

2017 ASTRO Annual Meeting  
Accepted Late-Breaking Abstracts

## Plenary Session

## LBA-1

**A Phase 3 Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High-Risk, Early-Stage Endometrial Cancer: A Gynecology Oncology Group Study**

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**Purpose/Objective(s):** To determine if vaginal cuff brachytherapy and chemotherapy (VCB/C) could increase recurrence-free survival (RFS) compared to pelvic external beam radiation therapy (PXRT). Secondary objectives included comparisons of overall survival (OS), patterns of failure, and frequency/severity of adverse events between the treatment arms.

**Materials/Methods:** A randomized phase 3 trial was performed in endometrial cancer patients meeting eligibility criteria. All patients were required to undergo hysterectomy. Eligible patients had stage I endometrioid histology with GOG 99-based high intermediate risk criteria (based on age, tumor grade, depth of invasion, and presence of lymphovascular space invasion), stage II, or stage I-II serous (S) or clear cell (CC) tumors. Central pathology review was performed. Patients assigned to PXRT were treated with standard 4-field or Intensity-Modulated Radiation Therapy (IMRT) techniques to a mean dose of 45 Gy over 5 weeks. Additional VCB was optional for patients with S/CC tumors or stage II disease. Patients assigned to VCB/C received HDR or LDR brachytherapy followed by paclitaxel 175 mg/m<sup>2</sup> (3 hour) + carboplatin AUC 6 q 21 days for a total of 3 cycles.

**Results:** A total of 601 pts were accrued; PXRT was assigned to 301 (18 did not receive study treatment) and VCB/C to 300 (9 did not receive study treatment). The median age was 63 years, 74% had stage I disease, and 89% underwent lymphadenectomy. Histology included 71% with endometrioid type, 15% S, and 5% CC. Nearly all pts completed the prescribed therapy (91% PXRT, 87% VCB/C). In the PXRT arm, IMRT was used in 36%, and vaginal cuff brachytherapy boost was added in approximately 35%. Acute toxicity was more common and more severe with VCB/C. Grade 3 or higher adverse events were reported in 32 patients on the PXRT arm versus 187 patients on the VCB/C arm. Grade 3 or higher late effects

were seen in 37 and 35 patients on the PXRT and VCB/C arms, respectively. With a median follow-up of 53 months, the 36 month RFS was 82% for both PXRT and VCB/C. The 36-month OS was 91% versus 88% for PXRT and VCB/C, respectively. No significant differences were noted between the two arms in terms of vaginal or distant failure. However, pelvic or para-aortic nodal recurrences were significantly more common in the VCB/C arm (25 vs 12), largely driven by the difference in pelvic nodal failure (20 vs 6 patients). There was no statistically significant treatment effect heterogeneity with respect to RFS among clinical-pathologic variables evaluated.

**Conclusion:** This study did not demonstrate a superiority of VCB/C to PXRT in women with HR endometrial cancer. Acute and late toxicity and pelvic and para-aortic nodal failure were more frequent in the VCB/C arm. Both arms appeared to be well tolerated with high completion rates. PXRT remains an effective, well-tolerated, and acceptable adjuvant treatment in patients with high risk, early-stage endometrial carcinoma.

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## LBA-2

**Radiobiological Analysis of Outcomes Using External Beam Radiotherapy Plus High Dose-Rate Brachytherapy (4x7 Gy or 2x9 Gy) for Cervical Cancer in a Multi-Institution Trial**

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**Purpose/Objective(s):** To compare loco-regional (LR) control and adverse effects (AE) of external beam radiotherapy (EBRT) in combination with 2 different fractionation schedules of HDR brachytherapy (HDRBT) with or without chemotherapy (CT) in cervical cancer.

**Materials/Methods:** A prospective, randomized, multicenter international trial of the IAEA tested four combinations of HDRBT and CT in cervical cancer. Eligible patients were women with stages IIB and IIIB cervical carcinoma being treated with curative intent and with no contraindications for EBRT, HDRBT and CT. All patients were to receive EBRT, 46 Gy in 23 fractions to the pelvis. Prescribed HDRBT dose in arm A was 4 applications of 7 Gy each to point 'A' while in arm B it was 2 applications of 9 Gy. Arms C and D were similar to arms A and B but with cisplatin (40mg/m<sup>2</sup>) in weeks 1 through 5. LR tumor control, overall survival and acute/late AE were compared between arms. Using a/b values of 10 Gy for tumor control and 3 Gy for late-AE, biological effective doses (BED) and equivalent doses (EQD2) were calculated for each arm. Arms A and C had BED<sub>10</sub>=102.8Gy<sub>10</sub> (EQD2= 85.7 Gy) and BED<sub>3</sub>=128.3Gy<sub>3</sub> (EQD2 = 77 Gy). For arms B and D, BED<sub>10</sub> and BED<sub>3</sub> were 89.4 Gy<sub>10</sub> (EQD2= 74.5 Gy) and 115.8 Gy<sub>3</sub> (EQD2= 69.4 Gy).

**Results:** Between September 2005 and May 2010, 601 patients were randomized. By center, there were 257 cases from Mumbai, 147 cases from Peru, 76 from South Africa, 53 from Brazil, 31 from Pakistan, 19 from Morocco, and 18 from Macedonia. Average age was 48.7 yr (26 - 71). Four hundred and forty patients had stage IIB cases, and 161 had stage IIIB ( $P = .7$  across arms). Overall 5-yr survival was 71% for IIB patients and 58% for IIIB patients ( $P = .03$ ). The 5-yr survival for all women, combined, was 67.2% (95% CI 62.7-71.2%). By treatment arm, 5-yr overall survival was: 62.2% in A, 68.3% in B, 73.1% in C, and 65.1% in D. By log-rank test, stratified by center and stage, there was no statistical difference in overall survival by study arm ( $P = .1$ ). For the 440 stage IIB patients, there was no statistical difference in survival with 4 HDR versus 2 HDR, and no difference with or without CT. Five-year tumor control and adverse effects are reported in table 1. Tumor control was lower in arms B and D compared to arms A and C ( $P = .0007$ ). No statistically significant difference in AE was found. The only effect of cisplatin was an increased-AE trend in the 2x9 Gy arm-B ( $P = .066$ ).

**Conclusion:** A dose-effect relationship was found for tumor control in our study. Local control was significantly superior for the arms including 4 fractions of 7 Gy HDRBT compared to 2 fractions of 9 Gy. No statistically significant differences in OS or AE were found between arms.

