Introduction/Background Scarcely evidence supports Cancer Antigen 125 (CA125) as a reliable recurrence biomarker in patients affected by Ovarian Cancer (OC) on maintenance treatment with PARP inhibitors (PARPi) or Bevacizumab after response to platinum-based therapy. Our aim is to assess concordance between CA125 increase and Response Evaluation Criteria In Solid Tumours (RECIST) progression in these patients.

Methodology The study includes 109 patients affected by CA125-sensitive OC on maintenance treatment with Bevacizumab (group A) or PARPi (group B) for at least two months after complete/partial response to platinum-based therapy. 55 patients underwent PARPi, 54 Bevacizumab. Data were concordant if CA125 increased within a month from radiological progression; otherwise they were considered discordant.

Results 38 (34.9%) patients relapsed under maintenance treatment; 18 (47.4%) had recurrence with PARPi, 20 (52.6%) under Bevacizumab. In group A concordant cases were 12 (60%), discordant cases accounted for 8 (40%). In the last category of patients in half cases CA125 increased before radiological progression, while in the other half marker was permanently negative; CA125 never increased after radiological progression. In group B concordant cases were 7 (38.9%), discordant ones were 11 (61.1%). In this last category of patients in 4 cases (36.4%) CA125 increased after radiological progression, while in the other 7 (63.6%) CA125 was constantly negative; marker never increased before radiological progression.

Conclusion In patients treated with PARPi CA125 does not always correlate with disease progression; in fact, in cases of relapse highlighted with imaging techniques, marker remains within the normal range. This contrasts with what happens in patients treated with Bevacizumab. In conclusion, CA125 and imaging should always be evaluated together.

Abstracts

Pembrolizumab Monotherapy for Advanced Clear Cell Gynaecological Cancer: Phase II Peacock Trial

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Introduction/Background Advanced clear cell gynaecological cancers (CCGC) have poor prognosis with objective response rates (ORR) to second-line chemotherapy between 0–8%. Preliminary clinical activity with PD-1 inhibitors have been described in CCGC. We investigated pembrolizumab monotherapy for advanced CCGC.

Methodology PEACOCC is a Phase II, multicentre, single-arm trial in patients with advanced CCGC who had ≥1 prior line of chemotherapy with progression (PD) at study entry. Pembrolizumab 200 mg iv q21 days was given until PD (RECIST v1.1), unacceptable adverse event (AE), 2 years (y) pembrolizumab completed, patient or clinician decision. Primary endpoint was progression-free survival (PFS) rate at 12 weeks (w) (H0≤15%; H1≥33%; 5% 1-sided α; 90% power). Secondary endpoints included ORR, duration of response (DOR), PFS, overall survival (OS) and safety.

Results 49 patients were enrolled with 48 evaluable. Median age 58.5 y (32–77 y), ECOC 0/1 54.2%/45.8%, 85.4% ovarian CCGC. Median number of prior systemic therapy 2 (1–6); 19 patients (39.6%) had received anti-angiogenic therapy. 42 patients completed median of 4 cycles pembrolizumab (1–25), 6 patients (12.5%) continue pembrolizumab, 16.7% patients had Grade(G)3 treatment-related AE (TRAE) of hyperthyroidism, acute kidney injury, raised alanine aminotransferase, raised alkaline phosphatase, anaemia, encephalitis and diabetic ketoacidosis. There were no G4 or G5 TRAE. 3 patients (6.3%) discontinued pembrolizumab due to TRAEs. The PFS rate at 12w was 43.8% (90% CI:31.5–56.6) exceeding the pre-stated lower bound of 15%. Best ORR was 24.0% (90%CI:15.1–37.3) (1 complete, 11 partial), with 1 y DOR rate 47.7% (95%CI:14.1–75.6). After a median follow-up of 2.1 y, median PFS was 12.2w (95%CI:5.9–32.9) and median OS 71.0w (95% CI:29.1–137.6).

Conclusion The PEACOCC trial suggests that pembrolizumab is effective in heavily pre-treated patients with advanced CCGC: 43.8% patients were alive and progression-free at 12w. Clinical outcomes were durable with limited toxicity. These promising results justify consideration of pembrolizumab monotherapy as a new standard-of-care for advanced CCGC.

Correlation Between CA125 Levels & Surgical Findings in Patients Undergoing Secondary Operations for Epithelial Ovarian Cancer

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Introduction/Background We aim to correlate serum CA 125 values after chemotherapy with clinical findings during second-look surgery.

Methodology This study was conducted on twenty-five patients with epithelial ovarian cancers undergoing second-look operations in our hospital between 2019 and 2021.

