

tumor stage, determined by endorectal ultrasound and CT scan, included 21 with T3N0 [72%], 5 T3N1, 1 T3Nx, 1 T4N0 and 1 with TxN1 disease. Mean distance from the anal verge was 4.4 cm [range 0 to 13 cm]. Median age was 57 years [range 33 to 77 years]. The population consisted of 22 males and 7 females. Median time of follow-up is 7 months [range 0-15 months].

Results: Sphincter preservation [SP] has been accomplished in 17 of 24 [71%] patients resected to date. Three patients did not undergo resection because of the development of metastatic disease in the interim between the completion of chemoradiation [CTX/XRT] and preoperative evaluation. The remaining 2 patients have not yet undergone resection. The surgical procedures included low anterior resection [N=9], proctectomy and coloanal anastomosis [N=3], transanal resection [N=2], and other sphincter saving procedures in the remaining 3 patients. Tumor down-staging was pathologically confirmed in 19 of the 24 [79%] resected patients, and 5 achieved a pathologic CR. Among the 15 tumors [67%] located ≤ 6 cm from the anal verge, SP was accomplished in 10 cases [67%]; 9 of 14 responders and 1 non-responder underwent SP in this group. Toxicity is comparable to that seen with conventional fractionation during CTX/XRT.

Conclusion: The SP rate with concomitant boost radiation has been highly favorable with rates of response which are higher than those previously reported for chemoradiation without administration of a boost. Further evaluation of this radiotherapeutic strategy appears warranted.

61 RANDOMIZED STUDY OF PREOPERATIVE CHEMORADIATION (CTR) IN LOCALLY ADVANCED RECTAL CANCER. PRELIMINARY RESULTS

Cionini L¹, Cartei F¹, Manfredi B¹, Laliscia C¹, Sainato A¹, Valentini V², Lupattelli M², Pizzi GB², Osti M², Santoni R²
Radiation Therapy, University of Pisa, Pisa, Italy¹; Italian Cooperative Group, Italy²

Purpose: to assess the compliance, the acute toxicity, the down-staging, local, distant recurrences.

Materials and Methods: Between Sept. 93 and Feb. 99, 583 patients with locally advanced rectal tumour (clinical T3-T4) entered in a randomized trial of preop. CRT followed or not by postop. CT. Tumour extent: fixed 100 (17.2%), tethered 372 (63.8%) or invading the perirectal fat at intrarectal imaging 90 (15.4%). Preoperative CRT: 45 Gy (180 cGy x 5 weekly); 5-FU 350 mg/mq and LEV 10 mg/mq on days 1 to 5 and 29 to 33, of the radiotherapy course. Postoperative CT: 5-FU 350 mg/mq and LEV 100 mg/mq day 1 to 5 for six cycles 3 weeks apart. Sex: males 388, females 195; median age 61 yrs; tumour stage T3:401, T4:98.

Results: Compliance to preop. CRT: 40 pts did not receive the full treatment (3 RT only, 37 1 CT course only). Surgery: information available for 473 (81%) pts out of whom 439 (93%) went surgery, 24 (5%) were not operable, 4 refused surgery, 5 died before surgery, 4 intercurrent deaths, 1 died for disease. Type of surgery: APR 152 (35%), LAR 281 (64%), palliative 6 (1.3%). Interval preop. CRT-surgery: median 39 days. Perioperative morbidity: anastomotic dehiscence 43 (9.5%), perineal abscess 11 (2.5%), intestinal occlusion requiring surgery 10. Operative specimen pathology: no residual tumour 74 (17%), tumour within the intestinal wall 1533 (35%), outside the intestinal wall 195 (44%), missing information 17 (4%); positive nodes 103 (23%); positive margins 12 (2.7%). Follow-up (minimum 6 months) after surgery 391; local recurrences alone 15 (4%); local and distant 10 (2.5%); distant only 75 (19.5%).

Conclusion: The combined preop. CRT was proved feasible with acceptable toxicity and resulted in considerable down-staging (274 pts - 62.4%) and low recurrence rate.

