p<0.001). Whereas sexual complaints were ageassociated, this was not the case for urinary and bowel complaints. Most patients (95.9%) would recommend (125) I seed brachytherapy to others.
Conclusions: Our data substantiate the favorable long-term QoL outcomes associated with modern brachytherapy techniques. Significant age differences were observed in all quality of life measures, with the largest occurring in sexual and urinary symptoms. Sexual function was significantly worse in patients 65 years of age and older ($p < 0.05$).

1273 POSTER

Differential diagnosis and therapy of iron restricted erythropoiesis in anaemic cancer patients: data from the TANDEM study

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Background: Iron restricted erythropoiesis in patients with anaemia of chronic disease (ACD) is often caused by disturbances in iron metabolism and distribution. Thomas et al. developed a diagnostic plot (Thomas-Plot, TP) for the differential diagnosis of iron supply in ACD patients (Thomas C. et.al., Clin. Chemistry 48; 7: 1066–76 (2002)). This plot combines the hemoglobin content of reticulocytes with the ferritin index (the quotient of soluble transferrin receptor and logarithm of ferritin). The aim of the plot is to identify the cause for the anaemia and to provide a therapeutic solution for the most efficacious treatment combination of erythropoiesis stimulating factors (ESF) and iron supplementation. In order to validate the TP in cancer patients we started a phase II trial (TANDEM) in which the anaemia therapy in cancer patients is given based on the differential diagnosis by the TP.
Material and methods: Patients with non-myeloid tumors, > 18 years old, expected to receive at least 3 more cycles of chemotherapy (> 6 weeks), with ferritin >20 ng/ml, and an indication for ESF therapy as per EORTC guidelines are initially analyzed using the TP (screening). TP classifies pts. in 1 of 4 quadrants (Q1–Q4). Pts. in Q2+Q3 receive no ESF but oral iron (3 × 100 mg Fe II/d). Pts. in Q1+Q4 receive 30,000 IU Epoetin beta (NeoRecormon®) sc. once weekly. In addition, pts. in Q4 receive 200 mg Fe-saccharat per week iv. up to 1 g. During the study pts. are monitored by TP every two weeks and anaemia therapy is adjusted accordingly.
Results: Up to now (April 2005), 59 pts. have been recruited by 8 centers. After screening, 8 pts. fell in Q2 and 7 pts. in Q3. These 15 pts. (25%) received oral iron therapy due to a prevalent iron deficiency. 35 pts. (75%) fell in Q1+Q4 and received ESF therapy with Epoetin beta. Those 4 pts. in Q4 received additionally i.v. Fe-saccharat, and subsequently moved to Q1 within the first 2 weeks of treatment. 25% of pts. under EPO-Therapy (Q1+Q4) moved to Q2 or Q3 after 2 weeks of treatment and then received oral iron in addition to ESF. The analyzable pts. receiving ESF therapy with Epoetin beta had an average hemoglobin increase of 0.7 g/dl from baseline after 4 weeks.
Conclusions: Our preliminary results indicate that the TP is a simple and useful tool for optimizing anemia management with ESF and iron in patients with cancer related and chemotherapy induced anemia.
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Impact of bevacizumab plus 5-FU/LV with or without irinotecan on quality of life in patients with metastatic colorectal cancer

