Introduction/Background Scarce 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 this 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.

2022-RA-1276-ESGO PEMBROLIZUMAB MONOTHERAPY FOR ADVANCED CLEAR CELL GYNAECOLOGICAL CANCER: PHASE II PEACOCC TRIAL

[1]Rowan E Miller, [2]Andrew Clamp, [3]Charlie Gourley, [4]Rene Roux, [5]Marcia Hall, [6]Michael-John Devlin, [7]Rachel Nirsimloo, [4]Valentinos Kounnis, [8]Laura Hughes, [9]Nicholas Counsell, [10]Laura Farrelly, [11]Rebecca S Kristeleit. *[1]Medical Oncology, University College London Hospital, London, UK; [2]The Christie NHS Foundation Trust, Manchester, UK; [3]Cancer Research UK Scotland Centre, University of Edinburgh, Edinburgh, UK; [4]Medical Oncology, Churchill Hospital, Oxford, UK; [5]Mount Vernon Cancer Centre, Northwood, UK; [6]Bart's Cancer Institute, London, UK; [7]Edinburgh Cancer Centre, Western General Hospital, Edinburgh, UK; [8]CRUK and UCL Cancer Trials Centre, Univeristy College London, London, UK; [9]CRUK and UCL Cancer Trials Centr, University College London, London, UK; [10]CRUK and UCL Cancer Trials Centre, University College London, London, UK; [11]Guy's and St Thomas' NHS Foundation Trust, London, UK*

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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) ($H_0 \leq 15\%$; $H_1 \geq 33\%$; 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), ECOG 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 25.0% (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.

2022-RA-1277-ESGO CORRELATION BETWEEN CA125 LEVELS & SURGICAL FINDINGS IN PATIENTS UNDERGOING SECONDARY OPERATIONS FOR EPITHELIAL OVARIAN CANCER

[1]Amani Jellali, [1]Malek Bouhani, [1]Takoua Chalouati, [1]Saida Sakhri, [1]Mehdi Mbarek, [2]Ghada Sahraoui, [1]Hanen Bouaziz, [1]Maher Slimane, [1]Khaled Rahal. *[1]Department of surgical oncology, Salah Azaiez Institute, Tunisia, Tunisia; [2]pathology department, Salah Azaiez Institute, Tunis, Tunisia*

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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