Palliative Care Abstracts

Presentation Number: 171

Interim Analysis Results Of A Phase II Trial Of Low Dose Radiotherapy For Palliation Of Diffuse Large B Cell Lymphoma

C. Furlan\textsuperscript{1}, P. Bulian\textsuperscript{1}, M. Spina\textsuperscript{1}, M. Michieli\textsuperscript{1}, A. Ermacora\textsuperscript{2}, U. Tirelli\textsuperscript{1}, M. Trovo\textsuperscript{1}, \textsuperscript{1}CRO Aviano National Cancer Institute, Aviano, Italy, \textsuperscript{2}Ospedale Santa Maria degli Angeli, Pordenone, Italy

Purpose/Objective(s): The primary objective of this phase II study is to assess the response to low-dose irradiation (LDRT) in patients with diffuse large B cell lymphoma (DLCBL) with indication for palliative irradiation.

Materials/Methods: We calculated by the two-stages Simon method a number of 11 patients required for the first step of the phase II study; if among these patients response number will be < 7 the study will be closed because of no-efficacy. Otherwise, accrual will be continued till 43 patients will be enrolled. Patients were administered LDRT consisting of 4 Gy in two fractions on symptomatic areas only. Clinical response was assessed 21 days after LDRT, and was defined as reduction > 50% of maximum diameter of the radiated lesions. Response evaluation was performed with CT-scan or clinical exam, depending upon depth of the mass. Toxicity was scored using the CTCAE v3.0. Quality of life was scored by the EORTC QLQ-C30 questionnaire, that was administered to all patients before and 21 days after the radiation course.

Results: Out of 14 radiated patients, 11 patients resulted evaluable for response and 3 patients died of disease before the planned visit at 21-day. The radiated sites were the following: 4 cutaneous, 5 nodal (3 abdominal, 1 cervical, 1 mediastinum), and 5 extranodal (1 bone, 1 orbital, 2 CNS). The overall response rate was 63% (7/11 patients), with 4 complete responses and 3 partial responses. Only 1 case of toxicity was noted (grade 2 nausea). Median duration of response was 12 months (range, 1-17 months). Among responders, only one patient progressed within the radiated field at the time of last follow-up visit. Eight patients answered to the QLQ-C30 questionnaires, and an improved quality of life was documented in 6 cases.

Conclusions: According to the trial design, LDRT is effective for palliation in patients with DLBCL and accrual will be continued.


Presentation Number: 172

Patient Reported Outcomes on the Impact of Single versus Multiple Fraction Palliative Radiotherapy for Uncomplicated Bone Metastases on Pain, Function and Degree of Symptom Distress

J. Conway\textsuperscript{1}, I. Olivotto\textsuperscript{1}, S. Miller\textsuperscript{2}, R. Halperin\textsuperscript{3}, D. Hoegler\textsuperscript{3}, W. Beckham\textsuperscript{4}, J. Stephen\textsuperscript{5}, H. Daudt\textsuperscript{6}, J. French\textsuperscript{1}, R. Olson\textsuperscript{2}, \textsuperscript{1}Vancouver Cancer Centre, Vancouver, BC, Canada, \textsuperscript{2}Centre for the North, Prince George, BC, Canada, \textsuperscript{3}Centre for the Southern Interior, Kelowna, BC, Canada, \textsuperscript{4}Vancouver Island Cancer Centre, Victoria, BC, Canada, \textsuperscript{5}Fraser Valley Cancer Centre, Surrey, BC, Canada

Purpose/Objective(s): To compare patient reported outcomes (PROs) following single fraction (SF) as compared with multiple fraction (MF) radiation therapy (RT) for uncomplicated bone metastases in a population-based cohort.

