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/m² + cisplatin 50 mg/m² 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) mapping has 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 54 (21.6%)	HT SLN 61 (24.4%)	HT LND 89 (35.6%)	HT LND SLN 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 limb lymphedema
BMI= Body mass index
*All surgeries were initially laparoscopic

Abstract 394 Table 2

Parameter	Surgical Morbidity		p value
	HT 54 (47.0%)	HT SLN 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 limb 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

Parameter	Surgical Morbidity		p value	Hazard Ratio vs No LND (95% CI)	p value
	No LND 115 (46%)	LND 135 (54%)			
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 limb lymphedema

*All surgeries were initially laparoscopic

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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 meta-plastic 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 occurred 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.