Results The average age of the patients was 59, 2 years. Twenty-one cases of stage III (84%) and 4 cases of stage VI (16%) high serous ovarian carcinoma. The CA125 level before chemotherapy was high in all cases with a mean rate of 932, 8 UI/ml. All the patients underwent multiple courses of neoadjuvant chemotherapy. The evaluation of response was clinically, radiologically, and biologically. Eight patients who had negative second-look findings gave normal serum CA125 levels. Of the 17 patients who were positive in second-look surgery, 10 had normal CA125 levels with a false negative rate of 58, 8%. Of the patients with normal CA125 levels at the time of operation, those with persistent disease had higher mean CA125 levels (22, 21 UI/ml) than those with no disease detected (12, 2 UI/ml). All the seven patients with elevated CA125 serum
levels were positive in their second-look. 70% of patients with residual tumors having the greatest diameter less than or equal to 2 cm had normal CA125 with a mean value of 21 u/ml. 42% of patients with tumors having the greatest diameter greater than 2 cm had normal CA125, while all the 8 patients with no macroscopic tumor during surgery had normal CA125 level. These results show that the residual tumor size found in the second-look was related to the serum CA125 level.

Conclusion As CA125 levels within normal limits gave more false negatives, the necessity of second-look surgery cannot be judged by serum CA125 assay though elevated CA125 levels do predict the presence of tumor.

Introduction/Background Indocyanine green is being widely used in gynecology oncology; specially in sentinel node detection in endometrial cancer. New applications are being studied, as sentinel node detection in ovarian cancer.

Methodology We are performing indocyanine green laparoscopic sentinel node detection in a woman affected by ovarian cancer. She had been diagnosed after an anexectomy for a suspicious ovarian mass in another center. We inject indocyanine green in the infundibulopelvic and the ovaric ligament in para-aortic and presacral areas, embedded in the lymphatic tissue became more receive the anatomical marks more clearly, the difference between the vessels and the lymphatic tissue became more.

Results After the detection of the sentinel nodes we perform the lymphadenectomy with the fluorescent camera on. We perceive the anatomical marks more clearly, the difference between the vessels and the lymphatic tissue became more individualized. Avoiding vessel injury is one of the challenges in the learning curve for para-aortic lymphadenectomy. Anatomical variations in the para-aortic region occurred in one third of the women.

Conclusion Indocyanine green is a useful tracer for sentinel node detection. We propose that it could be a learning tool for beginners in the lymphadenectomy technique and in cases of special difficulty, for example in anatomical variations.

Introduction/Background Proper diagnosis of abnormal ovarian masses determines the extent of surgical procedure and adjuvant chemo/radiation treatment. Occasionally, invasive, radiologic and laboratory tests are inconclusive and planning of upcoming steps in management requires individual approach. Detailed description of such cases in scientific literature could be beneficial for the management of similar occurrences.

Methodology 54 year old patient admitted to the onco-gynecology department with pain and unpleasant sensation in right hypogastric area. Contrast-enhanced CT scan revealed non-contrast-enhancing, nonhomogeneous cystic mass, 10.6 cm in diameter in place of right ovary. 2.7 cm and 2.3 cm masses were visualized in pararectal and presacral areas, embedded in retroperitoneal fat. Ovarian markers were within normal inhibitors as part of treatment for relapsed ovarian cancer. The 71-year-old was diagnosed with high-grade serous ovarian carcinoma (HGSOC), FIGO stage IIIB, BRCA-1 positive, in 2013 and underwent extensive treatment for almost ten years. First-line therapy included six cycles of carboplatin-paclitaxel plus bevacizumab between January and May, 2013 followed by maintenance with bevacizumab until March, 2014. After relapsing in June, 2017 the patient underwent salvage surgery with complete resection and platinum rechallenge therapy with six cycles of carboplatin-caelyx plus bevacizumab. As maintenance therapy all three PARP-inhibitors were used consecutively from May, 2018 two of which had to be discontinued due to side effects. First niraparib following recurrent thrombocytopenia, then olaparib for abdominal pain. To enable treatment with a PARP-inhibitor, she received rucaparib from October, 2018 until her second relapse in June, 2020. After another salvage surgery with complete resection she was given three cycles of carboplatin and one cycle of cisplatin from September, 2020 to January, 2021. She has received maintenance therapy with rucaparib since March, 2021 with manageable side effects.

Methodology Patient's file, Excel, patient interview

Results Rucaparib caused a slower and smaller decrease in platelet count. Transaminases only increased slightly without reaching adverse effect level according to CTCAE, making it an asymptomatic laboratory finding.

Conclusion This report gives an example of how to manage potential side effects during PARP-inhibitor therapy in routine clinical practice. Even after intolerance of two PARP-inhibitors, another was tolerated, showing that switching PARP-inhibitors during therapy is possible. Patients react differently to side effects of PARP-inhibitors, further studies should focus on predictive clinical and pharmacodynamic parameters to identify individual toxicity for optimization of the efficacy of PARP-inhibitors.