6034 POSTER

Whole abdomino-pelvic radiotherapy (WART) with curative intent in the management of patients with stage I–II mesenteric follicular lymphoma (FL)

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Background: Involved-field radiotherapy provides long-term disease-free survival in ~40% of patients with stage I-II FL, but many clinicians are hesitant to recommend this therapy for patients with mesenteric involvement due to concerns over potential acute and late toxicity. We therefore report our experience using WART with curative intent in patients with FL involving mesenteric lymph nodes.
Methods: Eligible patients had stage I-II, grade 1−2 (or low-grade) FL involving the mesentery. WART was delivered in 1.5 Gy fractions to the whole abdomen/pelvis to 24 Gy, with shielding designed to limit kidney and liver doses to 15 & 18 Gy, respectively. Technique then generally changed to an inverted-Y or para-aortic strip to 30 Gy. Some patients received a further boost to 36 Gy for larger nodal masses.
Results: 20 eligible patients were identified from 1995–2006. Median age was 61 years (range 43−76). All but 4 patients received chemotherapy prior to WART, the most common regimen being cyclophosphamide, vincristine & prednisone.
At a median follow-up of 47 months (range 3–134), 4 patients had progressed (at 3, 4, 16 and 33 months), 3 of which occurred both within and outside the radiation field. The majority of patients (12 of 16) who had initial chemotherapy had a partial response prior to commencing WART. 16 patients achieved a complete response (CR) after WART. All 12 patients who had restaging PET after WART achieved a CR, 11 of whom remain progression-free. 5-year actuarial freedom from progression was 76% (±11%). 5-year actuarial overall survival was 89% (±8%).
All patients completed WART, which was generally well tolerated acutely, with lethargy and mild/moderate diarrhoea and nausea being the most common acute toxicities. 2 patients required treatment breaks due to acute gastro-intestinal (GI) toxicity. 4 patients had grade 3 haematologic toxicity, while no patients had grade 4 or higher toxicity. 1 patient who is disease-free at 10 months has ongoing intermittent GI symptoms (grade 2 nausea, grade 1 vomiting & diarrhoea) despite normal investigations. There are no reports of late renal toxicity or myelodysplastic syndrome.
Conclusions: WART can be safely and effectively delivered. Results of treatment are consistent with those reported for FL involving non-mesenteric sites. It may be curative in some patients with stage I-II FL involving the mesentery.

6035 POSTER

Small bowel lymphomas – a five year retrospective study from the developing world

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Introduction: We have evaluated 197 GI lymphomas from 2001 and 2006 and specifically looked at the small bowel lymphomas.
Aims and Methods: the inpatient and outpatient records of 33 small bowel lymphomas were included and analysis was done in various aspects such as clinical presentation, mode of treatment, diagnosis, their relapse and remission rate.
Results: There were 30[90%] males and 3[9%] females. 88% were within 60 years of age with a mean age of 38 yrs, 50% percentage fall within in 2nd and 4th decade. 96% were B cell lymphoma and 1 (3%) was T cell lymphoma. Among B cell lymphoma 66% were diffuse large cell, 9% were Burkitt's, 18% were MALT and 3% were T cell lymphomas. 27 (81%) patients underwent laprotomy for the diagnosis as they primarily presented with bowel symptoms and in the rest the diagnosis was made by either colonoscopy ileal biopsy or trucut biopsy of the exophytic mass. 4 (12%) had peritonitis at presentation, 2 (6%) had enterocutaneous fistulae. 60% of them had abdominal mass and pain. Only 3 (9%) had anemia at presentation and 2 (6%) had renal transplantation. All of them had small bowel resection except two who had right hemi colectomy. 10 (30%) were lost to follow up. Among 23 patients 3 (9%) died in the postoperative period due to sepsis and DIC, 2 (6%) died of neutropenia due to chemo, the rest had received chemotherapy. Primary chemo used is CHOP as first line. 5 (15%) had relapsed at 62 months follow up. 3 (60%) recurrences were seen in MALT group. High LDH at the time of follow up is a strong predictor of recurrence. The site of recurrence was seen in intestine, nodal, and liver. At the median follow up of 3−5 years (range 1−5), 15 (65%) are alive and well.
Conclusion: Small intestinal lymphoma is not unusual in developing countries, males are the majority, 2nd and 4th decade has more common incidence. LDH is not high at the time of initial diagnosis but raised at the time of recurrence. MALT lymphoma has more incidence of recurrence and the overall prognosis is good.