**Table 1: LBA-2**

Study arm	5 yr Tumor control (+) %, 95% CI	GU G3-5 toxicity (*)	GU fistula	GI G3-5 toxicity (*)	GI fistula
Arm A EBRT 46 Gy plus HDRBT (4x7 Gy)	88 (81-92) %	7.3%	0%	4%	1.3%
Arm B EBRT 46 Gy plus HDRBT (2x9 Gy)	78 (71-84) %	6.7%	0.6%	4%	1.3%
Arm C (Arm A + CDDP)	89 (82-94) %	5.3%	0.6%	6%	0%
Arm D (Arm B + CDDP)	75 (67-82) %	7.2%	0%	5.9%	0%

GU: Genito-urinary. GI: Gastro-intestinal.

(+):  $P = .0007$ .

(\*): excluding fistula.

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## LBA-3

### Consolidative Radiotherapy for Limited Metastatic Non-Small Cell Lung Cancer: A Randomized Phase 2 Trial

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**Purpose/Objective(s):** Maintenance systemic therapy has shown statistically significant but modest benefits in progression free survival (PFS) and overall survival (OS) for patients with stage IV non-small cell lung cancer (NSCLC). This trial sought to determine if intervening with non-invasive, stereotactic body radiation therapy (SBRT) prior to maintenance chemotherapy in patients with limited metastatic NSCLC led to significant improvements in PFS.

**Materials/Methods:** Patients with stage IV NSCLC who achieved a partial response or stable disease to induction chemotherapy with six or fewer sites of limited metastatic disease (including primary) were randomized to maintenance chemotherapy or consolidative SBRT to all sites of disease followed by maintenance chemotherapy. The primary endpoint was PFS, with secondary endpoints including toxicity, local and distant tumor control, and patterns of failure.

**Results:** A total of 29 patients were enrolled from April 2014 to July 2016, with 14 patients in the SBRT plus maintenance chemotherapy arm and 15 patients in the maintenance chemotherapy alone arm. The trial was stopped to accrual early after an unplanned interim analysis found a significant improvement in PFS in the SBRT plus maintenance chemotherapy arm of 9.7 months versus 3.5 months in the maintenance chemotherapy alone arm ( $P = .013$ ). Toxicity was similar in both arms. There were no in-field failures with fewer overall recurrences in the SBRT arm.

**Conclusion:** Consolidative SBRT prior to maintenance chemotherapy was beneficial, nearly tripling PFS in patients with limited metastatic NSCLC compared to maintenance chemotherapy alone, with no difference in toxicity. It is promising that a phase 3 study, based on this and other trials, has been activated by NRG (NRG LU 002, NCT03137771) to answer the benefit of local therapy on OS.

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## Clinical Trials Session

### LBA-4

#### PACIFIC: A Double-Blind, Placebo-Controlled Phase 3 Study of Durvalumab as Consolidation Therapy After Chemoradiation in Patients with Locally Advanced, Unresectable Non-Small Cell Lung Cancer

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**Purpose/Objective(s):** Most patients (pts) with locally advanced, unresectable non-small cell lung cancer (NSCLC) progress despite concurrent chemoradiation therapy (cCRT). Here we report interim results from a global, phase 3 study (NCT02125461) of the anti-PD-L1 Durvalumab as consolidation therapy in Stage III pts without progression following platinum-based cCRT.

**Materials/Methods:** Pts with a WHO performance status 0/1 (any PD-L1 status) who received  $\geq 2$  cycles of platinum-based cCRT without progression were randomized (2:1) 1–42 days post-cCRT to receive Durvalumab 10 mg/kg IV Q2W or placebo for up to 12 months, stratified by age, sex, and smoking history. Co-primary endpoints were progression-free survival (PFS; blinded independent central review, RECIST v1.1) and overall survival (OS). Secondary endpoints included 12- and 18-month PFS rates, objective response rate (ORR), duration of response (DoR), time to death or distant metastasis (TTDM), and safety.

**Results:** Between May 2014 and April 2016, 713 pts were randomized, 709 of whom received consolidated treatment (Durvalumab,  $n=473$ ; placebo,  $n=236$ ). Baseline characteristics were well balanced. As of February 13, 2017 (data cutoff), median follow-up was 14.5 months. Median PFS from randomization was significantly longer with Durvalumab (16.8 months, 95% CI, 13.0–18.1) versus placebo (5.6 months, 95% CI, 4.6–7.8; stratified HR 0.52, 95% CI, 0.42–0.65;  $P<.0001$ ). 12- and 18-month PFS rates were 55.9% versus 35.3% and 44.2% versus 27.0%, respectively. ORR was higher (28.4% vs 16.0%;  $P<.001$ ) and median DoR was longer (not reached vs 13.8 months) with Durvalumab consolidation therapy. Median TTDM was longer with Durvalumab (23.2 vs 14.6 months; stratified HR 0.52, 95% CI, 0.39–0.69;  $P<.0001$ ). OS data were immature at the time of interim PFS analysis. Comparing Durvalumab with placebo, grade 3/4 adverse events (AEs) occurred in 29.9% and 26.1%; most common was pneumonia (4.4% vs 3.8%). 15.4% and 9.8% discontinued due to AEs.

**Conclusion:** Durvalumab demonstrated significant and clinically meaningful improvement in PFS, which was supported by secondary endpoints, and was well tolerated. Durvalumab is a promising therapeutic option in this setting.

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## LBA-5

### Phase 2 5-Arm Trial of Ipilimumab Plus Lung or Liver Stereotactic Radiation for Patients with Advanced Malignancies

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**Purpose/Objective(s):** We present early toxicity and efficacy findings from a phase 2 trial that combines CTLA4 blockade (ipilimumab) with stereotactic ablative radiation therapy (SABR) targeting metastatic lung or liver lesions in patients with solid tumors.

