endpoints were emesis-free and nausea-free rates during the five days following HEC in up to six cycles. Safety was also evaluated.
Results: 158 patients with lung cancer were included in the study. Median age was 64 years, most of the patients were male (76.6%), with stage IV lung cancer (74.7%) and all of them were treated with cisplatin dosage of ⩾75 mg/sqm. Efficacy results are reported in the table. The most commonly reported side effects were mild constipation, headache and hickup.

Variable	Cycle					
	1	2	3	4	5	6
CR %	74	77.2	80	79.2	81.8	83.2
No emesis %	92.4	93	91.6	90.3	91.7	94.1
No nausea %	58.9	67.1	65.2	63.6	66.1	69.7

Conclusions: This study shows that, in lung cancer patients, the antiemetic efficacy of the triple combination palonosetron aprepitant, and dexamethasone could be sustained for up to six cycles of cisplatin-based HEC. These data confirm that adequate control in the first cycle of chemotherapy is more likely to be associated with control of CINV in subsequent cycles.

3066 POSTER

Erythropoiesis-stimulating Agents for the Treatment of Chemotherapy-induced Anemia and Mortality: a Meta-analysis of Individual Patient Data From Japanese Randomized Trials

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Background: Erythropoiesis-stimulating agents (ESAs) reduce the need for transfusions and improve quality of life in cancer patients receiving chemotherapy, but several clinical trials have suggested that ESAs may have a negative impact on survival in cancer patients. The FDA and European Medicines Agency have requested a change in the product labels for ESAs and restricted their initiation and target hemoglobin (Hb) levels to minimize the risk when they are used in patients with chemotherapy-induced anemia (CIA).
Materials and Methods: To evaluate the efficacy and safety of ESAs, including the impact on overall survival (OS) and thromboembolic events (TEE), we conducted a meta-analysis of 3 Japanese randomized, placebo-controlled trials (epoetin beta or darbepoetin alfa n = 273, placebo n = 238) in patients with CIA. Individual patient data were provided by Chugai and Kyowa Hakko Kirin. An association between the Hb level achieved during treatment and the risk of mortality was examined using landmark analysis.
Results: ESAs significantly reduced the risk of transfusion (relative risk 0.47, 95% CI 0.29–0.76). No statistically significant effect on OS was observed with ESAs (hazard ratio [HR] 1.00, 95% CI 0.75–1.34). A prespecified subgroup analysis showed no strong interaction between the baseline Hb level and the effect of ESAs on OS. Among ESA-treated patients, a mean Hb level of 11 < to 11.5 g/dL during the 3 month treatment period was associated with the lowest risk of mortality (HR 0.43, 95% CI 0.17–1.07; reference: mean Hb ⩽10 g/dL), but the highest achieved Hb level during the treatment period in each patient had no impact on OS. No increase of TEE was observed in the ESA-treated patients (0.7% vs 1.7% placebo).
Conclusions: Treatment with ESAs reduced the risk of transfusion without a negative impact on OS in Japanese patients with CIA.

3067 POSTER

SAMITAL®: a New Challenge for the Treatment of Oral Mucositis Induced by Chemoradiotherapy

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Background: Oral mucositis constitutes a widely diffused concomitant effect of chemoradiotherapy (CT/RT). The development of oral mucositis is a complex process which starts from tissue damage injury produced by CT/RT and rapidly degenerates in severe ulceration followed by inflammation, pain and infection. Oral mucositis, despite its relevance in worsening the quality of life and the therapeutical chances of oncological patients, is still considered an unmet need. In this framework, SAMITAL® has been developed by rationally combining three highly standardized botanical extracts each one endowed with specific pharmacological properties which can globally contribute to the relief of all the four key stages of mucositis.
Materials and Methods: Five clinical studies have been conducted using SAMITAL®. From 2008 to 2011, a total of 93 oncological patients (73 adults and 20 paediatric subjects) with mucositis induced by CT/RT have been treated with SAMITAL® (oral soluble lozenges or granules for suspension) 3−4 times daily, for almost the entire CT/RT regimen (4−50 days). Primary end-points: reduction of the progression of oral mucositis (according to WHO Scale), clinical tolerability and compliance. Secondary end-points: oropharyngeal pain intensity and continuity of CT/RT program.
Results: SAMITAL® was effective in controlling symptoms of severe mucositis, in improving recovery of lesions and in reducing the progression. A positive effect on dysphagia was also observed associated with an improvement of painful symptoms. An extensive enhancement of the quality of life was observed in all the patients who completed SAMITAL® treatment. Clinical tolerability and compliance were acceptable. Adverse events were infrequent and included mild vomiting and nausea (6/93, <6%), which resolved rapidly. Finally a general clinical advantage has been observed in all these studies, due to the better tolerability of CT/RT resulting in the maintenance of the complete therapeutic regimen.
Conclusions: Clinical evidences accumulated so far demonstrated that SAMITAL® has good tolerability and good efficacy. The effects were particularly relevant in term of reduction of mucositis and pain, recovery of swallowing and nutritional impairment; improvement of life quality, overall clinical advantage with completion of CT/RT regimen. These results encourage and support additional Phase II/III clinical studies on SAMITAL®.

3068 POSTER

Aprepitant is Active in Biological Therapies Induced Severe Pruritus − Final Results of the Italian Proof of Concept Study

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Background: Increasing evidences prove the involvement of keratinocytes NK1 receptors in the pathogenesis of pruritus: this prospective study aims to evaluate the role of aprepitant, a NK1 receptor antagonist, in the treatment of severe pruritus induced by biological therapies.
Materials and Methods: 30 patients (15 Male/15 Female), 63 years as mean age, affected by lung cancer (12), colorectal cancer (13) or other tumours (5), who developed severe pruritus (VAS ⩾7) during treatment with erlotinib (12), cetuximab (13), panitumumab (1), lapatinib (1), sunitinib (2) and imatinib (1) were enrolled. After the onset of severe, steroid or antihistaminic resistant pruritus, aprepitant was administered (125 mg day 1; 80 mg day 3; 80 mg day 5). Pruritus intensity was evaluated by VAS score before and after aprepitant administration (day 7 and every other following week until day 90 or the recurrence moment).
Results: Initial pruritus intensity was 10 in 3 patients, 9 in 6, 8 in 14 and 7 in 7 (median 8). After 1 week of aprepitant therapy the reported pruritus intensity was 0 in 14 patients, 1 in 6, 2 in 4, 3 in 4, 4 in 1 and 6 in 1 (median 1). The median decrease was 88%. Moreover, 93% of patients responded to aprepitant (decrease >50%), 2 did not (respectively, 50% and 30% of intensity reduction). Median duration of one cycle effect was 25 days (7−90 days).
Conclusions: This study assessed aprepitant activity in the management of biological therapies induced severe pruritus. Randomized studies are necessary to compare aprepitant activity with those of standard therapies.