2 cm is given. Small bowel dose is not to exceed 50 Gy point dose. A 3 or 4 field box technique is utilized. All patients receive prolonged venous infusion 5 Fluorouracil with the RT, followed by postoperative chemotherapy for 4 cycles.
**Results:** 22 of 30 patients have been accrued. Preoperative stage shows 14 T3N0 and 8 T3N1 patients. One patient did not complete chemotherapy due to Grade 3 GI toxicity. Postoperative pathology of the first 18 patients shows 3 complete responses − T0N0, 1 T1N0, 5 T2N0, 4 T3N0, 3 T3N1. One patient developed distant metastases and did not have surgery. One patient declined recommended surgery and had local excision alone, which showed no residual disease. One patient whose pathology showed incomplete TME has had a local recurrence. In total, two patients have developed distant liver metastases.
**Conclusions:** Involved field rectal RT is feasible. The dose to small bowel and bladder is reduced. Data from the remainder of the patients will be presented with discussion of dosimetric and clinical toxicity data.

| | Mean Dose | | | |
|---|---|---|---|---|
| | Small Bowel (cGy) | | Bladder (cGy) | |
| Patient | Involved Field | Standard | Involved Field | Standard |
| 2 | 36.4 | 387.0 | 1,575.1 | 3,550.8 |
| 3 | 1,179.3 | 2,357.6 | 2,804.1 | 4,028.1 |
| 4 | 973.2 | 2,644.9 | 3,754.9 | 4,052.0 |
| 5 | 338.5 | 388.2 | 3,458.9 | 4,183.3 |
| 6 | 2,289.3 | 3,146.5 | 3,942.6 | 4,273.9 |
| 7 | 352.0 | 225.0 | 3,808.0 | 3,796.0 |
| 8 | 2,998.6 | 3,118.4 | 3,785.0 | 3,872.0 |
| 9 | 2,105.8 | 2,241.4 | 4,009.9 | 4,534.9 |
| 10 | 187.7 | 1,102.4 | 3,601.3 | 4,394.1 |
| 11 | 1,231.6 | 1,562.6 | 4,205.5 | 4,415.4 |
| 12 | 270.4 | 1,030.6 | 4,076.1 | 4,353.4 |
| 13 | 912.2 | 4,722.9 | 3,289.0 | 3,988.8 |
| 14 | 272.5 | 1,369.4 | 3,694.9 | 4,346.6 |
| 15 | 279.1 | 253.3 | 3,931.5 | 4,302.1 |
| 16 | 2,237.5 | 2,084.6 | 3,518.4 | 4,489.4 |
| 17 | 1,015.4 | 1,295.2 | 3,946.6 | 4,398.4 |
| 18 | 788.2 | 755.5 | 4,890.7 | 5,062.9 |
| 20 | 407.0 | 2,078.4 | 4,508.3 | 4,458.4 |
| Average | 993.0 | 1,709.1 | 3,711.2 | 4,250.0 |

**6039** POSTER

**Pathologic Complete Response (pCR) after preoperative radiochemotherapy in cT3M0 rectal cancer patients: an analysis from a large database**

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**Background:** Many studies reported that patients responding with a pathologic complete response (pCR) after preoperative radiochemotherapy have very good long-term outcome. Predicting a pCR at diagnosis will be important in an attempt to modulate the treatment for each patient (i.e. less invasive surgery).
The purpose of this analysis is to retrospectively evaluate the impact of progressive intensified schedules of preoperative radiochemotherapy on pT0N0 in rectal cancer patients treated in our institution since 1985.
**Matherial and Methods:** from a large database containing 1420 patients, a group of 405 patients between 1985–2008 was collected retrospectively. The patients were diagnosed with rectal cancer with cT-stage 3 and cM-stage 0 and were treated with preoperative chemoradiotherapy (CRT: 45−55 Gy, 1 or 2 drugs). Surgery was performed 6−10 weeks after treatment and pathologic reports were reviewed for complete response (ypT0N0). Collected pre-treatment variables included sex, age, cN-stage, tumor distance from the anorectal ring, number of involved rectum quartiles (Qrt), tumor length, volume index (Qrt × tumor length), and concomitant chemo type. Post-treatment were collected for 408 patients: the volume index and the relative difference between pre- and post treatment evaluations of tumor distance, Qrt, tumor length and volume index. Multivariate analysis was performed with a 2-norm support vector machine (SVM). Performance of the model was expressed as the Area Under the Curve (AUC) of the Receiver Operating Characteristic (ROC) curves and assessed with leave-one-out (LOO) cross-validation. A nomogram was build from the model output.
**Results:** CRT resulted in a ypT0N0 for 20% of the patients. Based on the AUCs (Mean ±SD) of the ROC-curves we found that the pre+post-treatment model has the highest performance (AUC = 0.65±0.04) compared to pretreatment alone (AUC = 0.62±0.03). Predictive pretreatment variables ranked to importance (i.e. weights): chemo type (0.11), cT (−0.097), tumor length (−0.065) and cN-stage (−0.053). Post-treatment the volume index was most important (−0.17).
**Conclusions:** the analysis shows the presence of predictive pT0N0 risk factors related to the intensification of the treatments, to some tumor characteristics at the diagnosis (cT, tumor length and cN-stage), and to the response to radiochemotherapy. A nomogram to predict pCR in cT3M0 patients after radiochemotherapy will be proposed.