Materials/Methods: Six centres at our institution participated in the Prospective Outcomes and Support Initiative (POSI), to record PROs prior to and 3 weeks following RT for uncomplicated bone metastases. Patients treated between May and December 2013 who provided PROs before and after RT were identified. PROs were standardized and designed to assess patients’ perception of pain, function and symptom distress using a non-dichotomous, ordinal, 5-point scale. Comparisons were made between patients who received SF versus MF RT. SFRT versus MFRT was at the discretion of the treating oncologist. A multivariate logistic
A Comparison of Palliative Inpatient Management Strategies For Cancer-Related Superior Vena Cava Obstruction

W. A. Hall1,2, C. E. Steuer3,2, D. C. Nickleach4,2, M. Behera3,2, T. K. Owonikoko3,2, K. A. Higgins1,2, F. R. Khuri3,2, W. J. Curran1,7, S. S. Ramalingam3,2, 1Emory University, Department of Radiation Oncology, Atlanta, GA, 2Winship Cancer Institute, Atlanta, GA, 3Emory University, Department of Hematology and Medical Oncology, Atlanta, GA, 4Emory University, Winship Biostatistics and Bioinformatics Shared Resource, Atlanta, GA

Purpose/Objective(s): The optimal palliative inpatient management strategy of cancer-related superior vena cava obstruction remains controversial. Chemotherapy (chemo), radiation therapy (RT) and venous stenting are common treatment strategies. We performed an analysis of the Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS) comparing the duration of inpatient stay, complication rates, and total charges associated with each palliative treatment strategy for cancer-related venous compression.

Materials/Methods: The HCUP-NIS database was used to identify cancer patients from 2006-2010 with a diagnosis of cancer related veno-compression. Inpatients with stage IV malignancy who underwent RT alone, stenting alone, chemo alone, combination chemo-RT or combination chemo-stenting were included. Patients who had a particularly radiosensitive (lymphoma) or radioresistant (melanoma) histology or had metastasis to the CNS were excluded from the analysis. The association of management strategy with four primary outcomes including length of hospital stay (LOS), treatment complications, inpatient death, and total hospital charges were examined. Multivariate (MV) logistic regression models were fit to predict complications and inpatient death and general linear models were used to predict LOS and total charges. Detailed patient characteristics collected and controlled for included age, gender, insurance, bone metastasis, discharge year, primary tumor site, type of hospital, hospital location (urban vs. rural) and medical comorbidities.

Results: Out of a total of 912 patients, 263 were managed with RT alone, 241 with stenting alone, 280 with chemo alone, 105 with chemo-RT, and 23 with chemo-stenting. The median patient age was 59 years; most common primary tumor site was lung (62.9%), median LOS was 6.27 days, and median total hospital charges were $47,746. On MV analysis patients treated with stenting alone (odds ratio [OR], 2.27; 95% CI, 1.52 to 3.40, p <0.001), or combination stenting-chemo [[OR], 2.94; 95% CI, 1.09 to 7.90, p <0.033] had a higher odds of inpatient complication events compared to RT alone. There were no statistically significant differences in LOS of inpatient deaths for patients managed with stenting alone as compared with RT alone. Finally, on MV analysis, stenting alone or combined chemo-stenting were both independently associated (p<0.001) with higher total hospital charges when compared with RT alone, controlling for all patient characteristics.
Conclusions: Chemo, RT-alone, and venous stenting are common palliative management strategies for malignant venous compression in hospitalized US patients. Each treatment had similar LOS. RT alone was associated with lower total hospital charges and fewer complications when compared with venous stenting for the palliative management of malignant venous compression.


Presentation Number: 174

Incidence of Pain Flare Following Palliative Radiotherapy for Symptomatic Bone Metastases: Multicenter Prospective Observational Study

A. Gomez-Iturriaga, J. Cacicedo, A. Navarro, F. Casquero, C. Carvajal, V. Morillo, P. Willisch, O. Del Hoyo, R. Ciervide, J. Lopez-Guerra, A. Illescas, E. Hortelano, R. Hernanz, P. Bilbao, Cruces University Hospital, Barakaldo, Spain, Instituto Catalan de Oncologia, Barcelona, Spain, Hospital de Castellon, Castellon, Spain, Hospital Meixoeiro, Vigo, Spain, Hospital San Chinarro, Madrid, Spain, Hospital Virgen del Rocio, Sevilla, Spain, Hospital Virgen Macarena, Sevilla, Spain, Hospital Ramon y Cajal, Madrid, Spain

Purpose/Objective(s): Palliative radiotherapy (RT) is a well-established treatment option for symptomatic bone metastases, with few treatment-related side effects. However, pain flare, a temporary worsening of bone pain in the irradiated metastatic site, has been recognized following RT. The aim of this study is to determine the incidence of pain flare following RT for painful bone metastases.