**Materials/Methods:** Patients with metastatic disease refractory to standard therapies with  $\geq 1$  lung or liver lesion amenable to SABR and  $\geq 1$  additional non-contiguous lesion were enrolled in a nonrandomized fashion. All patients were to receive ipilimumab (3 mg/kg every 3 weeks for 4 cycles) plus radiation given either concomitantly (SABR started on day 2 of cycle 1) or sequentially (SABR given 1 week after the 2<sup>nd</sup> dose of ipilimumab). The 5 treatment groups were as follows: concomitant liver 50 Gy, concomitant lung 50 Gy, sequential liver 50 Gy, sequential lung 50 Gy, and sequential 60 Gy (lung or liver for larger lesions). 50 Gy was given in 4 fractions and 60 Gy was given in 10 fractions. Toxicity was scored per the Common Terminology Criteria for Adverse Events v4.0 and were evaluated by medical and radiation oncologists. Disease response was scored per the immune-related response criteria (irRC) by an experienced radiologist. Best responses were reported as complete response (CR), partial response (PR; size decrease  $\geq 50\%$ ), progressive disease (PD; size increase  $\geq 25\%$ ), or stable disease (SD; not meeting criteria for PR/CR or PD). The Kaplan-Meier method and log-rank tests were used to assess progression-free survival (PFS) and overall survival (OS).

**Results:** Among 100 patients (20 in each treatment group), the most common primary histologies were adeno- ( $n=55$ ) and squamous cell ( $n=13$ ) carcinomas. No grade 4-5 toxicity was observed; 27 grade 3 toxicities were related to ipilimumab (colitis [ $n=8$ ], diarrhea [ $n=7$ ], liver enzyme elevation [ $n=3$ ], bilirubin elevation [ $n=1$ ], intestinal obstruction [ $n=1$ ], hypophysitis [ $n=3$ ], and rash [ $n=4$ ]). Two grade 3 toxicities were attributed to combined ipilimumab plus SABR: liver enzyme increase (1%) and pneumonitis (1%). The concurrent and sequential lung groups had 45% and 50% of SD, and 10% and 0% PR, respectively. The concurrent and sequential liver groups showed 35% and 30% of SD, and 5% and 0% PR, respectively. Within the sequential 60 Gy group, 60% showed a favorable response. Lesions from non-small cell lung cancer had the highest rate of clinical benefit (SD + PR) at 67%. There was no CR to report. Median PFS time for all patients was 5 months (95% confidence interval [CI] 2.7–7.2) and median OS time was 12 months (95% CI 9.3–14.6). At 12 months, PFS and OS were better for the sequential lung group than for the sequential liver group (PFS  $P=.055$ , CI = 3.7–6.4; OS  $P=.059$ , CI = 7.9–20). However, no differences in PFS ( $P=.2$ ) or OS ( $P=.3$ ) were found between the concurrent lung and liver groups.

**Conclusion:** These data suggest that combinations of ipilimumab and SABR have acceptable toxicity profiles and sequential treatment may provide significant clinical benefits in term of response and survival, warranting further evaluation.

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## LBA-6

### Tumor Treating Fields (TTFields)—A Novel Cancer Treatment Modality: Translating Preclinical Evidence and Engineering Into a Survival Benefit with Delayed Decline in Quality of Life



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**Purpose/Objective(s):** Tumor treating fields (TTFields) is a novel non-ionizing radiation cancer treatment modality using a patient-operated home-use device that delivers 200 kHz alternating electrical fields to the brain. TTFields interfere with cell division and selectively disrupt mitosis by interfering with the spatial alignment of polar macromolecules within the cell. TTFields also inhibit DNA damage repair of double strand breaks. Maintenance of quality of life during therapy with TTFields was compared to standard therapy alone.

**Materials/Methods:** TTFields were tested in a large phase 3 trial in patients with newly diagnosed GBM (EF-14;  $n=695$ ). Patients who had completed radiochemotherapy were randomized to either standard temozolomide (TMZ) chemotherapy alone, or to TTFields and TMZ. Progression-free and overall survival were the main endpoints, with quality of life (QoL) as a predefined and important secondary endpoint. QoL was assessed longitudinally using the EORTC QLQ C-30 with brain cancer module (BN-20) questionnaires.

**Results:** TTFields added to standard adjuvant temozolomide (TMZ) chemotherapy led to a significant prolongation of both progression-free and overall survival (HR 0.63 [CI 0.53-0.76];  $P=.000059$ ). Toxicity was comparable between the two treatment arms with the exception of the expected mild-moderate skin toxicity due to the electrode placement on the TTFields treated patients. All predefined clinical and molecular subgroups benefitted from TTFields. More TTFields patients reported stable or improved scores on global health status, pain, physical functioning, and leg weakness (all  $P \leq .01$ ), while the area under the curve for improvement or stability over time was not significantly different between groups. Deterioration-free survival was significantly longer with TTFields for global health, physical and emotional functioning, pain, and leg weakness (all  $P < .01$ ). Time to deterioration was shorter for itchy skin and longer for pain (both  $P < .001$ ).

**Conclusion:** TTFields are an effective non-ionizing radiation treatment for GBM with a novel mechanism of action and unique delivery method. Patients become rapidly independent in handling the device allowing patients to control their treatment at home. Deterioration of key QOL scales is delayed in patients treated with TTFields.

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## LBA-7

### A Randomized Controlled Trial Evaluating the Utility of a Patient Decision Aid to Improve Clinical Trial (RAVES 08.03) Related Decision-Making



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**Purpose/Objective(s):** Randomized controlled clinical trials are considered the 'gold standard' for evaluating medical treatments. However, recruitment to clinical trials is low overall, with both patients and clinicians reporting difficulties with the consent process. Decision Aids (DAs) may improve this process by ensuring patients weigh up the pros and cons of all their options and make informed value-sensitive decisions. DAs have demonstrated efficacy in improving knowledge and reducing decisional conflict during decision-making about medical treatments. We aimed to evaluate the utility of a DA for potential participants of a clinical trial (Trans-Tasman Radiation Oncology Group's RAVES 08.03), in reducing decisional conflict; improving knowledge, understanding, and attitudes towards RAVES; reducing anxiety and decisional regret; and potentially improving informed trial recruitment.

**Materials/Methods:** Potential participants for the RAVES clinical trial were invited to participate in the current study. Participants were randomized to receive the RAVES RCT's participant information sheet with or without a DA. Questionnaires were administered at baseline, one and six months. The primary outcome measure was decisional conflict. Secondary outcome measures included knowledge regarding RAVES, understanding and attitudes towards RAVES, anxiety, decisional satisfaction, decisional regret, and recruitment to the RAVES RCT.

