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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.

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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

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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