immunostimulatory activity of the PD-1 inhibitor pembrolizumab may be enhanced by concurrent chemoradiotherapy (CCRT). After the KEYNOTE-158 study, in which pembrolizumab showed durable antitumor activity, pembrolizumab monotherapy was approved for patients with PD-L1-positive recurrent or metastatic cervical cancer who progressed during or after chemotherapy. ENGOT-cx11/GOG 3047/KEYNOTE-A18 (NCT04221945) is a phase 3, randomized, placebo-controlled study evaluating pembrolizumab with CCRT for the treatment of high-risk, locally advanced cervical cancer.

Methodology Approximately 980 patients with high-risk (International Federation of Gynecology and Obstetrics 2014 stage IB2-IIB with node-positive disease or stage III-IVA), locally advanced, histologically confirmed cervical cancer who have not received systemic therapy, immunotherapy, definitive surgery, or radiation will be randomized 1:1 to receive either 5 cycles of pembrolizumab 200 mg every 3 weeks (Q3W) + CCRT followed by 15 cycles of pembrolizumab 400 mg Q6W or 5 cycles of placebo Q3W + CCRT followed by 15 cycles of placebo Q6W. CCRT includes 5 cycles (optional 6th dose) of cisplatin 40 mg/m² Q1W + EBRT followed by brachytherapy. Randomization is stratified by planned EBRT type (intensity-modulated radiotherapy [IMRT] or volumetric-modulated arc therapy [VMAT] vs non-IMRT or non-VMAT), cancer stage at screening (stage IB2-IIB vs III-IVA), and planned total radiotherapy dose. Treatment will continue until the patient has received 20 cycles of pembrolizumab (5 cycles 200 mg Q3W, 15 cycles 400 mg Q6W) vs placebo (~2 years) or until disease progression, unacceptable toxicity, or withdrawal. Primary endpoints are progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors version 1.1 by investigator and overall survival (OS). Secondary endpoints include PFS by blinded independent central review, PFS at 2 years, OS at 3 years, complete response at 12 weeks, objective response rate, PFS and OS by PD-L1 status, quality of life, and safety. Enrolment began May 2020 and is planned for 193 sites in 30 countries.

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MRI BASED TUMOUR RADIOMICS IN CARCINOMA CERVIX: A POTENTIAL PREDICTOR OF RESPONSE TO CHEMORADIATION

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10.1136/ijgc-2021-ESGO.22

Introduction/Background* To determine if baseline T2weighted (T2W) MRI texture parameters can predict response to chemoradiation in cervical carcinoma.

Methodology Seventy-four patients of locally advanced carcinoma cervix treated with definitive chemoradiation (45Gy in 25 fractions and weekly cisplatin (40 mg/m²) and image guided brachytherapy between 2017 and 2019 were included. Gross tumour volume (GTV) and high risk clinical target volume (HRCTV) was delineated on T2W MRI at baseline and at brachytherapy using the texture analysis software. Tumour regression >75% was considered as a surrogate of good response. Multiple tumour slices were sampled and first order

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statistics were applied to produce 6 texture parameters, namely mean intensity, standard deviation, entropy, mean positive pixels, skewness, and kurtosis. After using fine, moderate, and coarse anatomical filters a total of 36 texture variables were generated.

Clinical variables namely histological subtype, tumour grade, FIGO 2009 stage and nodal status were documented. These clinical variables along with texture parameters were compared with treatment response using the Mann-Whitney U test. Lasso regression was used to select texture parameters that best correlated with treatment response. These were used to develop support vector machine (SVM) models which were validated using 10-fold cross validation. The most parsimonious model was described in terms of area under curve (AUC) and metrics of diagnostic accuracy.

Result(s)* The median age was 50 years (range 34 to 65). Overall, 63 (85%) had squamous cell carcinoma. Half of the included patients (37/74) had positive pelvic or para-aortic lymph nodes. As per FIGO 2018 criteria 23 (31%) and 51 (69%) patients were stage II and III, respectively. Good response was seen in 10/74 patients. None of the clinical variables discriminated between response. However, high mean and skewness, and low entropy and kurtosis did significantly correlate with poor response. Using 15 selected features, the best SVM model had an AUC of 0.85 and accurately classified 86.5% cases, with sensitivity and specificity of 55% and 93%, respectively.

Conclusion* Tumour radiomics can be utilized to predict response to chemoradiation whereas baseline clinical parameters do not predict for response. Baseline texture analysis can be an important tool to predict response to chemoradiation.

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SOCIOECONOMIC FACTORS ASSOCIATED WITH PREVALENCE AND STAGING OF CERVICAL CANCER

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10.1136/ijgc-2021-ESGO.23