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SIMILAR DISTRIBUTION OF SENTINEL LYMPH NODES AND NODAL METASTASES IN CERVICAL AND ENDOMETRIAL CANCER. A PROSPECTIVE STUDY BASED ON LYMPHATIC ANATOMY

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10.1136/ijgc-2021-ESGO.644

Introduction/Background* Comparing the anatomical distribution of pelvic sentinel lymph nodes (SLN) in cervical and endometrial cancer.

Methodology Detailed SLN mapping results were prospectively retrieved in cervical ($n=145$) or high risk endometrial cancer ($n=201$) patients. Cervically injected Indocyanine Green (ICG), allowing for reinjection, was used as tracer. An anatomically based definition of SLNs was adhered to evaluating the upper (UPP) and lower (LPP) paracervical lymphatic pathways. The positions of SLNs were intraoperatively depicted on an anatomical chart. A completory pelvic lymphadenectomy was performed in all patients and in addition, xx underwent a paraaortic lymphadenectomy. Mapping rates and anatomical distribution of SLNs were compared between groups.

Result(s)* The bilateral mapping rate was 97.9% and 95.0% for cervical and endometrial cancer respectively. All pelvic node positive women (cervical cancer $n=19$, endometrial cancer $n=37$) had at least one metastatic SLN. The proportion of typically positioned (interiliac and proximal obturator fossa) SLNs along the UPP was similar between groups (78.1% vs 82.1%, $p=.09$) with a similar distribution of SLN metastases; 54.1% and 48.6% respectively were located in the obturator fossa. Anatomically typical positions could not be defined along the LPP.

Conclusion* A cervical injection of ICG results in similar anatomical distributions of SLNs and SLN metastases in cervical and endometrial cancer with no false negative SLNs. Provided adherence to an anatomically defined algorithm sensitivity results for a SLN concept in endometrial and cervical cancer can be pooled. Hence, an SLN concept can be implemented in cervical cancer patients.

Diagnostics

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AN EVALUATION OF THE PERFORMANCE OF MOLECULAR ASSAYS TO IDENTIFY HOMOLOGOUS RECOMBINATION DEFICIENCY-POSITIVE TUMOURS IN OVARIAN CANCER

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10.1136/ijgc-2021-ESGO.645

Introduction/Background* Homologous recombination deficiency (HRD), resulting from defects in the homologous recombination repair pathway, is a common feature of high-grade serous (HGS) ovarian cancer (OC) and predictive of sensitivity to PARP inhibitors. Developing reliable methods to determine HRD status of tumours is important to optimise clinical benefits of PARP inhibitors. Evaluation of HRD by genomic instability or *BRCA1* and/or *BRCA2* mutation

(BRCAm) is emerging as an important tool in OC. Here, we present a performance evaluation of two available molecular assays with potential to identify HRD-positive tumours by genomic instability in OC, compared with Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.; US FDA-approved and EU CE-IVD marked).

Methodology Analytical performance of FoundationOne CDx (F1CDx; Foundation Medicine, Inc.), a US FDA-approved complementary diagnostic for genomic loss of heterozygosity in OC, and AmoyDx HRD Focus Panel (Amoy Diagnostics Co., Ltd) assays (both EU CE-IVD marked) were evaluated in a commercial clinical laboratory setting. Assay performance was evaluated as positive (PPA), negative (NPA) and overall (OPA) percent agreement with HRD status (determined by myChoice CDx) of archival samples from patients with non-gBRCAm platinum-sensitive HGS or endometrioid OC tumours. The assays determine genomic instability by different methodologies. Data are summarised descriptively.

Result(s)* Both F1CDx and AmoyDx HRD Focus Panel molecular HRD assays demonstrated analytical concordance with myChoice CDx, with differing levels of sensitivity and specificity at manufacturer-recommended cut-offs. F1CDx demonstrated the following agreements on genomic instability with myChoice CDx: PPA 67.6%, NPA 85.7% and OPA 77.0% ($N=148$). AmoyDx HRD Focus Panel demonstrated the following agreements on genomic instability with myChoice CDx: PPA 92.0%, NPA 52.1% and OPA 72.4% using the existing algorithm and PPA 88.0%, NPA 75.0% and OPA 81.6% using a newly developed algorithm ($N=98$). Assay concordance for BRCAm detection was not undertaken because of limited BRCAm tumour samples.

Conclusion* F1CDx and AmoyDx HRD Focus Panel molecular HRD assays demonstrated concordance with, but not full equivalence to, myChoice CDx. Having multiple assays (providing their performance is adequate) to identify patients whose tumours harbour HRD is important to inform treatment decisions, as well as providing greater choice for clinicians and clinical laboratories.

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NEW INDEX BASED ON HUMAN EPIDIDYMIS PROTEIN 4 PERFORMS BETTER THAN RISK OF OVARIAN MALIGNANCY ALGORITHM IN PREMENOPAUSAL PATIENTS WITH PELVIC MASS

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10.1136/ijgc-2021-ESGO.646

Introduction/Background* Human epididymis protein 4 (HE4) has been reported as a promising biomarker in the assessment of the risk of malignancy in patients, diagnosed with pelvic mass. However, reference limits of HE4 do not provide clinically relevant discrimination between malignant and benign ovarian diseases. The clinical significance of well-known Risk of Ovarian Malignancy Algorithm (ROMA), which includes both HE4 and CA125, and its superiority over CA125 alone are still questionable.