62 A PROSPECTIVE EVALUATION OF THE TIMING OF POST-OPERATIVE RADIOTHERAPY FOR HETEROTOPIC OSSIFICATION FOLLOWING TRAUMATIC ACETABULAR FRACTURES

Childs HA, Cole T, Smith JT, Alonso JE, Stannard JP, Spencer SA, Fiveash JB, Westfall AO, Kim RY
University of Alabama at Birmingham, Birmingham, AL, USA

Objective: Preoperative and immediate irradiation of traumatic acetabular fractures (TAF), although known to reduce the incidence of heterotopic ossification (HO), can cause significant organizational and logistic difficulties. We prospectively followed the incidence of HO associated with surgical repair of traumatic acetabular fractures and prophylactic radiotherapy on post-operative days 1, 2, 3 and 4 to determine an acceptable time interval and allow for a more structured treatment format. Also, we sought to update our large experience and further validate our treatment philosophy.

Methods: A report from our institution in 1995 demonstrated dramatic reductions in the incidence of HO with radiotherapy following surgical repair of TAF. Between 1987 and 1998, 302 patients have had these fractures repaired through surgical approaches at high risk of HO, 259 have had adjuvant radiotherapy and 224 of these have adequate follow up. Beginning in June of 1995, we began a prospective study, irradiating 168 patients on post-operative days one, two, or three. There are also 19 patients that were delayed further secondary to medical difficulties. The entire cohort was then combined and retrospectively analyzed to compare with patients that did not receive radiotherapy.

Results: All patients treated since June 1995 received 700 cGy/1 fx with a median follow up of 238 days. There was a fairly homogeneous distribution of patients regarding the surgery to radiation time: 60 patients received radiation within 24 hours of surgery, 46 within 2 days, 53 within 3 days, 13 within 4 days, and 6 were delayed greater than four days. There was no statistical difference in incidence of HO with delaying irradiation for up to four days post-op ($p=1.0$ w/ Fisher's exact test). HO occurred in 3.5% of the patients that received irradiation within four days versus 50% of those patients receiving radiation after four days, with a mean Brooker grade of I versus II respectively ($p=0.001$). We then re-analyzed the entire cohort to update our retrospective review. There were two other dosing schedules used: 2 patients received 800 cGy/1 fx and 6 received 1000 cGy/5 fx. The overall incidence of HO after radiation was 5.1% and only one patient had a Brooker grade of III. 43 patients that did not receive radiation served as controls and had a 59.4% incidence of HO with 33% having grades III or IV. We analyzed potential variables associated with HO and found that only the surgery to radiation time interval ($p=0.007$), type of surgery ($p<0.001$), and dose of radiation ($p=0.003$) were significant. Interestingly, we also have equal numbers of patients that did and

did not receive NSAIDs in addition to radiation and there was no difference in HO formation ($p=1.0$ w/ Fisher's exact 2-tailed test). We also examined potential complications and found no increase in wound complications or delayed healing with radiation.

Conclusion: We report the largest known series of traumatic acetabular fractures treated with routine post-operative radiation to prevent heterotopic bone formation. In our prospective study, we noted no perceptible increase in heterotopic bone formation with up to a four day interval between surgery and radiotherapy, even in high risk patients. This allows for a more structured treatment schedule as well as allowing the patient more time to heal and recover from surgery, thus making them more comfortable as well. Updated results from our overall series continue to demonstrate that post-operative radiation decreases the incidence and severity of HO after TAF.

63 PRE-AND POSTOPERATIVE RADIOTHERAPY 1 X 7 Gy TO PREVENT HETEROTOPIC OSSIFICATION AFTER HIP ARTHROPLASTY: A PROSPECTIVE RANDOMIZED STUDY (HOP 3 STUDY)

Kosziorowski A, Seegenschmiedt MH, Quack G, Krodel A

Alfred-Krupp-Hospital, Essen, Germany

Purpose: Many uncontrolled, but only a few controlled studies with different radiotherapy (RT) regimens have shown effective prophylaxis of heterotopic ossification (HO) after hip arthroplasty by means of pre- and postoperative RT. Most studies have been compromised by low patient accrual and poorly specified eligibility criteria. In the past, we have conducted two strictly randomized trials to compare *different RT dose regimes* (Seegenschmiedt et al, *IJROBP* 1994 & 1997). This controlled randomized study analyzes the importance of *RT timing* by comparing the pre- and postoperative RT application of 1 x 7Gy for patients at various risk groups to develop HO after hip arthroplasty.