6036 POSTER

Low dose thalidomide as maintenance in multiple myeloma

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Background: Autologous hematopoietic stem cell transplantation (ASCT) following chemotherapy improves survival and decrease relapse rate in patients with multiple myeloma. However, patients not eligible for ASCT relapse earlier demanding search for new treatment modalities.
Aim: was to evaluate the effect of low dose thalidomide as a maintenance treatment in patient with first complete remission not candidate for autologous bone marrow transplantation, and its effect on disease free survival.
Patients: the study was carried out on 102 patients randomized in two groups, group I (44 patients) and group II (48 patients). Group I received 50 mg thalidomide daily, and group II did not receive any maintenance treatment.
Results: the follow up period was 40 months, median age for group I was 62 years and 64 years for group II. Males to females ratio was 3:1 for both groups. Regarding types of myeloma; IgG kappa myloma represent 70% in group I and 75% in group II, IgG lambda 20% and 19% in group I and II respectively. Out of 44 patients in group I, only 12 patients relapsed during follow up period, 9 of them died, while 40 patients relapsed from group II, 26 of them died with a significant difference between both groups (P?0.01).
Conclusion: from the present study we concluded that maintenance with low dose thalidomide may show beneficial results over those without maintenance treatment in preventing relapse. However, further studies must be done to compare low dose thalidomide and ABMT following CR.

Lung Cancer

Oral presentations (Tue, 25 Sep, 09.00−11.00) **Lung cancer (1)**

6500 ORAL

Randomized phase II trial using concomitant chemoradiation plus induction (I) or consolidation (C) chemotherapy (CT) for unresectable stage III non-small cell lung cancer (NSCLC) patients (pts). Mature results of the SLCG 0008 study

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Background: Neither the optimal sequence of treatment nor the best combination CT is yet well-defined in pts receiving concomitant therapy.
Methods: Patients with unresectable stage III NSCLC with IK > 70 and weight loss <5% were initially randomized to sequential treatment (arm A), concurrent CT/TRT followed by consolidation (C) CT (arm B) or induction (I) CT followed by CT/TRT (arm C). Based on RTOG 9410 results, arm A was closed and the study continues with two concomitant arms (B, C). All pts receive 2 cycles of Docetaxel (D) 40 mg/m^2 d1, 8 plus Gemcitabine (G) 1200 mg/m^2 d1, 8 as I or C therapy. Concomitant treatment includes D 20 mg/m^2 and carboplatin (Cb) AUC 2 weekly plus 60 Gy TRT.
Results: From May 2001 to June 2006, 151 pts were included (A: 19, B: 66, C: 66). Due to the early closing of arm A, only data of evaluable

arms B and C pts are reported: toxicity 127 pts (B: 63, C: 64) and response 110 pts (B: 53, C: 57). All groups are well-matched for baseline disease characteristics. Toxicity grade 3−4 by CTC and RTOG criteria was: esophagitis 19.5% (arm B) and 14.2% (arm C); pneumonitis 8.8% (arm B) and 10% (arm C). Neutropenia during I or C therapy: 22% (B) and 6.2% (C). Thrombocytopenia 8% (B) and 3% (C). Neutropenia during concomitant therapy: 6.3% (B) and 6% (C). No thrombocytopenia or severe anemia was found during CT/TRT. The reduction CT rate was superior in consolidation (35%) than in induction (15%) and in arm C during concomitant therapy (22.4% C, 6.5% B). Delay of CT dose was similar in B and C arms during I or C (22% B, 20% C) but superior in arm C during concurrent treatment (19.6% B, 30.6% C). The final response rates were 57% (B) and 56.9% (C). A trend for longer time to progression (TTP) was found (B: 7.6 months [mo] and C: 9.2 mo; $p = 0.12$) but with similar overall survival (B: 14.3 mo and C: 14.7 mo; $p = 0.38$).
Conclusions: Non-platinum CT plus concomitant chemoradiation offer similar response rate and a favorable hematological toxicity profile in unresectable stage III NSCLC pts. No differences in OS but a trend for longer TTP in arm C (I followed by concurrent approach) has been found. Final data are pending in order to select the best sequence for further studies.

6501 ORAL

Global Lung Oncology Branch trial 3 (GLOB 3): Quality of Life (QoL) results of a randomised multinational Phase III trial of oral and i.v. vinorelbine (NVB) plus cisplatin (CDDP) versus docetaxel (DTX) plus CDDP as first-line treatment for advanced non-small cell lung cancer (NSCLC)