**Results:** One-hundred and twenty-nine men were randomized to the DA (63) and control (66) arms. Decisional conflict was significantly lower over 6 months ( $P=.048$ ) in the DA arm. Knowledge regarding the RAVES RCT was significantly higher at 6 months ( $P=.033$ ) in the DA arm. 20.6% of the DA arm (13 of 63) and 9% of the control arm (6 of 66) entered the RAVES RCT. The DA significantly increased RAVES recruitment in the cohort recruited by urologists: all 6 of the 92 men who entered RAVES were from the Decision Aid arm ( $P=.01$ ). The DA made no difference in RAVES participation in the cohort recruited by radiation oncologists (7 from the Decision Aid arm vs 5 from the control arm).

**Conclusion:** This study demonstrates the utility of a DA in reducing decisional conflict and improving trial knowledge in men with cancer who are making decisions regarding RCT participation. The DA also improved trial recruitment in a subgroup of patients. These findings have implications for the planning, design, and conduct of future clinical trials.

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## Late-breaking Abstracts Special Session

## LBA-8

### Impact of <sup>18</sup>F-fluciclovine PET/CT on Clinical Management of Patients with Recurrent Prostate Cancer: Results from the Phase 3 FALCON Trial



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**Purpose/Objective(s):** When biochemical recurrence (BCR) of prostate cancer is suspected, early and accurate localization of metastases facilitates treatment when tumors are small and most amenable to localized therapy, and may guide clinicians in making management plans regarding salvage therapy. Here, we present results of a preplanned analysis of the FALCON trial (NCT02578940), which assessed the impact of PET/CT imaging with <sup>18</sup>F-fluciclovine on clinical management choices for men with BCR of prostate cancer.

**Materials/Methods:** Men with a first BCR episode following radical curative therapy who were being considered for curative-intent salvage therapy were recruited at six UK sites. Intended management plans were recorded prior to <sup>18</sup>F-fluciclovine PET/CT imaging. The primary outcome measure was the impact of a <sup>18</sup>F-fluciclovine PET/CT scan on clinical management. Post-scan changes to treatment modality (e.g., salvage radiation therapy [RT] to hormone deprivation) were classed as 'major,' while changes within a modality (e.g. alteration to salvage RT fields) were classed as 'other.' Diagnostic accuracy using clinical follow-up, histological correlation, and concordance on multimodal imaging as a truth standard was studied as a secondary outcome. Based upon an expected ~40% change in management, a preplanned analysis of the first 85 evaluable patients was performed with intent to terminate recruitment for overwhelming efficacy if the number of treatment changes was greater than 45 (52.9%; 97.5% CI: 40.3–62.3%), or for futility, if fewer than 8 (9.4%, 97.5% CI: 3.6–18.9%).

**Results:** Between December 2015 and February 2017, 85 evaluable patients (median age at screening, 67.0 y; median post-BCR PSA, 0.63 ng/mL) were imaged. Fifty-six (65.9%) had previously had a radical prostatectomy. <sup>18</sup>F-fluciclovine detected lesions in the prostate/bed or extraprostatic region in 40.0% and 22.4% of scans, respectively. Therapeutic management was revised post-scan in 52/85 (61.2%) patients. For 41/52 (78.8%) patients, the decision was made due to a positive finding on the <sup>18</sup>F-fluciclovine scan. Major revisions were made for 32/52 (61.5%) of those subjects with updated plans. Salvage treatment was revised to watchful waiting for 13/85 patients (15.3%) and to systemic therapy for 18/85 (21.2%), while 20/85 (23.5%) patients had their planned RT field modified post-scan to include a boost to a positive lesion or to widen the field to include the whole pelvis. As a result of these findings, recruitment was stopped as the preset condition defining overwhelming efficacy was met.

**Conclusion:** This prospective study shows that <sup>18</sup>F-fluciclovine PET/CT has substantial impact on the clinical management of men with a first BCR of prostate cancer after curative-intent therapy. Future studies to assess the long-term impact of these management changes on disease outcomes are warranted.

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Wilson: Employee shareholder; Blue Earth Diagnostics. F.V. Gleeson: Oxford University, OUH NHS FT.

## LBA-9

### <sup>68</sup>Ga-PSMA PET/CT Mapping of Early Biochemical Recurrence (PSA < 1 ng/mL) After Primary Surgery in 270 Patients: Impact on Salvage Radiation Therapy Planning

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**Purpose/Objective(s):** Target volumes for salvage prostate radiation therapy (SRT) are usually drawn in the absence of visibly recurrent disease. However, <sup>68</sup>Ga-PSMA PET/CT detects prostate cancer recurrences with accuracy superior to conventional imaging, at PSA values low enough to impact volume delineations for routine SRT. We conducted this study to i) determine how often volumes based on the Radiation Therapy Oncology Group (RTOG) consensus guidelines cover <sup>68</sup>Ga-PSMA PET/CT defined disease in patients with serum PSA levels <1 ng/ml after radical prostatectomy, ii) map the recurrence pattern of early biochemically recurrent prostate cancer after prostatectomy, and iii) assess the potential impact of <sup>68</sup>Ga-PSMA PET/CT on SRT.

**Materials/Methods:** This is a post-hoc analysis of an intention to treat a population of 270 patients who underwent <sup>68</sup>Ga-PSMA PET/CT in 4 institutions for biochemical recurrence after prostatectomy without prior radiotherapy at PSA<1 ng/mL. RTOG consensus clinical target volumes (consensus CTVs) that included both the prostate bed and pelvic lymph nodes (LN) were contoured on the CT portion of PET/CT by an experienced radiation oncologist blinded to the PET findings. <sup>68</sup>Ga-PSMA PET/CT images were analyzed by an experienced nuclear medicine physician. PSMA avid lesions were compared with the consensus CTVs. PSMA avid lesions not covered by planning volumes based on the consensus CTVs were considered to have a major potential impact on treatment planning.

**Results:** The median PSA at the time of <sup>68</sup>Ga-PSMA PET/CT was 0.48 ± 0.25 (range 0.03-1 ng/ml). Of 270 patients, 132 (49%) had a positive <sup>68</sup>Ga-PSMA PET/CT study. Fifty-two patients (19% of all patients, 39% of patients with a positive <sup>68</sup>Ga-PSMA PET/CT) had at least one PSMA avid lesion not covered by planning based on the consensus CTVs and would have been inadequately treated using these volumes. Thirty-three patients (12% of all patients, 25% of patients with a positive <sup>68</sup>Ga-PSMA PET/CT) had extra-pelvic PSMA avid lesions, and 19 (7% of all patients, 14% of patients with a positive <sup>68</sup>Ga-PSMA PET/CT) had PSMA avid lesions within the pelvis but not covered by consensus CTVs.

