microRNAs (miRNA-9 5p, miRNA-31 3p, miRNA-125a 5p, miRNA-125b 5p, miRNA-200a 5p) showed differential expression in complete responders compared to non-responders but their expression did not reach statistical significance level (p value > 0.05).

**Conclusion:** miRNA-100 5p can serve as a potential molecular biomarker in predicting clinical response to chemoradiation in locally advanced Carcinoma cervix patients. Its role should be further investigated in larger study population.


### 3171

**Phase II Trial of Flaxseed to Prevent Acute Complications After Chemoradiation for Lung Cancer**

T.L. Lim,1 R. Pietrofesa,2 E. Arguirí,2 C. Koumenis,1 S.J. Feigenberg,1 C.B. Simone, II,3 R. Rengan,4 K.A. Cengel,1 W.P. Levin,1 M. Christofidou-Solomidou,2 and A.T. Berman1

1Department of Radiation Oncology, University of Pennsylvania, Philadelphia, PA, 2Department of Radiation Oncology, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Korea, Republic of South Korea, 3Memorial Sloan Kettering Cancer Center, New York, NY, 4Department of Radiation Oncology, University of Washington, Seattle, WA

**Purpose/Objective(s):** The effectiveness of radiotherapy for thoracic malignancies is limited by acute radiation-induced complications such as radiation pneumonitis (RP) and radiation esophagitis (RE). Based on preclinical work from our lab, the present single-arm phase II trial investigated the feasibility of administering 8-9 weeks of flaxseed (FS), a whole grain with anti-inflammatory and anti-oxidative properties, as a radioprotector in patients receiving chemoradiation (RT) therapy for non-small cell lung cancer (NSCLC). Herein, we report outcomes of the primary endpoint of RP and the secondary study endpoints of RE and clinical outcomes.

**Materials/Methods:** Between June 2015 and February 2018, patients with locally advanced or metastatic NSCLC where definitive chemoradiation (RT) was planned were enrolled. Finely ground FS in 40-gram packets were provided to patients for daily consumption in any patient-desired formulation 1 week prior to RT and continued throughout RT as tolerated. RP and RE grades were assigned according to the CTCAE v4.0 scale.

**Results:** Of 33 patients enrolled, 5 patients (15%) did not receive RT, 4 (12%) withdrew after enrollment and before FS consumption, and 4 (12%) did not return a FS consumption log. The remaining 20 patients (61%) had documented RT and FS ingestion with a mean FS consumption and standard deviation of 5 ± 2.8 weeks. Baseline characteristics are described in the table. For the primary study endpoint, 1 patient (3% of all enrolled patients and 5% of patients who ingested FS), with unverifiable FS consumption, developed Grade 3 RP. Regarding secondary study endpoints, 12 patients (36%) developed Grade ≤ 2 RE, but no patients developed Grade ≥ 3 RE. 12 patients (36%) reported difficulty tolerating FS consumption. Median overall survival and progression free survival for the cohort were 24 and 12 months, respectively, with no significant differences between those who did and did not consume any FS.

**Conclusion:** Despite the low incidence of acute radiation-induced complications reported in patients consuming FS in the present phase II study, the low FS tolerability inhibits accurate determination of FS effect in reducing acute radiation-induced complications. As a result, further FS investigations should focus on optimizing FS formulation for improved tolerability and better evaluation of FS efficacy.


### 3172

**Tumor-related Leukocytosis Is Associated With A Suppressive Tumor Immune Microenvironment In Cancer Patients**

K.H. Kim,1 J.S. Chang,2 and Y.B. Kim3; 1Department of Radiation Oncology, Yonsei Cancer Center, Seoul 120-752, Korea, Republic of South Korea, 2Department of Radiation Oncology, Yonsei Cancer Center; Yonsei University College of Medicine, Seoul, Seoul, Korea, Republic of South Korea

**Purpose/Objective(s):** Tumor-related leukocytosis (TRL) is correlated with poor survival in various types of cancers, but the microenvironment of TRL-associated human tumors has not been fully elucidated.

**Materials/Methods:** The transcriptional signatures of tumor tissues obtained from cervical cancer patients with TRL (TS) and without TRL (TRLmns) were compared. As a surrogate for TRL diagnosis, a leukocytosis signature (LS) score was derived using genes differentially expressed between TRLTS and TRLmns tumors. The immunological profiles of patients in the TCGA database with high (LS>0.65) or low (LS<0.5) LS scores were compared.

**Results:** TRLTS tumors were transcriptionally distinct from TRLmns tumors, exhibiting up-regulation of radioresistance and down-regulation of adaptive immune response-related genes. In the TCGA cervical cancer cohort (n = 303), patients with high LS had inferior survival rates compared to those with low LS (P = 0.023). LS>0.65 tumors were enriched in radioresistance, wound healing, and myeloid-derived suppressor cell (MDSC) signatures and had a higher infiltration of M2 macrophages and a lower infiltration of M1 macrophages and lymphocytes. LS>0.65 tumors also expressed higher levels of CXCR2 chemokines, CSF2, and CSF3. In the pan-cancer cohort (n = 9984), LS>0.65 tumors also exhibited poor survival, signatures of a suppressive immune microenvironment, and higher expression of CXCR2 chemokines.

**Conclusion:** Our data provide evidence for a suppressive immune microenvironment in patients with TRL and suggest promising targets, such as the CXCR2-axis.

**Author Disclosure:** K. Kim: None. J. Chang: None. Y. Kim: None.