overall survival, safety and QoL. After giving informed consent, QoL was evaluated using the EORTC Q 30 breast cancer module, an established and validated questionnaire published by the European Organisation for Research and Treatment of Cancer. In addition, geriatric assessment was examined using the Charlson or the VES 13 score. The EORTC Q 30 was completed at study entry, 18 weeks and 6 months after randomization and annually from year 1 to year 5. A total of 1,394 pts (697 per arm) with 497 events are needed to show an improvement in 5-year DFS from 65% to 71.5% with X, assuming a drop-out rate of 5%. This provides 80% power to detect a clinically relevant difference between the treatment arms at $\alpha = 0.05$ (two-sided).
Results: Between 06/2004 and 08/2008 1409 pts were recruited in 172 German centers; 706 pts received I alone and 703 pts received X+I. The median age was 71 years (range 64−88). At study entry, the median Charlson Score was 0 (range 0−3) and the median VES 13 score was 1 (range 0−27). 762 pts answered the EORTC Q 30 questionnaire at baseline (388 pts in the I only arm and 374 in the I+X arm), representing 54% feedback. During the follow-up period, 596 pts answered and returned their questionnaire (300 I alone and 296 I+X).
Conclusion: This is the first study evaluating the impact of adjuvant therapy on elderly breast cancer pts. First QoL results will be presented at the meeting.

4017 POSTER

Antiangiogenetic drugs in combination with irinotecan (IRI) and capecitabine (XEL) in ACRC elderly patients: first data about safety and efficacy

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Background: Older individuals always experienced enhanced susceptibility to the side effects of cytotoxic chemotherapy. The aim of the study was to evaluate impact of bevacizumab (BEV) in combination with IRI and XEL in ACRC elderly patients.
Materials and Methods: 44 (20f-24 m) elderly patients with advanced colorectal cancer (median age: 72; range: 67−80) were enrolled. Comprehensive Geriatric Assessment (CGA) was performed to assess eligibility for chemotherapy. The dose of IRI and XEL was adjusted according to Kintzel-Dorr formula. Primary endpoint: clinical response rates (RR) according to WHO criteria. Secondary endpoints: toxicity profile using NCI-CTC v2.0 and quality of life (QoL) score measured through EORTC QLQ-C30 questionnaires. All patients were evaluated for common treatment-related adverse events with regard to haematological and liver toxicity, nausea and vomiting, stomatitis, diarrhea, hand/foot syndrome and sensory neuropathy, according to the ECOG Common Toxicity Criteria.
Results: Based on CGA, 39 Patients were included into groups I-II, according to Balducci's classification of frailty and treated with IRI (200 mg/m^2) + BEV (7.5 mg/Kg) on day 1, and XEL (fixed dose of 1000 mg b.i.d) assumed orally from day 2 to day 15, every 3 weeks for 6 months. None of the pts needed any delay in drugs delivery. Tumor response rates observed were 46% (CR+PR). Clinical benefit, including Stable disease, was 79%. No grade-4 toxicity was experienced. QoL score improvement was noted in all pts after treatment.
Conclusions: In elderly colorectal cancer patients the dose reduction of XEL through fixed daily dose administration of 1000 mg b.i.d. allows to reach a good tolerability profile with a significant reduction of all grades toxicity compared to dosage calculated according to patients' body surface. We have employed a fixed dose of XEL to obviate the inherent difficulties in dosing with different tablet sizes and to improve compliance with oral chemotherapy assumption in patients with a worse IADL profile. This regimen seems to be active and safe and authors believe that dose reduction improves tolerability without a decrease in efficacy. DFS and OS is under evaluation.

4018 POSTER

LINAC stereotactic radiotherapy of brain metastasis in elderly patients

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Background: Elderly patients very often suffer from cerebro-vascular impairment. It is known, that vascular damage enhances the risk for side effects such as dementia after whole brain radiotherapy. For patients with a limited number of brain metastases stereotactic radiosurgery is an ideal alternative. In this retrospective analysis survival and palliative effect of stereotactic radiotherapy of brain metastasis in patients 70 years and older was analysed.
Methods: From 350 patients treated in our clinic from January 2003 to December 2008 by stereotactic radiotherapy of brain metastases all patients 70 years and older were analysed.
Results: 63 patients were 70 years and older (median 74 years, range 70−87 years). 52% of the patients were male, 48% were female. The most frequent primary tumors were NSCLC (41%), colorectal cancer (18%), kidney cancer (14%) and breast cancer (10%). In 53 patients (84%) radiosurgery was performed, 10 patients (14%) received stereotactic fractionated radiotherapy. Median survival of all patients was 6 months. 1 year survival was 23%. Cause of death was extracranial tumor progression in 55% of the patients, only 7% died because of cerebral tumor progression, in 38% cause of death is unknown. 42 patients (67%) showed symptoms at time of radiotherapy. Within the first 6 months after stereotactic radiotherapy symptoms were reduced in 38.5% of the patients and aggravated in 23%. In 21 patients (57%) longer follow up showed durable improvement.
Conclusion: Stereotactic radiotherapy is a gentle treatment for brain metastasis even for elderly patients. Short median survival after treatment is mainly due to extracranial disease progression. Symptom reduction is possible in more than 50% of the patients.

Paediatric oncology

SIOPE Society session

(Mon, 21 Sep, 11:00−13:00)

4100 ORAL

Genetic characterization of a new subgroup of childhood precursor B-ALL with a very poor prognosis

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Background: Relapse risk stratification based on cytogenetic abnormality is becoming more important in pediatric acute lymphoblastic leukemia and gives the clinician the opportunity to adjust the intensity of therapy. To predict the cytogenetic abnormality we have selected a set of 110 probes, with a high accuracy. Interestingly, a group of formerly B-other patients clustered together with the BCR-ABL positive patients, but lacking the BCR-ABL translocation. This new defined group represents 15−20% of the B-cell leukemia and has an unfavourable prognosis equally to the BCR-ABL positive patients; therefore we describe this group as BCR-ABL like. In this study we investigate the genetic background of this new defined group.
Material and Methods: We have selected 44 BCR-ABL like patients, 15 BCR-ABL positive patients and 25 B-ALL patients with other cytogenetic abnormalities (MLL rearranged, E2A-PBX1 translocation, TEL-AML translocation, and other B-cell leukemias without hyperdiploidy). We applied an array-comparative genomic hybridization analysis on these patient samples. Additionally, we sequenced for microdeletions in VPREB1 and Ikaros.
Results: In 82% of the BCR-ABL like patients, we found an abnormality in one or more genes involved in B-lymphocyte development (PAX5, Ikaros, EBF1, E2A, VPREB1) versus 80% in the BCR-ABL positive patients versus 40% in the B-other patients. In PAX5 we report mono-allelic, bi-allelic deletions and inactivating point mutations. In Ikaros we both found deletions and presence of isoform6, based on a deletion of exon 3 to 7. We also have found mono-allelic deletions in EBF1. VPREB1 showed mono-allelic deletions and bi-allelic deletions, correlating with lower VPREB1 mRNA expression.
Conclusions: We describe a novel high-risk subgroup of pediatric B-cell acute lymphoblastic leukemia, representing a prominent part of the ALL. The clinical behavior of this group is comparable to BCR-ABL positive patients, but lacking a BCR-ABL fusion gene. B-cell development genes are frequently mutated. Currently, research is focusing on finding a specific genetic marker with future therapeutic options.