## IGCS19-0199

392 **PRE AND POST TREATMENT PELVIC BONE DENSITY AND LOW BACK ACHE ANALYSIS IN PATIENTS OF CARCINOMA CERVIX UNDERGOING CHEMORADIATION-AN INTERIM ANALYSIS OF AN ONGOING TRIAL**

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**Objectives** Low back ache is often reported by cervical cancer patients post radiation treatment. We hypothesized that pelvic radiation therapy might lead to bone density changes. Hence a prospective clinical trial to evaluate pelvic bone density changes, if any and low back ache was sought in patients of locally advanced carcinoma cervix undergoing concurrent chemoradiation therapy (CCRT) at our institute. We hereby present an interim analysis of our study.
**Methods** Data of 57 patients was analysed. Pelvic bone density was assessed using Dual Energy X-ray Absorptiometry (DEXA) scan which was done pre and post (at 1 year) of CCRT. Also pre and post RT Pain and disability scoring was done using Oswestry Low Back Pain Disability scale. Results were statistically analysed.
**Results** The mean pre and post RT BMDs at the radiated lumbar vertebra 5 (L5) was 0.815g/cm2 and 0.679 gm/cm2 and mean T score for radiated femoral neck (FN) was -1.586 and -2.435, respectively. Similarly at non-irradiated thoracic vertebrae 12 (D12) site pre and post RT mean BMD values were -1.326 gm/cm2 and -2.440 gm/cm2 respectively. Results were statistically significant ($p<0.001$). Median Low back ache score for pre RT was 3 and post RT was 4.Median disability index was 27.9 pre RT and 30.8 post RT. Statistically significant pain and disability score was observed ($p<0.001$).
**Conclusions** Though our interim analysis showed that radiation treatment might lead to significant changes in pelvic bone density and increase in low back and disability score, definitive conclusion could only be drawn after completion of the trial.

## IGCS19-0383

393 **KEYNOTE-826: A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF PEMBROLIZUMAB PLUS CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF PERSISTENT, RECURRENT, OR METASTATIC CERVICAL CANCER**

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**Objectives** For patients with recurrent/metastatic cervical cancer, incorporation of anti-angiogenesis therapy with chemotherapy yields a modest survival benefit of 3.7 months over chemotherapy alone (Tewari et al. *NEJM*. 2014). The rationale for checkpoint inhibition is supported by programmed death ligand-1 (PD-L1) expression in some cervical cancers (~70%), with a higher proportion noted in squamous cell carcinoma vs adenocarcinoma. Based on the 14.3% objective response in KEYNOTE-158, the US FDA granted accelerated approval to pembrolizumab for PD-L1–positive cervical cancer for second-line therapy and beyond.
**Methods** KEYNOTE-826 is a phase 3, randomized, double-blind, placebo-controlled, multinational trial of chemotherapy with pembrolizumab or placebo for first-line treatment of recurrent, persistent, or metastatic cervical cancer. Patients not previously treated with chemotherapy for recurrence and not amenable to curative treatment will be randomized 1:1 to chemotherapy + pembrolizumab 200 mg or placebo every 3 weeks. The chemotherapy regimen (paclitaxel 175 mg/m$^2$ + cisplatin 50 mg/m$^2$ or carboplatin AUC 5, with or without bevacizumab 15 mg/kg) will be selected by investigators pre-randomization. Stratification factors include metastatic status at diagnosis (yes/no), bevacizumab use (yes/no), and tumor PD-L1 status (combined positive score <1, 1 to <10, or ≥10). Treatment will continue until disease progression, unacceptable toxicity, or voluntary patient withdrawal for up to 35 cycles (~2 years). Primary endpoints are progression-free survival (PFS) per RECIST v1.1 assessed by blinded independent central review and overall survival. Secondary endpoints are objective response, duration of response, 12-month PFS, patient-reported quality of life, and safety. Enrollment is ongoing globally. ClinicalTrials.gov identifier: NCT03635567.