**Conclusion:** This multicenter post-hoc analysis revealed that the addition of a <sup>68</sup>Ga-PSMA PET to CT would have a major impact on SRT in 52 of 270 (19%) patients with early biochemical recurrence (PSA<1.0 ng/ml) after radical prostatectomy. This impact may justify a randomized imaging trial in a similar patient cohort offered SRT with or without <sup>68</sup>Ga-PSMA PET/CT powered for a clinical outcome. Furthermore, in patients with a positive PSMA-PET, consensus CTVs failed to cover recurrences in 52 of 132 (39%) of patients. 33 (25%) of these 132 patients had M1 disease, a majority of which (66%) were oligometastatic M1a or M1b (1 to 5 extrapelvic sites). The frequency of oligometastatic patients in



this cohort suggests a clinical trial incorporating metastasis-directed therapy is feasible even at low PSA values if patients are imaged with PSMA-PET/CT.

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## LBA-10

### Prospective Validation of Transforming Growth Factor-Beta (TGF- $\beta$ ) Polymorphism C509T as a Predictor of Radiation-Induced Fibrosis in Early Stage Breast Cancer Patients



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**Purpose/Objective(s):** TGF- $\beta$  plays a central role in mediating post-radiation fibrosis. Prior literature posits that single nucleotide polymorphisms in the TGF- $\beta$  gene may account for differences in fibrosis risk, but prospective validation is lacking. The C509T polymorphism in the promoter region of the TGF- $\beta$  gene is associated with increased expression and elevated circulating levels of TGF- $\beta$ . We sought to prospectively validate the C509T variant allele as a predictor of breast fibrosis.

**Materials/Methods:** Patients were recruited from a prospective randomized trial comparing two whole breast irradiation dosing schedules. The trial was prospectively designed to yield 83% power to test the hypothesis that C509T is associated with a fourfold increase in grade 2+ breast fibrosis assessed at 3 years post-radiation using the SOMA scale, assuming 150 participants and  $\alpha=0.05$ . Exploratory, pre-specified analyses tested the association of C509T with patient-reported cosmetic and functional outcomes assessed using the Breast Cancer Treatment Outcomes Scale (BCTOS), cosmetic outcome graded on the RTOG scale by a three-physician panel blinded to randomization arm, and NCI CTCAEv4. Hypotheses were tested using Fisher's exact, Chi-square, or Student's t-test as appropriate. Multivariable logistic regression identified predictors of grade 2+ breast fibrosis.

**Results:** TGF- $\beta$  genotype and 3-year follow-up were available for 174 of 287 patients enrolled in the trial, of whom 89 (51%) had at least one copy of C509T. C509T was present in 75% of Hispanics compared to 48% of whites and 35% of blacks ( $P=.01$ ), but it was not associated with other baseline covariables. The primary outcome, grade 2+ breast fibrosis, was present in 14% of patients with C509T compared to 4% of patients without it ( $P=.02$ ). In multivariable analysis, only C509T (OR=5.2, 95% CI 1.3-20.7,  $P=.02$ ) and post-operative cosmetic outcome (OR=7.7, 95% CI 2.5-23.4,  $P<.001$ ) predicted breast fibrosis risk. The randomization arm did not predict breast fibrosis ( $P=.98$ ) and did not interact with TGF- $\beta$  genotype ( $P=.94$ ). C509T was also associated with adverse patient-reported functional outcome ( $P=.04$ ), with a trend toward increased risk of moderate to large shoulder stiffness (11% vs 4%;  $P=.08$ ). C509T was also associated with greater risk of grade 2 NCI CTC breast atrophy (17% vs 7%;  $P=.047$ ). C509T was not associated with patient-reported ( $P=.52$ ) or panel-assessed ( $P=.51$ ) cosmetic outcome.

**Conclusion:** This study prospectively validates the C509T allele of TGF- $\beta$  as a key predictor of breast fibrosis risk and other adverse outcomes. TGF- $\beta$  genotype may be helpful for patient selection, risk stratification, and radiation mitigation strategies.

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## LBA-11

### Quality of Life After Active Surveillance, Radical Prostatectomy, and External Beam Radiation—4 Year Results of a Prospective, Population-Based Cohort



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**Purpose/Objective(s):** Quality of life (QOL) is a primary factor in the decision-making process for patients with prostate cancer, but long-term comparative data from modern treatments are lacking. Our prior publication [JAMA 317(11):1141-1150, 2017] reported results to 2 years, but longer term follow-up may demonstrate further changes in QOL in radical prostatectomy (RP) and external beam radiation (RT) patients.

**Materials/Methods:** A population-based cohort of 1350 patients with newly diagnosed prostate cancer was enrolled from 2010-2013 throughout the North Carolina Cancer Registry. This is the only fully prospective population-based cohort where all baseline data were collected before treatment. QOL was assessed using the validated Prostate Cancer Symptom Indices; higher scores (0-100) indicate worse QOL. Propensity-weighted mean scores were compared between each treatment group versus active surveillance (AS).

**Results:** AS (N=387) patients had worsening sexual, urinary, and bowel QOL scores over time (Table). Compared to AS, RP (N=548) patients had worse short-term and long-term sexual function and urinary incontinence. RT (N=285) is associated with worse bowel symptoms at 3 months but not after. No clinically meaningful difference in QOL between RT and AS at 4 years. Results stratified by baseline QOL levels will be presented in detail.

**Conclusion:** With longer follow-up, QOL worsened for AS patients in all domains, while there were no meaningful improvements in RP patients' sexual dysfunction and urinary incontinence after 1 year. QOL in RT and AS patients are similar at 4 years.

	Baseline	3mo	1yr	2yr	3yr	4yr
Sexual: AS	44.7	45.5	48.5	56.8	53.7	58.8
Sexual: RP	41.9	81.3*	76.0*	73.1*	74.7*	74.7
Sexual: RT	43.3	59.0	58.4	59.9	62.7	62.6
Incontinence: AS	11.1	12.5	14.6	18.0	16.6	20.3
Incontinence: RP	9.9	45.2*	33.5*	32.6*	31.9*	32.3*
Incontinence: RT	10.8	16.4	16.3	17.9	19.7	19.5
Bowel: AS	6.1	7.3	7.4	6.3	7.1	7.5
Bowel: RP	6.3	6.8	6.1	5.5	5.3	5.2
Bowel: RT	5.8	12.2*	9.3	9.9	8.2	6.4

+ urinary irritation scores do not fit in 10x10 Table; will be presented.  
\* denotes clinically meaningful difference based on 1/2 SD.

