2022-RA-657-ESGO ENGOT-OV65/KEYNOTE-B96: PHASE 3, RANDOMIZED, DOUBLE-BLIND STUDY OF PEMBROLIZUMAB VERSUS PLACEBO PLUS PACLITAXEL WITH OPTIONAL BEVACIZUMAB FOR PLATINUM-RESISTANT RECURRENT OVARIAN CANCER

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Introduction/Background Despite therapeutic advances in ovarian cancer, platinum-resistant recurrent ovarian cancer remains an area of high unmet clinical need and there is an urgent need for new treatments to further improve clinical outcomes. ENGOT-ov65/KEYNOTE-B96 (NCT05116189) compares the efficacy and safety of pembrolizumab plus weekly paclitaxel (± bevacizumab) versus placebo plus weekly paclitaxel (± bevacizumab) in patients with platinum-resistant recurrent ovarian cancer.

Methodology In this randomized, placebo-controlled, double-blind, phase 3 study, eligible patients are aged ≥18 years with histologically confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma with 1–2 prior lines of systemic therapy, including at least 1 prior platinum-based therapy with ≥4 cycles in first line. Patients must have platinum-resistant disease (radiographic evidence of disease progression ≤6 months after last platinum-based therapy dose), be eligible for paclitaxel (with/without bevacizumab per investigator discretion), and have ECOG PS ≤1, radiographically evaluable disease per RECIST version 1.1, and a tumour sample for central evaluation of PD-L1 status. Approximately 616 patients will be randomized 1:1 to receive pembrolizumab 400 mg IV or placebo Q6W for up to 18 cycles (~2 years) plus paclitaxel 80 mg/m^2 on days 1, 8, and 15 of each Q3W cycle (with/without bevacizumab 10 mg/kg Q2W per investigator discretion) until disease progression or unacceptable toxicity. Primary endpoint is PFS per RECIST version 1.1 by investigator review. Secondary endpoints are OS, PFS per RECIST version 1.1 by blinded independent central review, safety, and patient-reported outcomes. Enrolment is ongoing.

Results N/A

Conclusion N/A

2022-RA-660-ESGO CHARACTERIZATION OF EXTENDED TREATMENT BENEFIT FROM THREE PHASE 1 AND 3 CLINICAL TRIALS EXAMINING PATIENTS WITH FOLATE RECEPTOR ALPHA-POSITIVE RECURRENT OVARIAN CANCER TREATED WITH SINGLE-AGENT MIRVETUXIMAB SORAVTANSINE

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Introduction/Background Mirvetuximab soravtansine (MIRV) is a first-in-class antibody-drug conjugate comprising a folate receptor alpha (FRα)-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent that has demonstrated significant antitumor activity in this difficult-to-treat ovarian cancer population. The objective was to characterize the patients with FRα-positive recurrent ovarian cancer who achieved extended treatment benefit ([ETB]; progression-free survival for >12 months) with MIRV monotherapy.

Methodology Retrospective pooled analysis included patients enrolled across three trials: phase 1 first-in-human, phase 3 FORWARD I, and phase 3 SORAYA. Analysis included patients with low, medium, and high FRα expression by immunohistochemistry. All patients received intravenous MIRV at 6 mg/kg, adjusted ideal body weight, every three weeks until disease progression or unacceptable toxicity.

Results Of the 464 patients included in the analysis, 40 ETB patients were identified: median age 63 years, median of one prior therapy, 52.5% with prior PARPi, and 60% with prior bevacizumab. ETB patients had an overall response rate of 75.0%, with 9 (22.5%) achieving a complete response and 21 (52.5%) achieving a partial response by RECIST v1.1 and demonstrated a median duration of response of 22.1 months (95% CI, 13.8–60.0; interquartile range 13.5–60.0). The most common treatment-related adverse events (TRAEs) (all grade, grade 3+) included blurred vision (60%, 0%), fatigue (50%, 2.5%), nausea (50%, 0%), and keratopathy (40%, 2.5%). Peripheral neuropathy was present in 35% (no grade 3+) and pneumonitis was present in 20% (no grade 3+). TRAEs led to dose delay or reduction in 65% and 47.5% of ETB patients, respectively, and discontinuation in six patients.