Materials: From October 1996 to September 1998, 178 hips in 174 patients (pts), were randomized to receive 1 x 7 Gy pre- or post-operative RT: Arm A: postoperative RT (RT 12-72 hours after hip surgery; $N_A = 88$ hips); arm B: preoperative RT (0-4 hours before hip surgery; $N_B = 90$ hips). The potential risk factors for the development of HO were equally distributed between both arms including all HO risk factors: (a) 48 (27%) hips with *high HO risk* (ipsi- or contralateral HO), (b) 89 (50%) hips with *medium HO risk* (grade 3-4 hypertrophic osterarthritis, repeated hip surgery, acetabulum fracture, infection, M. Forrestier, M. Bechterer, M. Paget); (c) 41 (23%) hips with *low HO risk* (hips with dysplasia and arthrosis, but without large osteophytes). Relevant patient (age, sex) disease (risk factors, Brooker and Harris score) and treatment parameters (surgical and RT details) were equally distributed in both treatment arms. Assessment of radiological "treatment failures" was based upon Brooker score comparison of HO seen on the immediate postoperative radiograph compared to FU radiographs obtained at least 6 months after hip surgery. Progression of HO was scored as radiological "treatment failure." For the assessment of functional "treatment failures" the Harris Score was applied.

Results: Both groups had a mean follow-up (FU) of 15.5 months. At a minimum FU of 6 months, a total of 159 (89%) hips were scored as responders, i.e. were without progression of HO; radiological "treatment failure" were observed in 19 (11%) hips; 12 (7%) had a HO progression of 1 Brooker grade, 5 (3%) hips of 2 Brooker grades and 2 (1%) hips of 3 Brooker grades. Arm A encountered 11 (6.2%) and arm B 8 (4.5%) radiological failures (non-significant). The distribution of radiological failures among the HO risk group was as follows: 8 of 48 (17%) high risk hips, 5 of 89 (6%) medium risk hips and 6 of 41 (15%) low risk hips showed HO progression, Radiological failures were independent of treatment schedule (arm A versus arm B) and risk groups as well as relevant patient and treatment factors. The mean Harris score improved overall by 53 points (arm A) and 49 points (arm B), respectively, and reached a mean overall score of 85 points. Functional "failures" occurred equally in both arms. In uni- and multivariate analysis no significant prognostic factors were assessed with regard to treatment failures.

Conclusions: Pre- and postoperative RT are equally effective for prophylaxis of HO after hip surgery even in high-risk patients without compromise of early implant fixation. Thus, RT provides an excellent treatment alternative for patients with contraindications to long-term steroids or NSAID medication. Preoperative RT appears to be a very convenient treatment schedule, because of savings in time and personnel.

64 RANDOMIZED STUDY FOR TREATMENT OPTIMIZATION IN EARLY STAGE DUPUYTREN'S CONTRACTURE

Seegenschmiedt HM, Olschewski T, Guntrum F

Alfried Krupp Krankenhaus, Essen, Germany

Purpose: Radiotherapy (RT) is effectively applied for various benign diseases including prevention of proliferation in Dupuytren's contracture (DC) (Keilholz et al., *IJROBP* 1996). Clinical studies report hypofractionated RT with different single and total RT doses (2-4 Gy/20-40 Gy). So far it is not clear, which minimal RT dose is sufficient and whether there is a dose-response relationship. We present data of a prospective randomized trial, which was designed to compare two RT schedules (low versus medium RT dose) for treatment optimization in early stage DC.

Methods: From 6/1997 to 12/1998, 168 pts (96 m., 72 f.) with early stage DC were referred for prophylactic RT to prevent disease progression. Initial analysis (4/1999) included 103 pts (59 m.; 44 f.) with 184 irradiated hands (81 bilateral; 22 unilateral) who had a 1 year FU period. DC was staged according to the modified Tubiana (1966) classification: 72 pts had DC stage N/I (extension deficit less than 10°); 28 pts DC stage I (11-45° deficit); 3 pts DC stage II (46-90° deficit). All pts were randomized to two RT schedules: group A (n = 89 hands) received 10 x 3Gy (total: 30 Gy) within 10 weeks in 2 RT series of each 5 x 3 Gy separated by 8 weeks; group B (n = 95 hands) received 7 x 3Gy (total: 21Gy) in 2 weeks with 3 fractions per week. 120 kV orthovoltage RT was applied using 8 x 10 cm or 10 x 15 cm standard cones (40 cm SSD) and lead rubber plates with individual cut-out shapes. Patient and disease parameters were equally distributed between both groups. Initial