Oral (O07)

Gynecologic Cancer Screening

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Diagnosis of early-stage epithelial ovarian cancer (EOC) using comprehensive serum glycopeptide spectra analysis combined with artificial intelligence (CSGSA-AI)

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Objective: We aimed to develop an artificial intelligence (AI)-based comprehensive serum glycopeptide spectra analysis (CSGSA-AI) method in combination with convolutional neural network (CNN) to detect aberrant glycans in serum samples of patients with epithelium ovarian cancer (EOC).

Methods: A total of 97 serum samples were collected from patients with early-stage EOC at the time of ovarian mass detection prior to the initiation of any treatment (stage I). The non-EOC control group (n=254) comprised both healthy women (n=220) and women with gynecologic benign diseases (n=34). We used AlexNet, the latest CNN-based technology, as a discrimination tool for CSGSA to identify early-stage EOC. To facilitate CNN training, we converted numerical data of glycopeptide expression to 2D barcode images and let CNN learn and distinguish early-stage EOC. CNN was trained using 60% samples and validated using 40% samples. To further enhance the learning efficacy and diagnostic performance of CNN, we added cancer antigen 125 (CA125) and HE4 information into the 2D barcode by changing the color (multicolored model).

Results: The sensitivity, specificity, positive predictive value, negative predictive value and area under the curve (AUC) of CSGSA-AI were 79%, 96%, 89%, 92%, and 88%, respectively. When CNN was trained with 2D barcodes colored on the basis of serum levels of CA125 and HE4 (multicolored model), AUC of 95% was achieved.

Conclusion: CSGSA-AI has the potential to be a useful tool for diagnosis of early-stage epithelial ovarian cancer.

Oral (O08)

Epithelial Ovarian Cancer including Borderline Tumor

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Quality-adjusted time without symptom or toxicity and quality-adjusted progression-free survival of first-line maintenance niraparib in patients with advanced ovarian cancer

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Objective: This post hoc analysis of the phase 3 PRIMA trial examined quality-adjusted time without symptom or toxicity (QA-TWiST) and quality-adjusted progression-free survival (QA-PFS) of patients with ovarian cancer on first-line maintenance niraparib vs. placebo.

Methods: QA-TWiST analyses were performed, defining TOX as the mean duration where patients experienced grade ≥ 2 adverse events (fatigue/asthenia, nausea, vomiting, abdominal pain, and abdominal bloating) from randomization to disease progression/censoring. Mean QA-TWiST was calculated as

$U_{TOX} \times TOX + U_{TWiST} \times TWiST$, where U_{TWiST} and U_{TOX} represent utilities applied to time spent in TWiST and TOX health states, respectively. U_{TWiST} was considered 1.00, i.e., the best possible quality of life for patients. U_{TOX} was calculated using EQ-5D index scores from the PRIMA trial. Restricted mean QA-PFS was calculated from the area under the quality-survival product function up to the last PFS of patients randomized to niraparib. **Results:** Maximum PFS was 27.8 months with niraparib. There were improvements in mean QA-TWiST for niraparib vs. placebo in the intention-to-treat (ITT) and homologous recombination deficient (HRd) cohorts, with mean (95% confidence interval [CI]) gains of 3.5 (1.7–5.6) and 5.9 (3.5–8.6) months, respectively. Similarly, QA-PFS was significantly longer with niraparib vs. placebo, with mean (95% CI) differences of 4.1 (2.2–5.8) and 6.5 (3.9–8.9) in the ITT and HRd cohorts, respectively.

Conclusion: In patients with ovarian cancer, first-line niraparib maintenance was associated with significant gains in QA-TWiST and QA-PFS vs. placebo, confirming the benefit of niraparib in the ITT population and HRd cohort.

Miscellaneous

Oral (OMi1)

Gestational Trophoblastic Neoplasia

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Phase II trial for Chemo-Resistant Gestational Trophoblastic Neoplasias with Pembrolizumab (CR-GTP)

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Background: Gestational trophoblastic neoplasia (GTN) represents a group of rare tumors that accounts for less than 1% of gynecologic cancers which arising from malignant transformation of trophoblast, a cell originating from placenta. Most patients with GTN are cured with chemotherapy, however 0.5%–5.0% of them die as a result of multi-drug resistance, necessitating novel approaches. Placental expression of paternal antigens make placenta a target for maternal immune recognition during pregnancy, and programmed death-ligand 1 (PD-L1) expression maintains gestational immune tolerance. Not known the exact mechanism, there is possible explanation by immune tolerance associated/derived from pregnancy. Therefore, targeting programmed cell death protein 1 (PD-1) inhibitory signaling with PD-1 inhibitor might be effective in

chemo-resistant GTN.

Methods: Participants are eligible to be included in the study. Female participants who are at least 18 years of age with histologically confirmed diagnosis of gestational trophoblastic neoplasia (hydatidiform-mole, invasive mole, gestational choriocarcinoma, placental site trophoblastic tumor, and epithelioid trophoblastic tumor) refractory or chemo-resistant to multi-agent chemotherapy (such as EMA-CO, EMA-EP, BEP, TP-TE, etc.) status will be enrolled in this study. Pembrolizumab 200 mg will be administered as a 30-minute intravenous infusion every 3 weeks. Radiological response assessed by the overall response according to iRECIST criteria every 3 cycles, and serologic response assessed by serum b-hCG at every 3 weeks. The serologic response is expected to show a decrease at least 50% of patients. We will test for four immunohistochemistry mismatch repair deficiency (MLH1/MSH2/MSH6/PMS2), microsatellite instability test, and PD-L1 expression, and we will further analyze the other immune response proteins (CD3, CD8, Granzyme B).

Oral (OMi2)

Gestational Trophoblastic Neoplasia

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Comparison of immuno-histochemical staining of programmed cell death ligand-1 (PD-L1) in placental site trophoblastic tumor and epithelioid trophoblastic tumor using 22C3, SP263, and SP142

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Objective: This study aims to evaluate programmed death-ligand 1 expression and concordance between 3 commercially available antibodies in placental site trophoblastic tumor (PSTT)/epithelioid trophoblastic tumor (ETT).

Methods: Serial histology sections from 14 patients diagnosed with PSTT or ETT underwent following immunohistochemistries; 22C3, SP263, SP142 on Ventana