Randomisation is stratified by surgery planned time point (neoadjuvant vs. adjuvant), surgical outcome (R0 vs R1), response to chemotherapy followed by bev (CR/NED vs. PR/SD) and study center. Primary endpoint is PFS per RECIST v1.1. Secondary endpoints are PFS2, quality of life, daily activity, time to next medical intervention, time to next subsequent therapy, safety assessments and OS. So far 35 patients are randomised in the study.

Results

Conclusion

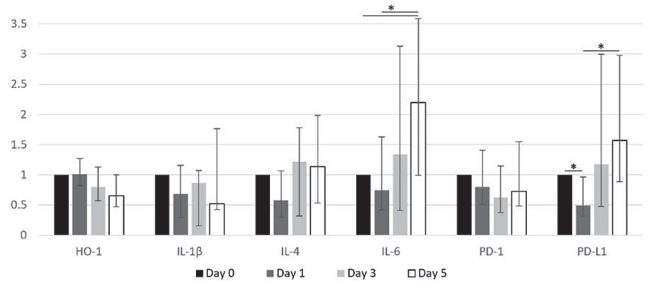
2022-RA-939-ESGO INFLUENCE OF CANCER AND SURGERY TO IMMUNOSUPPRESSIVE AND PROINFLAMMATORY FACTORS IN OVARIAN CANCER PATIENTS' PBMCS

[1]Jonas Ulevicius, [1]Aldona Jasiukaitiene, [1]Zilvinas Dambrauskas, [1]Antanas Gulbinas, [2]Saulius Paskauskas, [2]Arturas Sukovas. *[1]Institute for Digestive Research, Laboratory of Surgical Gastroenterology, Lithuanian University of Health Sciences, Kaunas, Lithuania; [2]Department of Obstetrics and Gynaecology, Lithuanian University of Health Sciences, Kaunas, Lithuania*

10.1136/ijgc-2022-ESGO.598

Introduction/Background Heme-oxygenase 1 (HO-1), programmed cell death protein 1 (PD-1) ant it's ligand (PD-L1) along with cytokines play an important role in ovarian cancer development. The changes of anti-cancer immunity in post-surgical period and its role in cancer progression are poorly understood. We intended to investigate HO-1, PD-1, PD-L1, immunosuppressive (IL-4) and proinflammatory (IL-1β, IL-6) interleukins expression in peripheral blood mononuclear cells (PBMCs).

Methodology The peripheral venous blood samples were collected before and after surgery on the 1st, 3rd and 5th day from 10 controls and 9 ovarian cancer patients (FIGO stage III-IV) for PBMCs isolation with FICOL Paque Premium and targets mRNA expression analysis. RNA extraction and synthesis of cDNA, quantitative real-time PCR assays were performed. Results are presented as median with interquartile range.



Abstract 2022-RA-939-ESGO Figure 1 Relative mRNA expression of HO-1, IL-1β, IL-4, IL-6, PD-1, PD-L1 genes in PBMCs from ovarian cancer patients on the 1st, 3rd and 5th day after surgery compared to the expression before the treatment. Bar graphs show median value and interquartile range *p<0.05

Results Median age of controls and cancer patients were 59 (26) and 58 (14) years respectively (p>0.05). The mRNA expression of all markers in PBMCs were significantly down-regulated in cancer patients before surgery comparing to controls (p<0.05). Relative median expression of HO-1, IL-1β, IL-4, IL-6, PD-1 and PD-L1 in controls and cancer patients respectively were 0.97 (0.33) vs 0.66 (0.5), 0.87 (1.95) vs 0.07 (0.16), 0.86 (1.39) vs 0.43 (0.61), 0.98 (1.15) vs 0.03 (0.03), 0.99 (0.94) vs 0.32 (0.50), 1.18 (0.66) vs 0.26 (0.36). Significant post-surgical changes in IL-6 and PD-L1 expression were observed along with not significant fluctuations of other targets expression (figure 1).

Conclusion Investigated components of anticancer immunity and immunosuppression mechanisms are affected by cancer and surgical treatment. Therefore, PBMCs are worthy targets for detailed investigation in this field.