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Background: Intravenous weekly NVB (NVBiv) and CDDP represents one of the reference treatments for advanced NSCLC. The oral formulation of NVB (NVBo) has been recently approved in NSCLC with similar efficacy as NVBiv. The aim of this trial was to compare efficacy, tolerance and QoL of a D1 NVBiv and D8 NVBo (NC) versus DTX in a CDDP-based combination (DC). Both regimens were given in 3-week cycles in advanced NSCLC chemonaive patients.
Methods: Patients were randomly assigned to receive CDDP 80 mg/m^2 with NVBiv 30 mg/m^2 on day 1 and NVBo 80 mg/m^2 on day 8, after a 1st cycle at NVBiv 25 mg/m^2 D1 and NVBo 60 mg/m^2 D8 (dose escalated in absence of grade 3/4 neutropenia), or CDDP 75 mg/m^2 and DTX 75 mg/m^2 on day 1, for a maximum of 6 cycles in both arms. The Lung Cancer Symptom Scale (LCSS) questionnaire was filled by the patient at D1 of each cycle before chemotherapy administration and at the end of study treatment.
Results: Between Feb. 2004 and Jan. 2006, 390 patients (NC/DC: 194/196) were randomised and 381 (190/191) treated. Patients characteristics showed no difference between both arms. Mean number of cycles were: NC 4.2±1.8, DC 4.4±1.9. There was no difference in terms of efficacy (ITT): Time to Treatment Failure (TTF)(months) [95% CI]: NC 3.2 [2.9−4.2], DC 4.1 [3.4−4.5]. Objective Response (OR)(RECIST) [95% CI] (after panel review): NC 27.4% [21.2−34.2], DC 27.2% [21.0−34.2]. Median Progression-Free Survival (PFS)(months) [95% CI]: NC 4.9 [4.4−5.9], DC 5.0 [4.3−6.1]. Median Survival (MS)(months) [95% CI]: NC 9.9 [8.6−11.6], DC 9.8 [8.8−11.5]. Tolerance was similar with grade 3/4 neutropenia NC 23.3%; DC 28.2%. Patients evaluability with LCSS questionnaire were 78.4% in NC & 79.6% in DC. The LCSS global score significantly decreased over time ($p < 0.0001$) without significant difference between both treatment arms ($p = 0.56$) as shown in the enclosed table.

Mean change from baseline ± standard error

	3 weeks	6 weeks	9 weeks	12 weeks	15 weeks	18 weeks
NC	−0.16±1.09	0.002±1.30	−0.55±1.57	−0.65±1.86	−4.26±2.30	−6.35±2.82
DC	−0.23±1.19	−0.92±1.39	−1.03±1.67	−3.21±1.72	−4.94±2.06	−5.61±2.35

There was a significant time effect with no treatment effect for the average symptom burden, general quality of life, asthenia, cough, dyspnea, distress & activity scores. For anorexia & haemoptysis, there was neither time effect nor treatment effect. An equal weight & Karnofsky performance status progressive deterioration has been evidenced in both arms.
Conclusions: NVB iv/oral and CDDP achieves similar efficacy as DC in terms of TTF, OR, PFS and MS with similar and acceptable tolerance as front-line chemotherapy for advanced NSCLC patients. QoL was also similar in this first face to face comparison of NC/DC given in 3-week cycles.

6502 ORAL

Pre-operative chemotherapy in patients with resectable non-small cell lung cancer (NSCLC): The MRC LU22/ NVALT 2/EORTC 08012 multi-centre randomised trial

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Background: The 5-year survival rate following surgery for patients with NSCLC is modest, and improvements are urgently required. In 1994 2 small trials showed striking results in favour of the addition of neo-adjuvant chemotherapy, and so the current trial was designed to investigate whether, in patients with operable NSCLC of any stage, neo-adjuvant platinum-based chemotherapy would improve outcomes.
Methods: The primary endpoint was overall survival, and the trial was designed to detect a 15% improvement in 3-year survival (from 40% to 55%) with neo-adjuvant chemotherapy, which required 450 patients and 233 events (deaths). Patients were randomised to receive either surgery alone (S), or 3 cycles of platinum-based chemotherapy prior to surgery (CT-S), clinicians choosing (pre-randomisation) the chemotherapy from 6 standard regimens. Quality of Life was assessed by patients completing the SF-36 questionnaire.
Results: 519 patients were randomised (S: 261, CT-S 258) from 70 centres in the UK, the Netherlands, Germany and Belgium. The median age of the patients was 63 years, 72% were male, 55% were performance status (PS) 0, and 61% had stage I disease. Neo-adjuvant chemotherapy appeared feasible (76% of patients received all 3 cycles of chemotherapy), resulted in a good response rate (4% CR, 45% PR), and appeared to cause down-staging in approximately 13% of patients. However the use of pre-operative chemotherapy did not affect the type of surgery performed (lobectomy: S 61%, CT-S 66%), the post-operative complication rate, or the QL of patients (apart from a reduction in 'role physical' domain in the CT-S group at 6 months). The time to (and sites of) relapse did not differ between the regimens, except that more patients in the CT-S group developed brain metastases (S 16, CT-S 31). A total of 244 patients have died (S 122, CT-S 122), and there is no evidence of a difference in terms of overall survival (HR 1.02, 95% CI 0.80, 1.31). Median, 1, 2 and 5 year survival in the S group were: 54 months, 83%, 69% and 45% respectively, and applying the HR to these figures gives, for the CT-S group: 53 months, 83%, 69% and 44% respectively.
Conclusions: This intergroup trial, which is the largest trial of neo-adjuvant chemotherapy in patients with resectable NSCLC, indicated that the addition of neo-adjuvant platinum-based chemotherapy did not lead to a benefit in overall survival.