**6040** POSTER

**A pilot study of neoadjuvant chemoradiation with higher dose enteric-coated tegafur/uracil plus leucovorin for locally advanced rectal cancer**

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**Background:** Neoadjuvant chemoradiation (CRT) with tegafur/uracil (UFT) 200–350 mg/m$^2$/day plus leucovorin (LV) 25−75 mg/day for 5 days a week with 45 Gy radiation (RT) for locally advanced rectal cancer (LARC) was known to be efficacious and tolerable, but higher dose UFT/LV and RT may improve pathologic response rate. We have performed a pilot study to evaluate pathologic response rate and toxicity profile of neoadjuvant CRT with higher dose enteric-coated tegafur-uracil (UFT-E)/LV.
**Materials and Methods:** Patients (pts) were planned to be treated with UFT-E 400 mg/m$^2$/day plus LV 90 mg/day for 7 days a week during RT 50.4 Gy. Main eligibility criteria were histologically proven rectal adenocarcinoma; T2−4 lesions; age >18 years; ECOG PS 0−1; no prior chemotherapy or pelvic irradiation. Total mesorectal excision was planned to be performed 4−8 weeks after completion of CRT.
**Results:** Between June 2008 to January 2009, 39 pts were enrolled; median age 57 years (40−92); M/F 26/13; PS 0/1 37/1; cT2/T3 2/33; N0/N+ 6/29; median tumor location from anal verge 6.0 cm (2.0−9.0). The median relative dose intensity of UFT-E was 95.0% (51.6–111.7). Three pts were given reduced dose RT (1 with 27 Gy, 2 with 45 Gy) due to grade 3/4 diarrhea; 5 pts needed UFT-E dose interruption due to toxicities. Grade 3/4 toxicities included leucopenia (2, 5.1%), neutropenia (3, 7.7%), hyperglycemia (4, 10.3%), elevated transaminase level (2, 5.1%), diarrhea (4, 10.3%), nausea (2, 5.1%), and pain (2, 5.1%). Of 36 pts who underwent surgery (all R0 resection), 22 (91.7%) were treated with sphincter saving procedure. Pathologic T0 and N0 were observed in 8 (22.2%) and 29 (80.6%) pts, respectively. Downstaging in T stage was achieved in 24 pts (66.6%). Pathologic complete responses were observed in 8 (22.2%) pts and another 7 (19.4%) pts had only minimal microscopic residual tumor.
**Conclusions:** Neoadjuvant CRT with higher dose UFT-E/LV showed favorable efficacy and tolerability. A phase II trial of CRT with higher dose UFT-E/LV is ongoing.

**6041** POSTER

**Evaluation of folate derivates in the neoadjuvant treatment of resectable rectal cancer with the antifolate pemetrexed**

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**Background:** Understanding the role of different folate derivates is essential in the understanding of the physiology of tumor growth. To our knowledge this is the first study introducing a sensitive liquid chromatography-mass spectrometry (LC-MS/MS) method to analyze folate levels in tumor and adjacent mucosa.
**Methods:** Between June 06 and January 08, 37 patients with a histologically proven diagnosis of operable rectal adenocarcinoma were enrolled. Pemetrexed was dosed at 500 mg/m$^2$ every 3 weeks, during