2022-RA-941-ESGO CEBOC, A SINGLE-ARM PHASE II TRIAL TO EVALUATE THE SAFETY OF CEDIRANIB IN THE PREVENTION OF BOWEL PERFORATION IN PLATINUM RESISTANT OVARIAN CANCER

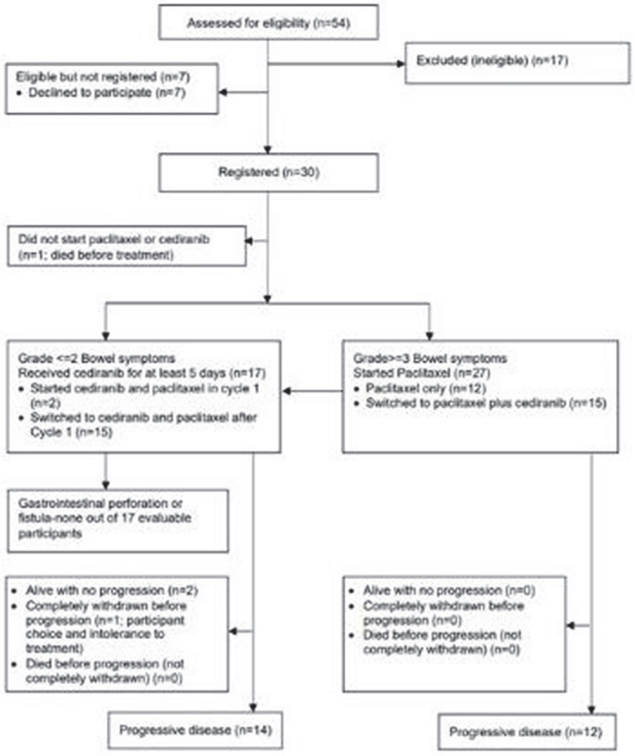
[1]Alexander Murphy, [2]Catharine Porter, [2]Ann White, [2]Alys Irving, [2]Ruby Ray, [2]Angela Casbard, [2]Tracie-Ann Madden, [1]Reem Mahmood, [1]Robert Morgan, [1]Julia Pugh, [1]Chelsey Wheeler, [1]Victoria Roberts, [1]Giorgio Arnetoli, [1]Zena Salih, [1]Jurjees Hasan, [1]Claire Mitchell, [1]Andrew Clamp, [1]Gordon Jayson. *[1]The Christie NHS Foundation Trust, Manchester, UK; [2]Centre for Trials Research, Cardiff University, Cardiff, UK*

10.1136/ijgc-2022-ESGO.599

Introduction/Background Systemic treatment of platinum-resistant advanced ovarian cancers (PROC) utilises cytotoxic chemotherapy and vascular endothelial growth factor receptor (VEGFR) inhibitors. However, patients at risk for malignant bowel obstruction (MBO) are excluded from this efficacious combination due to risk of bowel perforation.

Methodology We conducted a Simon's two-stage trial combining oral VEGFR inhibitor cediranib (20 mg/day) with weekly paclitaxel (70 mg/m^2), in participants with recurrent PROC and clinical and/or radiological features indicating an increased risk of developing MBO. Primary endpoint was number of patients free of grade 3–5 gastrointestinal perforation (GIP) or fistula, from those who received ≥5 days and ≤18 weeks cediranib, causally related to cediranib. With 90% power and 5% significance, 24 evaluable patients were required, with 22 free of GIP or fistula to demonstrate safety. Cediranib could start with chemotherapy, or at cycle 2 or 3, once bowel symptoms were CTCAE grade ≤2. Previous bevacizumab exposure and prior MBO were permitted. Patients were continued on cediranib maintenance after paclitaxel completion, and optionally proceeded to cediranib plus olaparib (300 mg bd) at disease progression.

Results 30 participants were enrolled from March 2018 to February 2021. 90% ECOG 0–1, 97% had symptoms showing risk of bowel obstruction. 1 patient died before any treatment. 12 received paclitaxel only (bowel symptoms didn't improve or deterioration) and subsequently progressed. 17 patients were evaluable for primary endpoint; none developed GIP or fistula. Three cediranib+paclitaxel participants developed bowel obstruction (any grade; including one receiving cediranib+olaparib). Three participants had grade 3+ SAEs causally related to cediranib+/-olaparib (one diarrhoea; one diarrhoea and TIA; one vomiting). Median progression-free survival was 5.4 months (95%CI: 4.18–8.25), and overall survival 15.2 months (95%CI: 8.52–20.5).



Abstract 2022-RA-941-ESGO Figure 1

Conclusion There is no evidence that combining cediranib and taxane chemotherapy is associated with serious toxicity or of developing GIP/fistula, although this is underpowered due to participant withdrawal.