Materials/Methods: Patients with bone metastases treated with RT were eligible. Worst pain scores and analgesic consumption were collected before, daily during, and for 10 days after treatment. Pain flare was defined as a 2-point increase in the worst pain score (0-10) compared to baseline with no decrease in analgesic intake, or a 25% increase in analgesic intake with no decrease in worst pain score. The Brief Pain Inventory (BPI) was administered to measure the “sensory” dimension of pain (intensity, or severity) and its “reactive” dimension (interference with daily function) before the RT treatment and at the 4-weeks follow-up evaluation. Descriptive statistics were reported. Response rate and 95% confidence intervals were calculated at 4 weeks after RT. A comparison of patients with pain flare vs. those without was performed. The relationships between the occurrence of pain flare and collected demographic variables were investigated.

Results: From June 2010 to December 2013, 160 patients were enrolled in this study. From this cohort, 94 patients with complete data were evaluable for pain flare. There were 61 (65%) men and 33 (35%) women. Median age was 66 years. The majority of patients had primary breast (12%), lung (31%), or prostate (22%) carcinoma and were treated with 8 Gy in a single fraction (28%) or 20 Gy in five fractions (65%). The overall pain flare incidence across all centers was 42/94 (44.7%). The majority of pain flares occurred on Days 1-5 (88%) as opposed to Days 6-10 (12%). The median duration of the pain flare was 2 days. There was no significant difference between patients who experienced a pain flare vs. those who did not in terms of sex, age, primary cancer site, radiation dose, previous systemic therapy, location or area of RT, or on any of the BPI items (p > 0.05). BPI scores showed a significant improvement at 4 weeks on all functional interference items (p < 0.05). The main differences were seen in the “worst pain” and “sleep” domains, both decreased from 7/10 at baseline to 4/10 at the 4-week follow-up.

Conclusions: Pain flare is a common event, occurring in nearly half of the patients that receive palliative RT for symptomatic bone metastases. Furthermore, RT for symptomatic bone metastases is a very effective palliative treatment, in terms of both pain control and functional interference.

Factors Influencing Vertebral Compression Fracture Specific to Renal Cell Carcinoma Spinal Metastases after Stereotactic Body Radiotherapy: A Multi-Institutional Study

I. Thibault¹, E. G. Atenafu¹, E. Chang², S. Chao³, A. Al-Omair¹, N. Boehling⁴, E. H. Balagamwala³, M. Cunha¹, L. Angelov⁵, P. Brown⁴, J. Suh³, L. D. Rhines⁴, M. G. Fehlings¹, A. Sahgal¹, ¹University of Toronto, Toronto, ON, Canada, ²University of Southern California, Los Angeles, CA, ³Cleveland Clinic, Cleveland, OH, ⁴M.D. Anderson Cancer Center, Houston, TX

Purpose/Objective(s): The aim of this multi-institutional analysis was to determine the risk of vertebral compression fracture (VCF) following spine stereotactic body radiotherapy (SBRT) specific to renal cell carcinoma (RCC) spinal metastases, and to determine clinical and dosimetric predictors.

Materials/Methods: Pooled data from 227 spinal tumor segments treated in 141 metastatic RCC patients were reviewed. The primary endpoint was development of a VCF following SBRT, either a de novo VCF or progression of a baseline VCF. Each spinal segment was also evaluated according to the six Spinal Instability Neoplastic Score (SINS) criteria (location, pain, bone lesion type, spinal alignment, posterolateral element involvement, presence of a baseline fracture) to evaluate the predictive significance.

Results: The median spine SBRT total dose, dose per fraction, and number of fractions was 16 Gy (range, 8-30 Gy), 14 Gy (range, 6-24 Gy), and 1 fraction (range, 1-5), respectively. 20% (46/227) had been previously radiated, 82% (187/227) were lytic, 21% (47/227) had a baseline VCF, and the median follow-up was 6.5 months. 36 VCF (36/227, 16%) were observed following SBRT, including 12 (12/180, 7%) de novo fractures and 24 (24/47, 51%) progressive fractures, and the median time to VCF was 2.4 months. VCF were observed in 43% (10/23), 24% (4/17) and 12% (22/187) of segments treated with 24Gy/fraction, 20-23Gy/fraction and ≤19Gy/fraction, respectively. Multivariate analysis identified dose per fraction (p=0.003), baseline VCF (p<0.001) and spinal misalignment (p<0.001) as predictors of VCF.

