#	I.v. 4 mg monthly	Both jaws	No	3 years	Oral surgery and subsequent abscess drainage
2	76	I.v. 6 mg every 2 weeks	Dental prosthesis	Yes	11 months	Sequestrectomy and plastic surgery
3	57	I.v. 6 mg monthly	Mandible	No	3 months	Resolved with bone decortication
4	70+	I.v. 6 mg monthly	Maxilla	Yes	5 years	Resolved with alveolar process resection
5	76*	I.v. 6 mg monthly	Mandible	Yes	2 months	Resolved with antibiotics
6	58*	Oral 50 mg once daily	Maxilla	Yes	4 months	Event persisted
7	54*	Oral 50 mg once daily	Mandible	Yes	6 months	Not recorded

<sup>\*</sup>Prior history of zoledronic acid treatment; #Prior history of clodronate treatment

1291 POSTER

Capecitabine (XEL)+Oxaliplatin (OX) in elderly people (EP) with Colorectal Cancer (CRC): Comparison of safety (S) and feasibility (F) of two different schedules. Preliminary findings

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Rationale: CRC incidence arise in older patients. Aging is associated with decreased functional reserve of multiple organ systems with worsening of behaviour of pharmacokinetics and pharmacodynamics of drugs. EP show enhanced susceptibility to cytotoxic therapy, especially for bone-marrow, mucosal, CNS and neuroperipheral (NPH) toxicity (TOX). Treatment of EP with CRC must take in account the prevention of these effects. Combination XEL+OX seems to be safe and feasible for this purpose especially if dose drugs adjustment will be performed.

Aims: To evaluate a flat dose schedule of XEL (1000 mg b.i.d.)+OX (130 mg/sqm) q3wks vs XEL (1000 mg/sqm b.i.d.)+OX (130 mg/sqm) q3wks.

Methods: a totally of 22 elderly PTS Dukes C stage CRC (m/age 70) were treated in our dept after written informed consent acquired. 11 pts (Group A) were treated as follows: XEL (1000 mg/sqm/os b.i.d.) d2–15+OX (130 mg/sqm/2 h/i.v.i.)(Schedule A). Another group of 11 pts (Group B) received XEL 1000 mg/b.i.d (flat dose)+OX (130 mg/sqm/2 h/i.v.i.)(Schedule B). We evaluated GFR of each patient and CHT was adjusted according with Kintzel&Dorr formula. All patients were evaluated for common treatment-related adverse events haematological, liver, mucosal, CNS&NPH TOX, N&V and HFS, according to the ECOG. All patients were also evaluated for ADL/IADL both with ECOG PS and number of comorbidities. Plasma VEGF's values was also evaluated.

Results: Both Group A & B were evaluated at the end of treatment. Group A PTS received about 80% of expected dose only; Group B received full expected dose; TOXs: Group A: haematological: 10 PTS = G1; 2 PTS = G2. Liver: 6 PTS = G1; 5 PTS = G2; 1 PTS = G3. HFS: 3 PTS = G2; 1 PTS = G3/4; CNS&NPH: 11 PTS = G1/2. Group B: haematological: 6 PTS = G1; Liver: 10 PTS = G1; CNS&NPH: 4 PTS = G1.

Conclusions: The study show that schedule B have more safe and feasible profile compared with schedule A. Further, XEL flat dose (according with Lokich, Canc. Invest., 2004) improves PTS compliance for oral delivery (no needs to different tablets for size and concentration to reach the expected dose). No delivery delay was necessary in schedule B PTS. Only slight general TOX was also noted in schedule B PTS vs schedule A. Author believe that XEL flat dose administration works as antiangiogenic control in CRC elderly PTS, with preservation of DI, even if a larger number of PTS will be necessary to permit statistical analysis. DFS and OS are still under evaluation.

## Publication

## Patient management (including cancer in the elderly, palliative care, symptom management, psychosocial aspects, quality of life management)

1292 PUBLICATION

Effectivness of recombinant human erythropoietin (epoetin beta, EPO) in improving hematological parameters and QOL in patients with chemotherapy-induced anemia. A double-blind, parallel-group, dose-finding study

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**Aim:** of this randomized, double-blind, parallel-group, dose-finding study is to evaluate the effectivness of recombinant human erythropoietin (epoetin beta, EPO) in improving hematologicals parameters and QOL.

Methods: Anemic patients (hemoglobin(Hb)) ≤11g/dl(undergoing chemotherapy for colorectal cancer or malignant lymphoma received EPO 20000 or 30000 IU subcutaneously once weekly for 12 weeks. Changes in QOL were assessed with the Functional Assessement of Cancer Therapy-Anemia(FACT-An) survey before (day 1 of chemotherapy), during (7-11 weeks) and at the end of EPO therapy.

Results: A total of 50 patients were enrolled in the study. The increase in Hb from baseline to the time of final evaluation (12 weeks) was dose-dependent(1.04 $\pm$ 1.75, and 1.75 $\pm$ 2.15 g/dl in the 20000 and 30000 IU groups, respectively), and the increase in the 30000 IU group was significant (p=0.008). The proportions of patients with an Hb increase  $\geqslant 2\,\text{g/dl}$  were 66.7 and 78.3% in the 20000 and 30000 IU groups respectively. The FACT-Fatique subscale score (FSS) before EPO therapy was high in these two groups. Changes in FSS were not dose-dependent, but the increase in FSS was significantly correlated with the Hb increase(r=0.434 p<0.001), and significantly greater in patients with an Hb increase  $\geqslant 2\,\text{g/dl}$ , compared to the patients with one of <2 g/dl (2.2 vs. -3.2 p=0.011). Multiple regression analysis showed that the FSS increase was significantly correlated with the Hb increase (p<0.001) and FSS values at the onset of EPO therapy (p<0.001). The transfusion rates after 4 weeks of therapy were 16,8% (20000 IU) and 0% (30000 IU). Dosedependent adverse events were not observed.

**Conclusions:** Once-weekly EPO at a dose of 30000 IU increased Hb levels in patients with chemotherapy-induced anemia and QOL benefits were significantly correlated with the Hb increase.

1293 PUBLICATION

Cancer pain control in the Eastern mediterranean region: many steps behind

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The World Health Organization (WHO) Eastern Mediterranean Region (EMR) comprises 22 developing countries of varied economic development. These countries constitute about 8% of the world population and have increasing cancer incidence with associated mortality and morbidity. The WHO monitors morphine consumption as an index of improvement in pain management & since1984 the world morphine consumption has been increasing in response to the WHO recommendations, suggesting improvement in global cancer pain control.

Objective: To assess cancer pain control in the EMR.

**Method:** United Nations' mid-year population estimates and International Narcotics Control Board data regarding morphine consumption were used to calculate the morphine consumption per capita for the World and the EMR, from 1996 to 2003. Globocan 2002 database was used to calculate the estimated cancer mortality in EMR.

Results: Although the EMR countries contain 4% of global estimated cancer mortality, they consumed only 0.002% of the global morphine consumption in 2003. World morphine consumption/capita has increased by 54% from 2.88 mg/capita in 1996 to 4.43 mg/capita in 2003. On the other hand there was almost no change in morphine consumption/capita in the EMR from 1996 (0.09 mg/capita) to 2003 (0.1 mg/capita).

Conclusion: These results indicate that cancer pain control in the EMR is completely inadequate with almost no improvement over the last years when compared to global trends. More attention should be paid to cancer pain control in the EMR, both on national and international levels with special attention to the barriers that prevent access to opioids in this region.