2022-RA-944-ESGO

REAL-WORLD SAFETY, BASELINE CHARACTERISTICS AND FIRST-YEAR THERAPY MANAGEMENT IN PATIENTS WITH *BRCA1*/*BRCA2*-MUTATED ADVANCED OVARIAN CANCER TREATED WITH OLAPARIB TABLETS IN THE FIRST-LINE MAINTENANCE SETTING: FIRST ANALYSIS OF THE PAN-EUROPEAN OVAL-1 STUDY

[1]Domenica Lorusso, [2]Charlie Gourley, [3]Delphine Garbay, [4]Bernard Jean Roger Asselain, [5]Francesco Raspagliesi, [6]Claudio Zamagni, [7]Alexandra Leary, [8]Charlotte Bellier, [9]Ros Glasspool, [10,11]Gordon Jayson, [12]Angela Whittle, [13]Ilaria Sabatucci, [14]Emmanuelle Grevat, [14]Muriel Licour, [15,16]Rowan Miller. *[1]Dipartimento scienze della salute della donna, del bambino e di sanita' pubblica, Fondazione Policlinico Universitario Agostino Gemelli IRCCS and Catholic University of Sacred Heart, Rome, Italy; [2]Cancer Research UK Scotland Centre, University of Edinburgh, Edinburgh, UK; [3]Clinique Tivoli Ducos, Bordeaux, France; [4]ARCAGY-GINECO, Paris, France; [5]Department Of Gynecologic Oncology, IRCCS National Cancer Institute, Milan, Italy; [6]IRCCS Azienda Ospedaliero-universitaria di Bologna, Bologna, Italy; [7]Institut Gustave-Roussy, Villejuif, France; [8]Départements De Cancérologie Gynécologique Et Sénologique, Centre Oscar Lambret, Lille, France; [9]Beatson West of Scotland Cancer Centre and Institute of Cancer Sciences, University of Glasgow, Glasgow, UK; [10]Department of Medical Oncology, The Christie NHS Foundation Trust and Division of Cancer Sciences, Manchester, UK; [11]Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK; [12]Medical Affairs Department, AstraZeneca, London, UK; [13]AstraZeneca, Milan, Italy; [14]AstraZeneca, Paris, France; [15]University College London Hospital, London, UK; [16]St Bartholomew's Hospital, London, UK*

10.1136/ijgc-2022-ESGO.600

Introduction/Background In this preliminary evaluation of the first 324 patients enrolled in the OVAL-1 study (NCT04532645), we report real-world characteristics and first-year therapy management among tumour or germline (t/g) *BRCA1*/*BRCA2*-mutated (t/gBRCAm) newly diagnosed advanced ovarian cancer (OC) patients who received maintenance olaparib across Italy, UK and France.

Abstract 2022-RA-944-ESGO Table 1 Baseline characteristics

Patients with AEs, n (%)	Italy (n=125)	UK (n=116)	France (n=83)
Most common pre-defined AEs	56 (44.8)	69 (59.5)	26 (31.3)
Nausea	6 (4.8)	15 (12.9)	5 (6.0)
Anaemia	33 (26.4)	23 (19.8)	7 (8.4)
Neutropenia	7 (5.6)	7 (6.0)	2 (2.4)
Fatigue	4 (3.2)	22 (19.0)	4 (4.8)
AEs leading to dose modification	45 (36.0)	52 (44.8)	20 (24.1)
Anaemia	30 (24.0)	17 (14.7)	5 (6.0)
Nausea	5 (4.0)	11 (9.5)	5 (6.0)
Fatigue	4 (3.2)	17 (14.7)	3 (3.6)
AEs leading to treatment interruption	44 (35.2)	40 (34.5)	18 (21.7)
AEs leading to treatment discontinuation	1 (0.8)	4 (3.4)	3 (3.6)

AE, adverse event

Abstract 2022-RA-944-ESGO Table 2 AEs

Patients with AEs, n (%)	Italy (n=125)	UK (n=116)	France (n=83)
Most common pre-defined AEs	56 (44.8)	69 (59.5)	26 (31.3)
Nausea	6 (4.8)	15 (12.9)	5 (6.0)
Anaemia	33 (26.4)	23 (19.8)	7 (8.4)
Neutropenia	7 (5.6)	7 (6.0)	2 (2.4)
Fatigue	4 (3.2)	22 (19.0)	4 (4.8)
AEs leading to dose modification	45 (36.0)	52 (44.8)	20 (24.1)
Anaemia	30 (24.0)	17 (14.7)	5 (6.0)
Nausea	5 (4.0)	11 (9.5)	5 (6.0)
Fatigue	4 (3.2)	17 (14.7)	3 (3.6)
AEs leading to treatment interruption	44 (35.2)	40 (34.5)	18 (21.7)
AEs leading to treatment discontinuation	1 (0.8)	4 (3.4)	3 (3.6)

AE, adverse event

Methodology This observational, retrospective study included patients who received maintenance olaparib (300 mg bid) for t/gBRCAm advanced OC following response to first-line platinum-based chemotherapy. Eligible patients received their first dose between January 2019 and June 2020 (index date). The planned enrolment is 350 patients. Data are collected from routine clinical practice. Adverse events (AEs) were defined as