Conclusion In a pooled analysis of 464 patients, MIRV monotherapy demonstrated ETB in ~10% patients. The safety profile consisted primarily of low-grade gastrointestinal and ocular events and reinforces MIRV's potential to become a new standard of care for FRα-positive ovarian cancer.

2022-RA-669-ESGO PERIOPERATIVE MANAGEMENT OF ADVANCED OVARIAN (TUBAL/PERITONEAL) CANCER PATIENTS. A SURVEY FROM MITO-MANGO GROUPS

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Introduction/Background The ESGO-quality indicators (QIs) for advanced ovarian cancer (AOC) have been assessed only by few Italian centres, and data are not available on the proportion of centres reaching the score considered for a satisfactory surgical management. There is great consensus that the ERAS approach is beneficial, but there is paucity of data concerning its application in AOC. This survey was aimed at gathering detailed information on perioperative management of AOC patients within MITO-MaNGO Groups.

Methodology A 66-item questionnaire, covering ESGO-QIs for AOC and ERAS items, was sent to MITO/MaNGO centres reporting to operate >20 AOC/year.

Results Thirty/34 questionnaires were analysed. The median ESGO-QIs score was 31.5, with 50% of centres resulting with a score ≥32 which provides satisfactory surgical management. The rates of concordance with ERAS guidelines were 46.6%, 74.1%, and 60.7%, respectively, for pre-operative, intra-operative, and post-operative items. The proportion of overall agreement was 61.3%, and with strong recommendations was 63.1%. Pre-operative diet, fasting/bowel preparation, correction of anaemia, post-operative feeding and early mobilization were the most controversial. A significant positive correlation was found between ESGO-QIs score and adherence to ERAS recommendations.

Conclusion This survey reveals a satisfactory surgical management in only half of the centres, and an at least sufficient adherence to ERAS recommendations. Higher the ESGO-QIs score stronger the adherence to ERAS recommendations, underlining the correlations between case volume, appropriate peri-operative management and quality of surgery.

2022-RA-672-ESGO COMPARISON OF QUALITY OF LIFE IN PATIENTS WITH PLATINUM-SENSITIVE RECURRENT OVARIAN, FALLOPIAN TUBE AND PERITONEAL CANCER TREATED WITH TRABECTEDIN PLUS PEGYLATED LIPOSOMAL DOXORUBICIN (PLD) OR STANDARD PLATINUM-BASED THERAPY: DATA LOOK OF THE NOGGO S16/ COMPASS TRIAL

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Introduction/Background Despite recent progress regarding surgical and medical management of primary ovarian cancer, relapses are still frequent and one of the most critical challenges in the clinical routine. There is a broad consensus that quality of life (QoL) should be one of the most relevant goals of any therapy in relapsed ovarian cancer.

Methodology We report the results of a data look of the multicentre, randomized (1:1), active-controlled, open-label phase IV NOGGO-S16/COMPASS trial performed in patients with recurrent, platinum-sensitive, ovarian, peritoneal or fallopian tube cancer. The scope of this trial is to evaluate QoL with EORTC QLQ-C30 and QLQ-OV28 questionnaires during/after chemotherapy either with platinum/taxane-free combination of trabectedin (Yondelis®) plus PLD or with standard platinum-based chemotherapy comprising combination of carboplatin with PLD, gemcitabine or paclitaxel. The current data look serves to characterise the included patient population.

Results Data from 76 patients screened have been analysed. Patients have a median age of 63 years (range: 21–82), the performance status score of 0/1 was recorded in 75 patients (98.7%), and most are BRCA-negative (77.4%). They are diagnosed with primary ovarian carcinoma (83.6%), primary peritoneal carcinoma (9.6%) and fallopian carcinoma (6.8%), and 79% of patients have a grade 3 histopathological staging. Poly (ADP-ribose) polymerase inhibitors or bevacizumab were given as prior maintenance therapy to 15.3% and 76.4% of