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## LBA-12

**Selective Bladder Preservation with Twice-Daily Radiation Plus 5-Fluorouracil/Cisplatin or Daily Radiation Plus Gemcitabine for Patients with Muscle Invasive Bladder Cancer—Primary Results of NRG/RTOG 0712: A Randomized Phase 2 Multicenter Trial**

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**Purpose/Objective(s):** To assess gemcitabine and daily radiation (GD) or 5-FU/cisplatin and twice-daily radiation (FCT) as the chemoradiation (CRT) component of a selective bladder preservation regimen.

**Materials/Methods:** Patients with T2-4a bladder cancer were randomized to FCT or GD as the CRT component of a selective bladder preservation regimen. Patients had a maximal transurethral resection and induction CRT to 40 Gy followed by cystoscopic assessment of response. Patients with a complete response (CR) received consolidation CRT to 64 Gy. Others were offered immediate cystectomy and no further CRT. Adjuvant gemcitabine/cisplatin chemotherapy was subsequently administered. The primary endpoint was the rate of distant metastasis at 3 years (DM3). Toxicity and other efficacy-related endpoints including CR and bladder intact distant metastasis-free survival at 3 years (BI-DMFS3) were also assessed. Using the Clopper-Pearson exact binomial method, the study required 32 analyzable patients for each arm, with a benchmark DM3 rate of 25% and a 1-sided significance level of 0.1. A treatment is considered of potential benefit, if the observed DM3 rate is <25%. If both meet this, toxicity will be used to select a regimen for a future trial. The study was not designed to statistically compare the treatment arms to each other.

**Results:** From 12/2008 to 4/2014, 70 patients were enrolled and 66 were eligible for analysis, 33 in each arm. Median follow-up is 4.3 years (range 0.4-7.8). DM3 was 22% and 16% for FCT and GD, respectively. BI-DMFS3 was 67% and 72%, respectively. Post-induction CR rates were 88% and 78%, respectively. Of 33 patients in the FCT group, 32 (97%) completed induction, 27 (93%) completed induction and consolidation, and 18 (54%) completed the entire protocol with adjuvant chemotherapy. Of 33 patients in the GD group, these figures were 31 (94%), 23 (92%), and 16 (48%), respectively. Of 33 patients in the FCT group, 21 (64%) had grade 3-4 toxicities during protocol treatment with 18 (54%), 2 (6%), and 2 (6%) experiencing grade 3-4 hematologic, gastrointestinal, and genitourinary toxicity, respectively. For 33 patients in the GD group, these figures were 18 (54%) overall and 14 (42%), 3 (9%) and 2 (6%), respectively.

**Conclusion:** Both regimens are promising, given DM3 rates <25%. As there was less toxicity in the GD arm, it would be reasonable to consider a gemcitabine based option as well as a cisplatin based regimen for future trials. It also suggests that daily radiation may be as effective as twice-daily radiation, which may broaden the appeal to patients for whom twice-daily radiation may not be practical.

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Committee; Bayer Healthcare. Consultant; Blue Earth Diagnostics. Advisory Board; EMD Serono/Pfizer, Genentech; ASTRO, Massachusetts Prostate Cancer Coalition, NCI, NRG Oncology. **A. Jani:** ADROP. **L. Souhami:** Honoraria; Varian Medical Systems. Travel Expenses; Varian Medical Systems. **O. Kucuk:** None. **J. Rodgers:** None. **H.M. Sandler:** Research Grant; ACR-RTOG. Consultant; Janssen, Blue Earth Diagnostics. Advisory Board; Ferring, Dendreon; NRG Oncology. **W.U. Shipley:** Stock; Pfizer. Member; NCI, BCAN.

## LBA-13

**Multi-Institutional Phase 2 Trial of High-Dose Stereotactic Body Radiation Therapy with Temporary Hydrogel Spacer for Low- and Intermediate-Risk Prostate Cancer**

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**Purpose/Objective(s):** High-dose stereotactic body radiation therapy (SBRT) yields very high rates of biochemical control for low- (LR) and intermediate-risk (IR) prostate cancer (PCa), but in our prior Phase 1/2 trial of SBRT for LR and IR PCa a degree of rectal injury (e.g., mucosal erosion or ulcer) was observed in all cases, with potential high grade toxicity associated with incidental dose to the rectal wall. We report outcomes of a multi-institutional phase 2 clinical trial of high-dose SBRT for LR and IR PCa patients following placement of a peri-rectal hydrogel spacer.

**Materials/Methods:** Eligible patients included men with localized PCa with Gleason score 6-7, PSA ≤15, and clinical/radiographic stage ≤ T2c. Patients underwent hydrogel spacer placement followed by 45 Gy in five fractions to the prostate only; concurrent hormone therapy was not used. Primary endpoints were reduction in the rate of rectal erosion/ulcer events within 9 months and rates of peri-rectal space creation ≥ 7.5 mm. Potential rectal erosion/ulceration was assessed at 1.5, 3, 6, and 9 months post-treatment by direct anoscopy. Toxicity using Common Toxicity Criteria for Adverse Events v.4.0, quality of life, dosimetric outcomes, and oncologic outcomes data were collected. The proposed study had >90% power to detect significant reduction in mucosal injury rate from the observed rate of 90% in the preceding Phase 1/2 clinical trial to < 70% (alpha=0.05, two-sided exact test).