# Uterine Cancer Including Sarcoma

## IGCS19-0081

394 **SENTINEL LYMPH NODE MAPPING VS SYSTEMATIC LYMPHADENECTOMY FOR ENDOMETRIAL CANCER: SURGICAL MORBIDITY AND LYMPHATIC COMPLICATIONS**

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**Objectives** Sentinel lymph node (SLN) mappinghas been proven to accurately stage endometrial cancer (EC). However, there is a lack of studies comparing the incidence of complications between different lymph node approaches in EC. Our objective is to define the complication rates of SLN biopsy in EC patients.
**Methods** We retrospectively analyzed all patients with EC surgically treated at Barretos Cancer Hospital between April 2013 and March 2018. We evaluated intraoperative complications and 30-day complications using the Memorial Sloan Lettering Cancer Center's Surgical Secondary Events

**Abstract 394 Table 1**

| Parameter | | Surgical Morbidity | | | | *p* value |
|---|---|---|---|---|---|---|
| | | HT | HT SLN | HT LND | HT LND SLN | |
| | | 54 (21.6%) | 61 (24.4%) | 89 (35.6%) | 46 (18.4%) | |
| Age | | 61 (35 - 89) | 60 (44 - 87) | 62 (31 - 80) | 63 (46 - 77) | 0.152 |
| BMI | | 31.8 (21.9 - 51.0) | 33(21.4 - 48.3) | 30.4 (18.0 - 46.3) | 29.3 (22.2 - 41.3) | 0.019 |
| ASA | | | | | | 0.410 |
| | 1 | 6 (11.5%) | 7 (11.5%) | 12 (13.6%) | 7 (15.2%) | |
| | 2 | 36 (69.2%) | 42 (68.9%) | 67 (76.1%) | 26 (78.3%) | |
| | 3 | 8 (15.4%) | 12(19.7%) | 8 (9.1%) | 3 (6.5%) | |
| | 4 | 2 (3.8%) | 0 (0.0%) | 1 (1.1%) | 0 (0.0%) | |
| Technique | | | | | | <0.001 |
| | Laparotomy | 5 (9.3%) | 0 (0.0%) | 10 (11.2%) | 0 (0.0%) | |
| | Laparoscopy | 48 (88.9%) | 45 (73.8%) | 71 (79.8%) | 30 (65.2%) | |
| | Converted* | 1 (1.9%) | 0 (0.0%) | 2 (2.2%) | 0 (0.0%) | |
| | Robotic | 0 (0.0%) | 16 (26.2%) | 6 (6.7%) | 16 (34.8%) | |
| Surgical time (minutes) | | 135.0 (50.0-270.0) | 152.5 (60.0-300.0) | 370.0 (80.0-600.0) | 240.0 (125.0-420.0) | <0.001 |
| Blood Loss (mL) | | 35.0 (0.0-500.0) | 20.0 (0.0-500.0) | 100.0(0.0-2300.0) | 45.0 (0.0-500.0) | <0.001 |
| Intra-operative complication | | | | | | 0.015 |
| | No | 54 (100.0%) | 60 (98.4%) | 80 (89.9%) | 40 (87.0%) | |
| | Vascular | 0 (0.0%) | 0 (0.0%) | 6 (6.7%) | 6(13.0%) | |
| | Urinary | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) | 0 (0.0%) | |
| | Neurological | 0 (0.0%) | 1 (1.6%) | 1 (1.1%) | 0 (0.0%) | |
| | Intestinal | 0 (0.0%) | 0 (0.0%) | 2 (2.2%) | 0 (0.0%) | |
| | All | 0 (0.0%) | 1 (1.6%) | 10 (11.2%) | 6 (13.0%) | 0.005 |
| 30-day Complication | | | | | | <0.01 |
| | No | 46 (85.3%) | 54 (88.5%) | 55 (61.8%) | 37 (80.4%) | |
| | I | 2 (3.7%) | 5 (8.2%) | 16 (18.0%) | 1 (2.2%) | |
| | II | 2 (3.7%) | 0 (0.0%) | 9 (10.1%) | 0 (0.0%) | |
| | III | 0 (0.0%) | 0 (0.0%) | 5 (5.6%) | 5 (10.9%) | |
| | IV | 1 (1.9%) | 2 (3.3%) | 2 (2.2%) | 2 (4.3%) | |
| | V | 3 (5.6%) | 0 (0.0%) | 2 (2.2%) | 2 (4.3%) | |
| | Yes | 8 (14.8%) | 7 (11.5%) | 34 (38.2%) | 9 (19.6%) | <0.01 |
| LLL | | | | | | 0.001 |
| | No | 54 (100.0%) | 61 (100.0%) | 80 (89.9%) | 46 (100.0%) | |
| | Yes | 0 (0.0%) | 0 (0.0%) | 9 (10.1%) | 0 (0.0%) | |

HT= hysterectomy plus salpingo-oophorectomy
HT + PLS= hysterectomy plus salpingo-oophorectomy and sentinel lymph node
HT + LND= hysterectomy plus salpingo-oophorectomy and lymph node dissection
HT + LND + SLN= hysterectomy plus salpingo-oophorectomy, sentinel lymph node and lymph node dissection
LLL= lower limp lymphedema
BMI= Body mass index
*All surgeries were initially laparoscopic

