Proffered Papers

performed according the AJCC Cancer staging Manual. The pCR was defined by no evidence of viable tumour cell on pathologic analysis. Local recurrence was defined as clinical, radiological or pathological evidence of tumour in any other site. The time to last follow up, local recurrence, or death was measured from the time of radical resection. Disease free and overall survival were estimated using the KM method, and differences between survival curves were determinated by using the long rank test. A P value of <0.05 was considered statistically significant.

**Results:** 37 pts had a complete response and 78 pts were not responders. Sphincher preservation, anteroposterior resection and endoscopic surgery were performed in 36 pts (97.2%). A patient with complete refused rectal surgery. Mean number of examinated lymphnodes was  $14.3\pm7.95$ . Median follow up was 60 months. In pCR pts no locoregional recurrence occured and distant metastase occured in 2 pts (5.4%). In the no responder group we found 18 local recurrence (p=0.0001) and 46 patients developed distant metastases (p=0.0001). The pCR group 5-years overall and disease free survival were 97% and 94% rispectively. During the follow up one patient died.

**Conclusions:** The improved ontological outcome in patients with rectal cancer who achieve a pCR appears related to their significantly decreased rate of distant failure when compared with no down staging patients. To further improve the oncological outcomes and sphincter preservation rates in patients with locally advanced rectal cancer, the molecular mechanism governing the rectal cancer response to preoperative CRT need to be explored.

6029 POSTER

Randomized phase III trial comparing preoperative versus postoperative radiotherapy with capecitabine in locally advanced roots! capecy

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**Background:** Preoperative chemoradiotherapy using bolus fluorouracil demonstrated the superiority of preoperative treatment in local control and sphincter preservation in locally advanced rectal cancer. We conducted a prospective, single-institutional, phase III trial which compared preoperative chemoradiotherapy with postoperative chemoradiotherapy using oral capecitabine. We present the final results of our trial in this report.

Materials and Methods: Patients with locally advanced rectal cancer (cT3 or N+) were randomly assigned to receive either preoperative (arm I) or postoperative (arm II) chemoradiotherapy. Preoperative radiotherapy was delivered to the pelvis at a dose of 46 Gy in 23 fractions, followed by a boost of 4 Gy in 2 fractions. Postoperative radiotherapy consisted of 50 Gy in 25 fractions to the pelvis without boost. Capecitabine (1,650 mg/m²/day) was administered concurrently during radiotherapy. Surgery was performed according to total mesorectal excision technique with the time interval of 4–6 weeks in both arms. This protocol was closed earlier than initially planned due to difficulty in patient enrollment.

Results: Between March 2004 and April 2006, 117 and 123 patients were randomly assigned to arm I and arm II, respectively. Clinical characteristics were well balanced between the two arms, except more low-lying (≤5 cm from anal verge) tumors in arm I (60% vs. 46%, p = 0.041). In the patients with lower-lying tumors, arm I showed higher rate of sphincter sparing surgery (68% vs. 42%, p = 0.008). After a median follow-up of 47 months, the 5-year cumulative incidence of local recurrence was non-significantly higher in arm II (3% vs. 6%, p = 0.335). The 5-year overall survival and disease-free survival rates were not different between two groups. Ninetynine patients (92.5%) in arm I and 84 patients (74.3%) in arm II completed chemoradiotherapy as planned. Grade 3 or higher acute toxicity was observed in 15% of the patients in arm I and 16% in arm II. Postoperative complications were also similar in both arms.

Conclusions: Preoperative or postoperative chemoradiotherapy with oral capecitabine was safe and well tolerated. Although we could not demonstrate significant benefit of preoperative chemoradiation in local control and survival, our data showed that increased rate of sphincter preservation was possible in lower-lying tumors without jeopardizing local control and surgical complication by preoperative chemoradiotherapy.

30 POSTER

## The use of the cell saver in rectal cancer surgery is safe

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Introduction: In T4 and locally recurrent rectal cancer the dissection planes often need to be extra anatomically. Blood loss in fibrotic tissue (after prior primary treatment or after recent radiochemotherapy) may be considerable. The use of the cell saver can help to reduce the need for donor blood. In non-oncological procedures the role of the cell-saver has been recognized. However, in oncological surgery the cell saver is being used much less for fear of disseminating tumour cells.

Patients and Methods: Our hospital is a centre for complex rectal cancer surgery. In more than half of the patients blood loss exceeds 2.5 litres. Since more than ten years, the cell saver is used to return filtered and washed erythrocytes to the patient in order to maintain the circulating red cell volume. Since 1994 until December 2006 290 patients have been treated for advanced rectal cancer and the data were collected prospectively. Four quartiles representing the volume of blood loss were created. (Q1 less than 1385 ml (n = 69), Q2 1385 up to 2500 ml (n = 76), Q3 2500 up to 4650 ml (n = 62), Q4 more than 4650 ml n = 69)).

Results: Univariate analysis showed that particularly in the largest blood loss quartiles outcome parameters were improved. Cancer specific survival at 5 years for patients in whom the cell saver was used (n = 151) per quartile blood loss volume compared to those without cell saving (n = 125) were 74%, 85%, 78%, 76% and 73%, 86%, 60%, 30% respectively (p = 0.042 in Q3 and p = 0.012 in Q4, overall p = 0.002). The percentages for metastasis free survival were 74%, 85%, 78%, 76% and 77%, 71%, 71%, and 37% respectively (p = 0.038 for Q4, overall n.s.). Other significant variables for oncological outcome were: free circumferential margin, lymphnode status, the use of neoadjuvant chemotherapy compared to radiotherapy alone and the use of adjuvant chemotherapy. After multivariate analysis the use of the cell saver did only show a positive trend, unlike the other variables, which remained significant.

Conclusion: Since 1994 the multimodality treatment of advanced rectal cancer has changed. It is difficult to establish the exact role of the cell saver in the oncological outcome of these patients. However modelling of multivariate analysis and stratification for all tumour variables did never show a negative outcome for the use of the cell saver. In all models the trend remained positive. Therefore we conclude, that introduction of the cell saver did not compromise oncological outcome and is safe to use in these kinds of patients.

6031 POSTER

Robotic radiosurgery in the local control of unresectable liver metastases in patients with colorectal cancer – preliminary results

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**Background:** The median survival of untreated patients with liver metastases ranges between 6 and 18 months, but unfortunately surgery may be performed in only 20% of cases. The aim of this preliminary study was to evaluate the usefulness of CyberKnife ® (Accuray Inc, Sunnyvale, CA) image-guided robotic stereotactic radiosurgery for local control of unresectable liver metastases.

Patients and Methods: Eight-teen consecutive patients with liver metastases from colorectal cancer, considered unsuitable for surgery, confirmed by ultrasound- or CT-guided biopsy or ultrasound-guided FNAB, were enrolled in the study. There were 11 men and 7 women, with an overall median age of 59 years (range 49–73 years). The inclusion criteria were: age between 50–75, no chemotherapy during the last 30 days, acceptable liver function (ALT and ALT<150 U/L, PT > 2.5%), Karnofsky performance score <3, no extra-hepatic disease on 18-FDG CT-PET, tumor size and estimated residual liver volume on CT-scan <6 cm and >700 mL, respectively.

**Results:** The overall tumor volume ranged from 25 to 185 mL (median 70 mL), and the irradiated volume was  $18\pm10$  mL (range 11-40 mL). The