**Results:** A total of 44 patients treated at 2 institutions were included; 7 patients (15.9%) had Gleason 6(3+3) PCa, 25 (56.8%) had Gleason 7(3+4) PCa, and 12 (27.3%) had Gleason 7(4+3) PCa. Median PSA at treatment was 6.5 (range 1.7-13.5). All patients received protocol therapy; overall rate of dosimetry noncompliance was 1.8%. A total of 6 rectal erosions/ulcers (five grade 1, one grade 2) were observed (13.6%), meeting the trial's primary objective. All of them were minimally symptomatic and resolved on repeat anoscopy within 6 months. Median space creation was 11.5 mm; only 1 spacer (2.3%) did not meet the protocol goal of ≥7.5mm of space created, but overall trial endpoint was met with >95% of patients with spacer distance of ≥ 7.5mm. At a median follow-up of 12 months, freedom from biochemical failure was 100%. There were no ≥ Grade 3 acute or chronic gastrointestinal toxicities. Acute and late urinary Grade 3 toxicities occurred in 2 (4.5%) of patients; one spacer site infection and one urinary tract pain, both resolved. No >Grade 3 toxicities occurred.

**Conclusion:** This is the first prospective study to evaluate the efficacy of hydrogel spacer for patients undergoing SBRT for PCa. Hydrogel spacer placement prior to high-dose SBRT treatment for PCa significantly reduces rectal erosion/ulcer events. This is expected to reduce long-term rectal toxicity; there are no high-grade rectal events noted on study to date.



Protocol patients will continue to be followed for toxicity, biochemical control, overall and disease specific survival, and quality of life outcomes.

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## LBA-14

### Two-Year Results for MC1273, a Phase 2

#### Evaluation of Aggressive Dose De-

#### Escalation for Adjuvant Chemoradiation in

#### HPV+ Oropharynx Squamous Cell Carcinoma (OPSCC)

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**Purpose/Objective(s):** Adjuvant therapy for HPV+ OPSCC has well-documented rates of grade  $\geq 2$  toxicities and 2-year disease free survival (DFS) (55% and 86.4% on RTOG 0234). The purpose of this study is to determine if dose de-escalation to 30-36 Gy for selected patients with HPV+ OPSCC can maintain historical rates for disease control while reducing toxicity and improving swallow function/QOL.

**Materials/Methods:** MC1273 is a single-arm phase 2 trial testing an aggressive course of treatment de-escalation following margin-clearing surgery and simultaneous neck dissection. Eligibility criteria included patients with p16+ OPSCC,  $\leq 10$  pack-year smoking history, and negative margins. Cohort A ( $\geq T3$ ,  $\geq N2$ , lymphovascular invasion, or perineural invasion) received 30 Gy delivered in 1.5 Gy b.i.d. over 12 days along with weekly docetaxel (15 mg/m<sup>2</sup>, days 1 & 8). Patients with +ECE were enrolled in Cohort B and received the same treatment plus a simultaneous integrated boost to nodal levels with ECE to 36 Gy in 1.8 Gy b.i.d. The primary endpoint was local/regional control at 2 years. Secondary endpoints included 2-yr disease free survival, toxicity, swallow function, and patient reported QOL. Each cohort was powered to detect a 10% LRF rate with 85% confidence. Patients received a modified barium swallow impairment profile (MBSImP) before, 1 month post, and 1 year post-radiation therapy (RT). Patients also had QOL assessments consisting of the University of Michigan Xerostomia QOL Scale (XeQOLS), Functional Assessment of Cancer Therapy-HN Ver 4 (FACT-HN), European Quality of Life (Eq)-5D, and the EORTC-HN assessed at pre-RT and 1, 3, 12, and 24 months post-RT.

**Results:** Accrual was from 9/13–6/16 ( $n = 80$ , Cohort A: 37, Cohort B: 43). Median follow-up as of 8/17 was 24 months; no patient died or was lost to follow-up. Local/regional control is 95% (3 local, 1 regional), distant control 94% ( $n = 5$ ), disease-free survival 89%. Swallowing function improved between pre-treatment and 12 months' follow-up (MBSImP 47.4 $\pm$ 5.2 vs 48.6 $\pm$ 4.8,  $P = .03$ ) and no patients required feeding tube placement. Grade 2/ $\geq 3$  toxicity rates at pre-TX, 1 yr, and 2 yr post-RT are 12%/3%, 1%/0%, and 10%/0%. All cumulative grade  $\geq 3$  toxicity occurred by 3 months ( $n = 14$  pts, 18%) and resolved by 6 months. One patient had a transient grade 4 hypotensive event related to a docetaxel infusion reaction. Only the XeQOLS worsened after treatment (70.3 $\pm$ 6.7 vs 64.8 $\pm$ 8.8,  $P < .0001$ ) while the EORTC-HN, FACT-HN, and Eq-5D remained essentially unchanged or improved.

**Conclusion:** Aggressive treatment de-escalation resulted in locoregional control rates comparable to historical controls, low toxicity, and no decrement in swallowing function or QOL. A follow-up phase 3, multi-center study is actively accruing.

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## LBA-15

### Healthcare Disparities in Cancer Patients

#### Receiving Radiation: Changes in Insurance

#### Status After Medicaid Expansion Under the

#### Affordable Care Act

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**Purpose/Objective(s):** The Patient Protection and Affordable Care Act (ACA) was designed to improve healthcare access by expanding insurance coverage including provisions aimed at decreasing disparities. Specifically for cancer patients, this includes improving access to high-quality cancer care which may include radiation therapy. This study compares insurance status in cancer patients receiving radiation before and after Medicaid expansion under the ACA. The hypothesis is that patients receiving radiation in fully expanded states were less likely to be uninsured.

**Materials/Methods:** All newly diagnosed cancer patients  $\geq 18$  and  $< 65$  years from 2011-2014, treated with radiation, were compiled from the Surveillance, Epidemiology, and End Results Database. Patients with multiple primary sites (if not first diagnosis) or with unknown insurance status were excluded. Insurance rates at diagnosis were examined before (2011-2013) and after Medicaid expansion (2014); rates were compared between states that fully expanded Medicaid in 2014 (EXP) and those that did not fully expand Medicaid in 2014 (non-EXP).