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Background: In a phase III trial, patients were treated first line with irinotecan, 5-FU, LV (IFL) plus placebo (n = 411) or bevacizumab (BV; Avastin), a monoclonal antibody to VEGF, plus IFL (n = 402). The addition of BV to IFL significantly prolonged progression-free survival (PFS) by 71% and overall survival (OS) by 30% [Hurwitz et al. J Clin Oncol 2004;22:2335–42]. In a phase II study, 209 subjects were randomized to 5-FU/LV+placebo (105) or 5-FU/LV+BV (104); addition of BV to 5-FU/LV significantly prolonged PFS [Kabbinavar et al. J Clin Oncol 2005;23: epub ahead of print February 28]. Evaluating changes in quality of life (QOL) was a secondary objective in both studies.
Methods: QOL endpoints were pre-specified; these included time to deterioration in QOL (TDQ), measured by the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) colon cancer subscale (CCS); Trial Outcome Index (TOI-C); and FACT-C score. QOL deterioration was prospectively defined based on a clinically meaningful decrease in scores: 3 points (CCS), 7 points (TOI-C), and 9 points (FACT-C). Median TDQ was evaluated for subjects with baseline and post-baseline assessments using the stratified log-rank test. Those who progressed or died before QOL declined were assigned TDQ of time to progression or death. Those who did not die or experience documented QOL deterioration or disease progression/death were censored at time of last QOL assessment. Those who discontinued without a post-baseline assessment or disease progression were censored at date of randomization.
Results: In the pivotal trial, baseline scores were available for 127/122 (CCS), 125/122 (TOI-C), and 124/121 (FACT-C) patients in the IFL and IFL+BV arms, respectively. There were no statistically significant differences in TDQ (CCS, TOI-C, or FACT-C) between treatment arms (Table 1). In the phase II study, baseline scores were available for 77/89 patients in the 5-FU/LV and 5-FU/LV + BV arms, respectively. Median TDQ as measured by TOI-C ($p = 0.0477$) and FACT-C score ($p = 0.0159$) was significantly prolonged for patients treated with 5-FU plus BV.

Table 1

	Median TDQ (months)		
	CCS	TOI-C	FACT-C
Pivotal trial			
IFL+placebo	2.73	3.29	3.94
IFL+BV	2.89	2.76	3.98
Phase II trial			
FL+placebo	3.02	2.30	2.63
FL+BV	3.12	3.22	3.61

Conclusions: When added to IFL, BV significantly prolonged OS and PFS without compromising QOL. Analyses of secondary measures of TDQ (TOI-C and FACT-C score) suggest a QOL gain with an increase in PFS for subjects receiving BV with 5-FU/LV.

1275 POSTER

Multidimensional geriatric parameters, family interference and awareness of disease during the obtainment of informed consent from elderly cancer patients: a prospective analysis

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Background: Limited awareness of disease in elderly cancer patients may be attributed to various patient-related factors (assessable through the multidimensional geriatric assessment-MGA) as well as to family opposition and physician's reluctance to disclose a dismal prognosis. Signature of widespread consent forms (CF) is not a reliable proof of adequate information.
Objective and Methods: To assess prospectively the degree of information given to elderly cancer patients (⩾ 65 years) and to evaluate how baseline MGA parameters (ECOG Performance Status-PS 0 vs ⩾ 1, Mini-Mental State-MMS ⩾ 24 vs < 23, Geriatric Depression Scale-GDS ⩽ 5 vs > 6, Activities of Daily Living-ADL = 6 vs ⩽ 5, Instrumental ADL = 8 vs ⩽ 7 and Charlson's score of comorbidity = 0 vs ⩾ 1) and family attitudes might interfere with the informed consent process. A short interview of the treating physician was performed after first prescription of chemotherapy; patients' frequencies were compared by means of Chi-squared test.
Results: From March 2004 to April 2005, 135 pts (56.3% males, median age 75, range 65–90 years) were eligible. Sixty-three percent of them had PS 0, 86% were independent in ADL and 77.8% in IADL, 84.5% had no signs of depression, 78.5% had no cognitive impairment and 50.3% had no relevant comorbidities. Six patients were not able to sign the CF, and 16 (12.4%) delegated a relative to read it. Seventy-seven percent of patients were fully aware of cancer according to the treating oncologist; yet, only 23% overtly asked for detailed information and estimation of prognosis. The physician admitted not having given the same level of information of younger patients to about 35.5% of patients, and particularly to those with advanced/incurable disease ($p = 0.004$). The family asked to hide the diagnosis in almost one fourth of cases, and expectedly, family opposition predicted unawareness of disease ($p < 0.001$) and attenuated information from the oncologist ($p < 0.001$). Significant association was found among