**Abstract 394 Table 2**

| Parameter | | Surgical Morbidity | | *p* value |
|---|---|---|---|---|
| | | HT | HT SLN | |
| | | 54 (47.0%) | 61 (53.0%) | |
| Age | | 61 (35 - 89) | 60 (44 - 87) | 0.632 |
| BMI | | 31.8 (21.9 - 51.0) | 33.0 (44.0 - 87.0) | 0.827 |
| ASA | | | | 0.562 |
| | 1 | 6 (11.5%) | 7 (11.5%) | |
| | 2 | 36 (89.2%) | 42 (68.9%) | |
| | 3 | 8 (15.4%) | 12 (19.7%) | |
| | 4 | 2 (3.8%) | 0 (0.0%) | |
| Technique | | | | <0.001 |
| | Laparotomy | 5 (9.3%) | 0 (0.0%) | |
| | Laparoscopy | 48 (88.9%) | 45 (73.8%) | |
| | Converted* | 1 (1.9%) | 0 (0.0%) | |
| | Robotic | 0 (0.0%) | 16 (26.2%) | |
| Surgical time (minutes) | | 135.0 (50.0-270.0) | 152.0 (60.0-300.0) | 0.016 |
| Blood Loss (mL) | | 35.0 (0.0-500.0) | 20.0 (0.0-500.0) | 0.386 |
| Intra-operative complication | | | | 1.0 |
| | No | 54 (100.0%) | 60 (98.4%) | |
| | Vascular | 0 (0.0%) | 0 (0.0%) | |
| | Urinary | 0 (0.0%) | 0 (0.0%) | |
| | Neurological | 0 (0.0%) | 1 (1.6%) | |
| | Intestinal | 0 (0.0%) | 0 (0.0%) | |
| | All | 0 (0.0%) | 1 (1.6%) | 1.0 |
| 30-day Complication | | | | 0.134 |
| | No | 46 (85.3%) | 54 (88.5%) | |
| | I | 2 (3.7%) | 5 (8.2%) | |
| | II | 2 (3.7%) | 0 (0.0%) | |
| | III | 0 (0.0%) | 0 (0.0%) | |
| | IV | 1 (1.9%) | 2 (3.3%) | |
| | V | 3 (5.6%) | 0 (0.0%) | |
| | Yes | 8 (14.8%) | 7 (11.5%) | |
| LLL | | | | 0.782 |
| | No | 54 (100.0%) | 61 (100.0%) | |
| | Yes | 0 (0.0%) | 0 (0.0%) | |

BMI= Body mass index
LLL= lower limp lymphedema
HT= hysterectomy plus salpingo-oophorectomy
HT + PLS= hysterectomy plus salpingo-oophorectomy and sentinel lymph node

Grading System, separating the patients into four groups: hysterectomy (HT); hysterectomy plus pelvic lymphadenectomy, with or without para-aortic dissection (HT+LND); hysterectomy plus sentinel biopsy (HT+SLN); and hysterectomy plus lymphadenectomy and sentinel biopsy (HT+SLN +LND).

**Results** As compared with the HT group, the HT+SLN group did not show any increased risk of complications in terms of intraoperative injury (0vs1; $p=1.0$) and 30-day complications (8vs7; $p=0.782$).The HT+LND group had an increased surgical time (370 min, $p<0.001$), greater intraoperative blood loss (100cc, $p<0.001$), and a higher incidence of injury during surgery (7%, $p=0.005$) and any 30-day complication (38.2%, $p=0.002$) as compared with HT+SLN. Performing LND was associated with a greater risk of 30-day complications (hazard ratio [HR]:14.25; 95% confidence interval [CI]:1.85–19.63) and intraoperative injury (HR:3.11; 95% CI:1.62–5.98).

**Conclusions** SLN mapping does not increase morbidity in the surgical treatment of EC patients, and compared with comprehensive lymphadenectomy, it has a lower risk of complications. Our findings support the use of the SLN algorithm in EC patients.

