patients experience persisting substantial symptoms. LAPERS/median prevalence ratios close to 1 indicate that the proportion of patients experiencing substantial symptoms displayed in the prevalence over time are the same individual patients with persisting symptoms.

Conclusions LAPERS method provides complementary information to prevalence and incidence rates. LAPERS provides a more appropriate tool for a valid assessment of patients' burden of substantial toxicity.

IGCS19-0619

19

A LARGE, MULTICENTER, RETROSPECTIVE STUDY ON EFFICACY AND SAFETY OF STEREOTACTIC BODY RADIOTHERAPY (SBRT) IN OLIGOMETASTATIC OVARIAN CANCER (MITO RT1 STUDY)

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Objectives The aim of this retrospective, multicenter study (MITO RT-01) was to define activity and safety of Stereotactic Body Radiotherapy (SBRT) in a very large, real life dataset of metastatic/persistent/recurrent ovarian cancer (MPR-OC) patients. Clinical and SBRT parameters have been analyzed in order to identify predictors of outcome.

Methods The endpoints of the study were the rate of complete response (CR) to SBRT, and the 24-month actuarial local control (LC) rate on "per lesion" basis. The secondary endpoints were acute and late toxicities, and the 24-month

actuarial late toxicity free survival. Toxicity was evaluated by RTOG/EORTC and CTC-AE scales, according to center policy. Logistic and Cox regression were used for the uni- and multivariate analysis of factors predicting clinical CR and actuarial outcomes.

Results CR, PR and SD were observed in 291 (65.2%), 106 (23.8%), and 33 (7.4%) lesions. Patient age <60 years, PTV <18 cm³, lymph node disease, and BED α/β 10 >70 Gy were associated with higher chance of CR in the multivariate analysis. With a median follow-up of 22 months (range: 3–120), the 24-month actuarial LC rate was 81.9%. Achievement of CR and total dose >25 Gy were associated with better LC rate in the multivariate analysis. Mild toxicity was experienced in 54 (20.7%) patients. The 24-month late toxicity free survival rate was 95.1%.

Conclusions This study confirms the activity and safety of SBRT in MPR-OC patients and identifies clinical and treatment parameters able to predict CR and LC rate.

IGCS19-0461

20

CLINICAL TRIAL WITH TOPICAL USE OF ESTROGEN, TESTOSTERONE AND VAGINAL DILATOR IN WOMEN WITH CERVICAL CANCER AFTER RADIOTHERAPY- EVALUATION OF QUALITY OF LIFE (QOL)

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Objectives With improved survival rates for locally advanced cervical cancer, research focus has shifted to treatment-related adverse events. A clinical trial was conducted to compare the effects of topical estrogen, topical testosterone and vaginal dilator in QOL of women after radiotherapy.

Methods Clinical trial of 195 women, randomized to receive topical estrogen (66), topical testosterone (34), vaginal dilator (29) or lubricating gel (66) for one year, starting soon after the end of radiotherapy from 01/2013 to 05/2018. The outcome variable was QOL evaluated by WHOQOL-bref. Evaluations were performed shortly after radiotherapy (afterRT), 4 months (4m), 8 months (8m) and one year after treatment (12m). Statistical analysis was carried out using ANOVA and multiple linear regression.

Results The mean age of women was 46.78 ($\pm$ 13.01) years, 61,03% were premenopausal and 73,84% had stage IIB-IIIB tumors. No changes were observed in the different WHOQOL-bref domains for the different treatment groups during the intervention period, except for the physical domain, where a significant improvement of the mean score was observed in the testosterone (after RT $\neq$ 8m,12m; 4m $\neq$ 8m; p <0.01) and vaginal dilator group (after RT $\neq$ 8m,12m; p <0.01). Multiple linear regression was performed to evaluate the factors associated with the percentual change in the WHOQOL-bref scores after 12 months of intervention. Having received teletherapy and brachytherapy (β =38.09, p <0.01) and using a vaginal dilator (β =24.43; p =0.01) were

independent factors associated with an improvement in the physical domain of WHOQOL-bref.

Conclusions Women who used a vaginal dilator showed improvement in the physical domain of QOL after 12 months of intervention.

IGCS19-0743

21 PREVALENCE OF BRCA1/2 MUTATION AND ALTERATIONS OF HOMOLOGOUS RECOMBINATION DEFICIENCY (HRD) IN UTERINE LEIOMYOSARCOMA: A RETROSPECTIVE, MONOCENTRIC STUDY

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Objectives Uterine leiomyosarcoma (uLMS) is a rare, very aggressive malignancy; molecular characterization is still uncertain, thus limiting the development of novel target based treatments.

This study aims at analyzing i) the prevalence rate of BRCA1/2 mutation and HRD alterations in ULMS, and ii) the association of BRCA1/2 and HRD abnormalities with clinical features.

Methods We planned to carry out a retrospective study on formalin-fixed paraffin-embedded (FFPE) samples of uLMS collected at the Fondazione Policlinico Universitario A. Gemelli, Rome. DNA extraction will be carried out using an automated device (MagCore HF16 Plus, Diatech Lab Line, Jesi, Italy). The mini Homologous Recombination Solution (mini HRS by SOPHiA GENETICS) is a capture-based target enrichment kit and full access to the SOPHiA DDM platform, able to identify mutations within BRCA1, BRCA2, TP53 and RAD51C genes on FFPE-deriving DNA.

Results The Next-Generation Sequencing (NGS) data were evaluable in 81 out of 92 FFPE deriving DNA samples. The mean coverage of each sample was 2000x, while the minimum acceptable for variant calling at 5% of MAF was 500x. The following pathogenic variants were identified: 21 patients with p53 mutation, all truncating or frameshift; 2 patients carriers of indel in Brca2; 3 patients with Brca1 truncating variants; 1 patient with both brca1 and brca2 mutations. Two novel p53 truncating variants have been identified. The evaluation of possible germline origin is now under evaluation for overall carrier patients alive.

Conclusions Final results could open novel perspectives terms of disease pathogenesis, and potential use of target based drugs (e.g. PARP inhibitors).

Plenary 4: Presidential Plenary

IGCS19-0758

22 OPEN VS. MINIMALLY INVASIVE RADICAL TRACHELECTOMY IN EARLY STAGE CERVICAL CANCER: INTERNATIONAL MULTICENTER IRTA STUDY RESULTS

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Objectives To compare disease-free survival (DFS) between patients who underwent open (ORT) versus minimally invasive (MIS) radical trachelectomy (RT) [laparoscopic (LRT) or robotic (RRT)].

Methods

Eligibility criteria included 1) RT and pelvic lymphadenectomy with/without sentinel lymph node mapping, 2) 1/2005 to 12/2017 3) squamous, adenocarcinoma, or adenosquamous histology, 4) stage IA2-IB1, 5) tumors ≤2 cm, 6) 15 or more cases per center.

Results A total of 698 patients [open (n=388) vs. MIS (310)] were included. The median follow-up time was 40.9 months (range, 1–179.1) [MIS 38.6 (range, <1–128.1) vs. open 68.3 (range, <1–200.8) (p<0.001)]. MIS patients had smaller tumors (no visible lesion: 76.8% vs 57.0%, < 1 cm: 1.9% vs. 2.8%, 1–2 cm: 21.3% vs. 40.2%, p<0.001) and lower rates of residual disease (42.9% vs. 56.2% p<0.001). (table 1) There were no differences in rates of parametrial involvement (2.1% vs. 1.3% p=0.055), vaginal involvement (0.8% vs. 1.4% p=0.198),