**Results:** A total of 197,290 patients were analyzed based on the above inclusion criteria. Median age was 55. The patients were 78% white, 60% were female, and 73% lived in EXP states. Prior to 2014, non-EXP states had nearly twice the rate of uninsured cancer patients. After expansion, there was a 52% relative drop in uninsured rates in EXP states (from 4.4% to 2.1%,  $P < .0001$ ), with a corresponding increase in Medicaid enrollment. In non-EXP states, there was a 5% relative drop in uninsured rates from 8.4% to 8.0% with increase in non-Medicaid insurance (75.7% to 77.1%) and decrease in Medicaid (15.9% to 14.9%);  $P < .0001$ . In EXP states, the uninsured rate decreased regardless of race (whites: relative decrease 56%, 4.3% to 1.9%; blacks: relative decrease 50%, 6.0% to 3.0%; both  $p < .0001$ ). In non-EXP states, there was a racial disparity with only whites showing a decrease in uninsured rates (whites: relative decrease 9%, 7.8% to 7.1%,  $P < .0001$ ; blacks: relative increase 7%, 9.9% to 10.6%,  $P = .37$ ). In EXP states, the uninsured rate decreased regardless of county poverty level (low poverty: relative decrease 46%, 3.9% to 2.1%; high poverty: relative decrease 60%, 4.5% to 1.8%; both  $P < .0001$ ). In non-EXP states, there was an apparent disparity with only those living in areas with the lowest poverty showing benefit (low poverty: relative decrease 27%, 4.8% to 3.5%,  $P = .04$ ; high poverty: relative increase 2%, 10.9 to 11.1%,  $P = .17$ ).

**Conclusion:** Medicaid expansion in 2014 significantly decreased the uninsured rates for cancer patients receiving radiation therapy. Non-expanded states appeared to have healthcare disparities benefiting primarily whites and those living in areas with the lowest poverty levels; these disparities were not found in expanded states. Further research should assess how these changes in healthcare disparities may affect cancer outcomes.

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993 Arizona State University, Vivor, LLC. Consultant; Genentech-Roche.  
 994 Stock; Novartis. **L. Havrilesky:** Employee; Bioventus. Research Grant;  
 995 AstraZeneca. **J.P. Chino:** Partner; Duke University Cancer Center.  
 996 Research Grant; Varian Medical Systems. Stock; NanoScint. Co-Founder/  
 997 Owner; NanoScint.

## LBA-16

### Cost of Acute and Follow-Up Care in Patients with Pre-Existing Psychiatric Diagnoses Undergoing Radiation Therapy



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1005 **Purpose/Objective(s):** Psychiatric health is an essential component of  
 1006 comprehensive cancer care. However, little has been done to quantify  
 1007 the impact of pre-existing psychiatric conditions on the cost of cancer  
 1008 care. In this study, we assess the acute and follow up costs for patients  
 1009 with and without psychiatric comorbidities undergoing radiation therapy  
 1010 (RT).

1011 **Materials/Methods:** A cost of care review was conducted for patients  
 1012 initially diagnosed with cancer and undergoing RT at a single institution  
 1013 from 2009 to 2014. Patients were denoted as having pre-existing psychiatric  
 1014 conditions if they were found to have billing codes for any of the 422  
 1015 ICD-9 psychiatric conditions 12 months prior to their cancer diagnosis.  
 1016 Elixhauser comorbidity index was calculated to assess other comorbidities.  
 1017 Acute and follow-up costs were collected as all costs 0 to 6 months  
 1018 and 6 to 24 months after the cancer diagnosis and subcategorized for

1024 clinic, emergency department (ED), hospital inpatient, and hospital  
 1025 outpatient costs. Standardized costs were obtained from our Cost Data  
 1026 Warehouse. Medicare reimbursement was applied to professional services,  
 1027 service line hospital charges were multiplied by Medicare cost report cost-  
 1028 to-charge ratios, and adjustments were made for inflation with the Gross  
 1029 Domestic Product (GDP) implicit price deflator to create 2014 standardized  
 1030 costs.

1031 **Results:** There were 1,275 patients diagnosed and treated at our institution  
 1032 and 126 (9.9%) had at least one pre-existing psychiatric diagnosis. Acute  
 1033 and long-term costs were both higher in the group with pre-existing psychiatric  
 1034 diagnoses (Table 1). The three largest differences in costs were  
 1035 follow-up ED costs, (208% higher,  $P = .0003$ ), follow-up hospital outpatient  
 1036 costs (193% higher,  $P = .04$ ), and follow-up hospital inpatient costs  
 1037 (190% higher,  $P = 0.002$ ). Age, race, sex, and treatment modalities were  
 1038 comparable between the groups, but the psychiatric group had a higher  
 1039 median number of comorbidities (5 versus 3) and the psychiatric group had  
 1040 more respiratory cancer diagnoses than the non-psychiatric group (31%  
 1041 versus 17%).

1042 **Conclusion:** Efforts to develop new payment models in radiation oncology  
 1043 should also consider measures to address behavioral health in order to  
 1044 reduce the total cost of care during and after RT. Addressing psychiatric  
 1045 comorbidities proactively may be a way to mitigate cost differential for  
 1046 these patients.

1047 **Author Disclosure:** **M.R. Waddle:** None. **T. Kaleem:** None. **S.K. Niazi:**  
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 1049 **D.I. Aljabri:** None. **J.Y. Habboush:** None. **R.C. Miller:** Consultant;  
 1050 Tekcapital, Plc, ASTRO, Belluscura Ltd. Stock; Belluscura Ltd., Tekcapital  
 1051 Plc. Stock Options; Belluscura Ltd., Tekcapital Plc.. Member, Board  
 1052 of Directors; Tekcapital, Plc. Non-Executive Director and Chair; Belluscura,  
 1053 Ltd. Board of Trustees member; Mayo Clinic Health System - Albert  
 1054 Lea/Austin.

		Pre-existing Psychiatric Diagnosis		Wilcoxon P-value
		Yes	No	
		Average Cost ± St Dev	Average Cost ± St Dev	
Acute Costs (0 - 6 months)	Total Cost	\$45,293 ± \$28,801	\$41,904 ± \$33,143	.039
	Clinic	\$24,418 ± \$14,971	\$22,200 ± \$16,229	.052
	ED	\$659 ± \$1,061	\$384 ± \$823	<.0001
	Hosp Inpt	\$13,482 ± \$20,262	\$13,895 ± \$25,385	.225
Follow-up (6-24 months)	Hosp Outpt	\$6,733 ± \$6,093	\$5,426 ± \$5,763	.002
	Total Cost	\$28,084 ± \$44,336	\$18,431 ± \$35,616	.003
	Clinic	\$10,623 ± \$20,915	\$9,314 ± \$18,594	.242
	ED	\$761 ± \$1,380	\$365 ± \$918	.0003
	Hosp Inpt	\$12,370 ± \$28,405	\$6,509 ± \$25,502	.002
	Hosp Outpt	\$4,330 ± \$12,625	\$2,244 ± \$5,560	.04