**Abstract 394 Table 3**

| | Surgical Morbidity | | | | |
|---|---|---|---|---|---|
| | No LND | LND | | Hazard Ratio vs | |
| Parameter | 115 (46%) | 135 (54%) | *p* value | No LND (95% CI) | *p* value |
| Age | 60 (35 - 89) | 63 (31 - 80) | 0.035 | | |
| BMI | 32.4 (21.4 - 51.0) | 29.85 (18.0 - 46.3) | 0.003 | | |
| ASA | | | 0.101 | | |
| 1 | 13 (11.5%) | 19 (14.2%) | | | |
| 2 | 78 (69.0%) | 103 (76.9%) | | | |
| 3 | 20 (17.7%) | 11 (8.2%) | | | |
| 4 | 2 (1.8%) | 1 (0.7%) | | | |
| Technique | | | 0.645 | | |
| Laparotomy | 5 (4.3%) | 10 (7.4%) | | | |
| Laparoscopy | 93 (80.9%) | 101 (74.8%) | | | |
| Converted* | 1 (0.9%) | 2 (1.5%) | | | |
| Robotic | 16 (13.9%) | 22 (16.3%) | | | |
| Surgical time (minutes) | 150.0 (50.0 - 300.0) | 270.0 (80.0 - 600.0) | <0.001 | | |
| Blood Loss (mL) | 27.5 (0.0 - 5000.0) | 80.0 (0.0 - 2300.0) | <0.001 | | |
| Intra-operative complication | | | 0.002 | | |
| No | 114 (99.1%) | 119 (88.1%) | | | |
| Vascular | 0 (0.0%) | 12 (8.9%) | | | |
| Urinary | 0 (0.0%) | 1 (0.75%) | | | |
| Neurological | 1 (0.9%) | 1 (0.75%) | | | |
| Intestinal | 0 (0.0%) | 2 (1.5%) | | | |
| Total | 1 (0.9%) | 16 (11.9%) | 0.001 | 14.25 (1.85 - 19.63) | 0.011 |
| 30-day Complication | | | 0.001 | | |
| No | 100 (87.0%) | 92 (68.1%) | | | |
| I | 7 (6.1%) | 17 (12.6%) | | | |
| II | 2 (1.7%) | 9 (6.7%) | | | |
| III | 0 (0.0%) | 10 (7.4%) | | | |
| IV | 3 (2.6%) | 3 (2.2%) | | | |
| V | 3 (2.6%) | 4 (3.0%) | | | |
| Yes | 15 (13.0%) | 43 (31.9%) | <0.001 | 3.11 (1.62 - 5.98) | 0.001 |
| Major Complications (III, IV or V) | 6 (5.2%) | 17 (12.6%) | <0.01 | 3.08 (1.16 - 8.14) | 0.023 |
| LLL | | | <0.01 | 8.14 (1.01 - 65.27) | 0.048 |
| No | 115 (100.0%) | 126 93.3%) | | | |
| Yes | 0 (0.0%) | 9 (6.7%) | | | |

BMI= Body mass index
HT= hysterectomy plus salpingo-oophorectomy
HT + PLS= hysterectomy plus salpingo-oophorectomy and sentinel lymph node
HT + LND= hysterectomy plus salpingo-oophorectomy and lymph node dissection
HT + LND + SLN= hysterectomy plus salpingo-oophorectomy, sentinel lymph node and lymph node dissection
No LND= combination of the HT and HT + PLS
LND= combination of the HT + LND and HT + LND + SLN
LLL= lower limp lymphedema
*All surgeries were initially laparoscopic

# IGCS19-0527

## 395 OUTCOMES OF CARBOTAXOL IN CARCINOSARCOMA: A RETROSPECTIVE STUDY AT THE BRAZILIAN NATIONAL CANCER INSTITUTE (INCA)

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**Objectives** Endometrial carcinosarcomas (EC) are rare metaplastic tumors with dual composition of mesenchymal and epithelial elements, seen as a good example of epithelial-mesenchymal transition (EMT). The current study evaluated the efficacy and safety of Carbotaxol (CT) as adjuvant and first-line (1L) palliative treatment for women with carcinosarcoma.

**Methods** This retrospective cohort of patients (pts) with EC treated with 3qw Carbotaxol at INCA between January 2012 and January 2017 assessed overall survival (OS), disease-free survival (DFS), progression-free survival (PFS), response rate (RR), and tolerability. All analyses were performed with the SPSS software, version 18.0.

**Results** A total of 48 pts were enrolled, median age 66.1 years, mostly with stage III disease (43.8%). The median OS for all pts was 21.5 m. For stage IV, OS was 11.1 m. The median DFS for pts treated with adjuvant CT was 20.5 m. For the 21 stage IV pts treated with 1L CT, the median PFS was 6.9 m and median OS was 12.3 m; partial response occured in 9.5%, stable disease in 28.6% and disease progression in 57.1%. The main side effects were asthenia, alopecia, vomiting and myelotoxicity.

**Conclusions** The combination of carboplatin and paclitaxel has been shown to be effective and safe for the treatment of EC. Staging was confirmed as a strong prognostic factor. The adverse events were manageable and there were no chemo-related deaths. The results were quite similar to those previously reported by multicenter studies.