1312 POSTER

Quality of life in women with breast cancer randomised to adjuvant treatment with marrow supported high dose chemotherapy with CTCb (BMT) or tailored FEC therapy: The SBG-9401 Study

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Purpose: To compare health related quality of life (HRQOL) in women randomised to to either adjuvant treatment with tailored FEC therapy for 9 courses (Arm A) versus induction FEC therapy for 3 courses followed by high dose chemotherapy with CTCb supported by peripheral blood stem cells (Arm B) at eight points during the first year from randomisation.

Patients: 408 high risk breast cancer patients (estimated relapse risk > 70% within 5 years on standard therapy) randomised in the SBG-9401 study.

Methods: The EORTC C-30 was completed at eight points, starting before randomisation.

Results: Between 80% and 90% patients responded at each assessment point. No statistically significant overall differences between arm A and B were found. PF, SF and QL changed ($p < 0.001$) during the course of treatment with a dip10 to 16 weeks after randomisation. At one year assessment, most women had recovered to levels found before start of treatment on SF (mean = 86) and QL (mean = 72). PF increased (mean = 84.4) but not to the original level (mean = 89.4). EF increased during course of treatment (mean = 67.8 before randomisation, 78.3 at one-year assessment). FA (mean = 20.5 before randomisation) peaked in both groups after 10 to 16 weeks (mean = 52.4 Arm A, 54.6 Arm B), but decreased subsequently (mean = 23.9 at one year).

Conclusion: All variables showed interactions between time and treatment higher levels of problems at time for BMT but faster recovery in Arm B than in Arm A. After one year, no differences between the arms were found.

Supportive care & quality of life

1313 POSTER

Multicentric randomized comparative study of ceftazidime plus amikacin vs ceftazidime plus perfloxacin in the treatment of febrile neutropenia

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Purpose: Combination of ceftazidime plus amikacin has been extensively used as initial empiric therapy of febrile neutropenic cancer patients. The new fluorinated quinolones demonstrate an excellent safety profile with lack of nephrotoxic potential and appear an appealing alternative to the aminoglycosides. This study evaluates the role of perfloxacin in combination with ceftazidime in comparison with the standard ceftazidime/amikacin treatment.

Patients-Methods: Patients with neutropenic fever (absolute neutrophil count [ANC] <1.0x103/mm3, fever >38oC for more than 2 hours) were randomized to receive empiric antibiotic treatment either with ceftazidime 2gr/8 hours (h) plus amikacin 20mg/kgr Body Weight in 3 doses (Arm A) or ceftazidime as above plus perfloxacin 400mg/12 hours, i.v. The minimal duration of treatment was 72 hours. After that treatment would continue for 7-10 days in case of improvement, otherwise vancomycin was added or study drug therapy discontinuated and other appropriate therapy instituted.

Results: Sixty-nine febrile episodes were treated 31 in arm A, 38 in arm B. Patients' characteristics were well balanced between the 2 groups, particularly in terms of ANC, G-CSF support etc, while 22% of patients suffered from haematological malignancies. There were no major toxicities in both arms. Moreover there was no difference between the two groups in the duration of hospitalization (median: 7 days). Four patients (13%) in group A and 2 (5%) in group B required an addition or change of the antibiotic treatment. The same trend was observed in favor of treatment B in terms of duration of neutropenic fever or episode-associated symptoms. There was a marginally statistically significant difference in favor of group B in terms of complete success of treatment (83% vs 92%, p= 0.08).

Conclusion: Treatment of febrile neutropenic episodes with empiric antibiotic therapy with a combination of the new fluorinated quinolone perfloxacin with ceftazidime appears to produce at least comparable results with the "standard" ceftazidime/amikacin combination.

1314 POSTER

Overuse and incorrect indication of histamine h2-receptor antagonist (HH2RA) and proton-pump inhibitors (PPI) in cancer patients (pts.)

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Background: HH2RA and PPI are demonstrated to be effective in symptomatic relief of dyspepsia and gastric lesions induced by nonsteroidal antiinflammatory drugs (NSAIDs) and chemotherapy. There is no evidence of benefit in preventing serious gastrointestinal complications in asymptomatic pts. HH2RA and PPI are often used in cancer pts. We have aimed to asses the correct indication of these drugs in our practice.

Patients and Methods: We retrospectively reviewed 33 medical histories of pts. that are using HH2RA or PPI, in an outpatient setting, at present. There were 19 men and 14 women. Median age was 55 years (range 25 -83). Four (12%) had a previous history of gastroduodenal ulcer (active only in one of them). Twenty (60%) were receiving chemotherapy, 7 (21%) were treated with NSAIDs, 8 (24%) with corticosteroids and 1 (3%) with both. Seven (21%) pts. were using HH2RA, 25 (76%) omeprazole and 1 (3%) rabeprazole. Median time of consume was 56 weeks (range 1 - 72).

Results: In 14 (42%) pts. HH2RA or PPI were prescribed due to dyspepsia or gastroduodenal ulcer treatment. 6 (18%) pts. received HH2RA or PPI as a clearly incorrect indication (5 after a routine use in a hospital admission and 1 as treatment after gastrectomy). In 13 (40%) the rational for indication was prevention of potential gastrointestinal complications (all of them were asymptomatic at the moment of prescription) due to the use of NSAIDs, corticosteroids or both.

Conclusions: 1) Treatment with HH2RA or PPI was avoidable in the majority of pts. in our series. 2) Use of these drugs is unjustifiable in a little but significant (18%) subset of pts. 3) Evidence-based indications are needed in routinary clinical practice.

1315 POSTER

Randomized, active-controlled, phase 1/2, dose-comparison study of NESP administered weekly or every 2 weeks in patients with solid tumors

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Purpose: Novel erythropoiesis stimulating protein (NESP) stimulates erythropoiesis by the same mechanism as rHuEPO. In patients with renal failure the serum half-life of NESP is 2- to 3-times longer than that of rHuEPO. In patients with cancer receiving chemotherapy, the serum half-life of NESP is approximately 40 hours. This study, done in 2 parts, assessed the safety and biological activity of NESP administered QW or Q2W in patients with solid tumors receiving multicycle chemotherapy. In Part A, NESP administered QW (0.5 to 8.0 μg/kg) was safe and well tolerated. Doses of NESP $\geq$ 1.5 μg/kg showed demonstrable activity. Efficacy increased with higher doses of NESP. In Part B, a similar cumulative weekly dose of NESP administered Q2W (ie, 3 to 9 μg/kg/Q2W) was investigated.

Methods: Patients with chemotherapy-induced anemia (hemoglobin [hgb] $\leq$ 11.0 g/dL) participated in this study. Patients were randomized to receive rHuEPO (40,000 U/week) or NESP (3.0, 5.0, 7.0, or 9.0 μg/kg/Q2W). Safety, hgb response and correction, and the incidence of RBC transfusions were evaluated.

Results: At least 54% of patients in all NESP groups achieved a hgb response or correction, and all doses met the CED criterion for efficacy when administered Q2W. A relatively low rate of blood transfusions was observed. NESP was well tolerated, was not associated with any safety concerns, and had a similar safety profile to rHuEPO (40,000 U/QW).

Conclusion: NESP was demonstrated to be effective at doses above 1.5 μg/kg QW and 3 μg/kg Q2W. NESP Q2W appeared to be as effective as NESP QW, suggesting that a less frequent dosing schedule is effective in treating anemia in patients with cancer receiving chemotherapy.