Conclusions: 16% of RCC spinal metastases fractured post-SBRT, with a short median time to VCF (2.4 months). As the majority of tumors were lytic, caution should be observed when treating these metastases with doses ≥20Gy/fraction, in patients with spinal misalignment and, in particular, those metastases with a baseline fracture.


Presentation Number: LBA2

ICORG 05-03: Prospective Randomized Non-Inferiority Phase 3 Trial Comparing Two Radiation Schedules in Malignant Spinal Cord Compression not Proceeding with Surgical Decompression

P. Thirion¹,², L. O'Sullivan*¹,², A. Clayton-Lea*¹,², C. Small*¹,³, O. McArdle*¹,², P. Kelly*¹,⁴, I. Parker*¹, J. O'Sullivan*¹,², D. Hacking*¹,⁶, C. Collins*², M. Pomeroy*¹,³, M. Moriarty*¹,⁶, ¹All Ireland Cooperative Oncology Research Group, Dublin, Ireland, ²St Luke's Radiation Oncology Network, Dublin, Ireland, ³Galway University Hospital, Galway, Ireland, ⁴Cork University Hospital, Cork, Ireland, ⁵Belfast City Hospital, Belfast, United Kingdom, ⁶Whitfield Clinic, Waterford, Ireland

Purpose / Objective(s): To prospectively compare two External Beam Radiation Therapy (EBRT) Fractionation Schedules (FS) in patients (pts) with Malignant Spinal Cord Compression (MSCC) not proceeding with surgical decompression.

Materials / Methods: An ICH-GCP compliant prospective (1:1) randomized non-inferiority phase 3 trial compared two EBRT-FS: arm 1 (control): 20 Gy / 5 fractions (#) vs. arm 2 (experimental): 10 Gy / 1 #, with 90% power, 5% significant level and +0.4 non-inferiority margin. The primary end-point was the change in mobility at 5 weeks (Modified Tomita score); the secondary end-points were change in bladder function at 5 weeks (in-house score), acute and long-term toxicity (RTOG scale), and overall survival (OS). Eligible pts had
pathologically proven metastatic cancer, excluding haematological/germ cell malignancies, and diagnosed with a MRI documented treatment naïve symptomatic MSCC.

**Results:** From 2006 to 2014, 5 institutions accrued 116 pts (1 non-eligible pt, no treatment allocation violation), 76 pts alive at 5 weeks were evaluable. The baseline characteristics were balanced between arms [♀/♂ ratio: 36/64, median age: 69 (range: 30-87), median baseline KPS: 60 (range: 30 - 100)]. The main primary tumour sites were prostate (24%), breast (20%) and lung (19%). The MSCC sites were cervical (4.3%), thoracic (67%), lumbar (23.5%), sacral (2.6%) and two synchronous levels (2.6%, 3 pts treated with same FS). Analysis of evaluable pts showed no statistically significant differences in 1) overall mobility score change at 5 week [Overall response (Improvement/Stability) rate: arm 1: 68.4% (10.5/57.9) vs. arm 2: 78.9% (10.5/68.4); mean mobility score change: arm 1: -0.29 vs. arm 2: -0.08, difference= -0.21, 95%CI: -0.56 to 0.14, +0.4 non-inferiority margin outside 95%CI] or 2) bladder function score change at 5 weeks [Overall response (Improvement/stability) rate: arm 1: 75.7% (10.8/ 64.9) vs. arm 2: 86.8% (2.6/84.); mean sphincter score change: arm 1: -0.22 vs arm 2: -0.16, difference = -0.06, 95%CI: -0.44 to 0.32]. The mobility deterioration free survival and overall survival median durations were similar in both arms respectively 1.4 months and 4 months. Independent favourable prognostic factors were 1) for 5 week mobility overall response: preserved baseline mobility, and 2) for OS: preserved baseline mobility, high baseline KPS, young age and non-lung primary. The reported overall toxicity was low with 1 G3-acute and 1 G3-long-term toxicity events (arm 2) and no higher grade toxicity reported.

**Conclusions:** With respect to mobility preservation, 10 Gy / 1 # is at least equivalent to 20 Gy / 5#. When using EBRT in similar pts, a single fraction schedule should be considered.