A RANDOMISED CLINICAL TRIAL INVESTIGATING OLAPARIB, DURVALUMAB AND AN ANTICANCER VACCINE, UV1 AS MAINTENANCE THERAPY IN PATIENTS WITH RECURRENT OVARIAN CANCER. ENGOT-OV56-NSGO-CTU-DOVACC

Introduction/Background Outcome of ovarian cancer patients has considerably improved by introduction of maintenance PARP inhibitors; however, most patients subsequently relapse and there is a need for further improvement. Combinations of targeted therapy and immunotherapy are of interest due to their single agent efficacy in different stages of ovarian cancer. To further enhance the response rate, one approach may be to integrate an anticancer vaccine aiming to activate an immune response against tumour-related antigens into a regime of combined targeted therapy and immunotherapy. This prospective, multicenter, open-label, randomized phase II maintenance study is evaluating the efficacy of UV1-olaparib-durvalumab combination as maintenance therapy after platinum combination therapy for BRCAwt patients with relapsed ovarian cancer.

Methodology Patients with BRCAwt epithelial ovarian cancer, relapsed >6 months after last chemotherapy (maximum 4 prior lines of chemotherapy), in response to last chemotherapy, ECOG performance status 0–1 are eligible.

Patients are randomized into one of the three treatment arms, (A:B:C), in a 1:1:2 randomization (n=184): Arm A (olaparib): 46 subjects; Arm B (durvalumab plus olaparib): 46 subjects; Arm C (olaparib plus durvalumab plus UV1): 92 subjects. Patients are stratified according to: HRD status, Previous lines of chemotherapy, in response to last chemotherapy, relapsed >6 months after last chemotherapy (maximum 4 prior lines of chemotherapy), in response to last chemotherapy, ECOG performance status 0–1 are eligible.

Primary objective is to compare the preliminary efficacy of maintenance treatment with olaparib (arm A) to that of olaparib plus durvalumab and UV1 (arm C). Study sponsor is the Nordic Society of Gynaecological Oncology – Clinical Trial Unit and is being conducted in six ENGOT cooperative groups (AGO-A, BGOG, DGOG, HeGOG, NOGGO, NSGO-CTU). (NCT04742075)

Results

Expected results Study is enrolling patients in 11 ENGOT countries.

Conclusion The positive outcome will further improve the outcome of our patients.

ULTRASOUND GUIDED BIOPSY, A USEFUL TOOL IN THE MANAGEMENT OF PRIMARY ADVANCED TUBO-OVARIAN CARCINOMA

Introduction/Background To assess the accuracy of pathological diagnosis at ultrasound (US)-guided biopsy versus surgery in patients with primary advanced tubo-ovarian carcinoma. Feasibility, adequacy, and safety of the procedure were also evaluated.

Methodology Consecutive women with pre-operative suspicious advanced tubo-ovarian carcinoma presenting at our hospital between July 2019 and September 2021 were enrolled. Feasibility was defined as the number of cases in which US-guided biopsy was possible according to tumour characteristics (morphology and site). Adequacy was defined as the possibility of a conclusive diagnosis in the sample collected. Safety was defined on the number of major complications.

Results 278 patients were eligible for the study; 158 were enrolled, while 120 were excluded due to logistic reasons or patient refusal (figure 1). US-guided biopsy was unfeasible in 30 (19%) patients. The samples obtained in the remaining 128 cases were all adequate (100%), and no major complications were noted. 26 (20%) patients started neoadjuvant chemotherapy on the bases of the diagnosis obtained by US, whereas 102 (80%) patients underwent surgery. Accuracy of US-guided biopsy versus surgery was 94% (96/102), with 6 false negative cases at US (6%). Site (pre-vescical peritoneum) and size (<8 mm) of the nodules resulted as major predictive factors for US-guided biopsy failure. US-guided biopsy correctly identified 86 primary invasive tubo-ovarian carcinomas and 10 metastatic tumours.

Abstract 2022-RA-1271-ESGO

Figure 1 Flow chart of the study population

Conclusion US-guided biopsy is a feasible, safe, and accurate method to provide histologically diagnosis in suspicious advanced tubo-ovarian cancer patients.

PRELIMINARY DATA ABOUT CORRELATION BETWEEN CA125 INCREASE AND RECIST PROGRESSION IN PATIENTS WITH RELAPSED OVARIAN CANCER TREATED WITH MAINTENANCE PARP INHIBITORS OR BEVACIZUMAB AFTER RESPONSE TO PLATINUM BASED CHEMOTHERAPY

Introduction/Background To assess the accuracy of pathological diagnosis at ultrasound (US)-guided biopsy versus surgery in patients with primary advanced tubo-ovarian carcinoma. Feasibility, adequacy, and safety of the procedure were also evaluated.

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Conclusion US-guided biopsy is a feasible, safe, and accurate method to provide histologically diagnosis in suspicious advanced tubo-ovarian cancer patients.

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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 discordant 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 discordant 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 discordant 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

CANCER: PHASE II PEACOCC TRIAL

ADVANCED CLEAR CELL GYNAECOLOGICAL CANCER: PHASE II PEACOCC TRIAL

Pebralizumab monotherapy for 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 v.1.1), 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), 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 12 w was 43.8% (90% CI:15.1–56.6) 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 12.2 w (95%CI:5.9–32.9) and median OS 71.0 w (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 v.1.1, unacceptable adverse event (AE), 2 years (y) pembrolizumab completed, patient or clinician decision. Primary end-