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EDMOND: A FEASIBILITY STUDY OF ELEMENTAL DIET AS AN ALTERNATIVE TO PARENTERAL NUTRITION FOR OVARIAN CANCER PATIENTS WITH INOPERABLE MALIGNANT BOWEL OBSTRUCTION

¹Agnieszka Michael, ²Lindsey Allan, ³Kate Bennett-Eastely, ⁴Rebecca Herbertson, ⁵Simon Skene. ¹University of Surrey; School of Biosciences and Medicine; ²Royal Surrey Foundation Trust; Oncology; ³University of Surrey; Clinical Trials Unit; ⁴Brighton and Sussex Hospital; Oncology; ⁵University of Surrey; Clinical Trials Unit, University of Surrey; School of Biosciences and Medicine

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Introduction/Background Inoperable bowel obstruction (IBO) occurs in up to 50% of patients diagnosed with ovarian cancer. Nutrition support for patients with IBO is challenging. Parenteral feeding (PN) is the recommended route for patients with a prognosis of > 2 months, however there is little evidence that it improves quality of life and the cost of it is very high. If PN is not available patients are frequently discharged home from hospital with sips of clear fluids only. Management of inoperable bowel obstruction remains a major challenge and clear guidelines are needed.

Elemental diet (ED) is a liquid diet that contains proteins in the form of amino acids, fats in the form of medium chain triglycerides, vitamins and trace minerals. ED is almost completely absorbed in the upper small intestine.

Methodology The primary objective of the study was to establish if ED can be used as an alternative to home PN in patients with IBO. The secondary aim was to examine the impact of ED on quality of life. The primary endpoints of the study were acceptability and tolerability of ED with respect to taste, and incidence of vomiting and pain. The secondary endpoints included the number of patients alive at the end of the study, quality of life, nutritional intake, and the number of women who can tolerate ED and subsequently be treated with palliative chemotherapy (as per standard of care).

Results 29 women with IBO caused by metastatic ovarian cancer were recruited into the EDMOND study. Of those 8 could not complete the trial due to disease progression, and 2 had missing data that was deemed irretrievable, leaving 19 patients who contributed data to the primary endpoint analysis. The mean age of the patients who continued the trial was 68 (SD 12.5). Preliminary analysis shows that 68.4% of patients met the primary endpoint and tolerated ED; the ED did not worsen the vomiting or pain as measured by Memorial Symptoms Assessment Scale. At baseline 72% of patients experienced vomiting and this number reduced to 28% by the end of week 1 of the study and to 23.5% by the end of week 2. 96% of patients reported pain at baseline and this proportion reduced to 72% and 76% by the end of week 1 and 2 respectively.

Conclusion ED is well tolerated by patients with IBO and can provide an acceptable feeding option for this group of patients.

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ORAL METRONOMIC CYCLOPHOSPHAMIDE IN RECURRENT OVARIAN CANCER: A SINGLE CENTRE EXPERIENCE

¹Daniela Attianese, ¹Enrico Badellino, ¹Michela Villa, ²Marco Bellero, ¹Roberta Massobrio, ¹Nicoletta Biglia, ¹Annmaria Ferrero. ¹Mauriziano Hospital; Academic Department Gynaecology; ²Mauriziano Hospital; Hospital Pharmacy

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Introduction/Background Oral metronomic cyclophosphamide (OMC) consists in the chronic administration of low, usually daily, doses of chemotherapy. The effective reduction of tumour growth, oral administration, low toxicity profile and low cost benefit women with relapsed ovarian cancer, especially heavily pretreated patients. We retrospectively evaluated the outcome of patients treated with OMC for recurrent ovarian cancer.

Methodology We selected patients treated with OMC (50 mg daily) from 2016 to 2020 at the Academic Department Gynaecology, Mauriziano Hospital, Torino, Italy. Progression free survival (PSF) and toxicities profile were evaluated.

Results Thirty-five patients were analyzed. 28 (87%) had FIGO stage III and IV disease at diagnosis and 59% had received ≥ 4 previous lines. Average age was 68 years (range 47–88). Before starting OMC 16% had ECOG 0, 65% ECOG 1 and 19% ECOG 2. Median PFS was 5 months. PFS was ≥ 6 months in 33% of patients, ≥ 12 months in 13% and ≥ 18 months in 7%. 52% experienced clinical benefit in terms of symptoms reduction. 3% of discontinuation for side effects and no G3-4 hematological toxicities reflected a low toxicity profile. Only nausea and fatigue G1-G2 were reported in 4 (12%) and 9 (28%) cases, respectively.

Conclusion OMC could be a feasible alternative therapy for recurrent ovarian cancer leading to an acceptable clinical response with a low toxicity profile, even if patients are heavily pretreated and with a suboptimal performance status.

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NIRAPARIB OUTCOMES IN BRCA WILD-TYPE PLATINUM SENSITIVE RECURRENT OVARIAN CANCER: A COMPARISON OF REAL-WORLD DATA TO THE NOVA TRIAL

Douglas Cartwright, Patricia Roxburgh, Barbara Stanley, Jennifer Brown, Alistair McLaren, Sarah Coulter, Carla Forte, Ros Glasspool. Beatson West of Scotland Cancer Centre

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Introduction/Background The PARP inhibitor (PARPi), niraparib, is EMA approved for maintenance treatment in platinum-sensitive recurrent ovarian cancer. The eligibility criteria set out in niraparib licence are less stringent than those in the NOVA trial, therefore outcomes may be different in the real-world to those observed in trial patients.¹ The optimal management of patients after progression on PARPi is unknown and the relationship between platinum free interval and probability of response to platinum may be modified after PARPi therapy. To investigate this, we performed a retrospective analysis of real-world niraparib use and compared it to the NOVA trial.

Methodology Data was collected retrospectively for all women receiving maintenance niraparib for BRCA wild-type, platinum

sensitive relapsed ovarian cancer between June 2017 and September 2019. Response to prior platinum, median progression-free survival (mPFS) after 1st and subsequent platinum, number of cycles of PARPi, dose, haematological toxicities, and PFS2I (start of subsequent therapy to physician assessed progression or death) were obtained through electronic records.

Results 37 patients received Niraparib in this timeframe. Median follow up was 16 months (range 5.7–37 months). Demographics were similar to previously published cohorts, however, only 11% (n=4) had a complete response (CR) to prior platinum therapy and 59% (n=22) had a partial response in comparison to 50% CR and 50% PR in the NOVA trial. 35 (95%) of patients had progressed on niraparib at the time of data collection. The mPFS on niraparib was 4.4 months (95% CI 3.7 – 6.7 months) in comparison to 9.3 months in the NOVA study. Patients who met the NOVA trial radiological and serological response criteria, had a mPFS at 5.1 months (n = 19) compared to 3.9 months (n = 18). Dosing and toxicity data will be reported in full at the meeting. 31 patients received subsequent therapy, 19 (61%) were treated with paclitaxel, 9 (29%) were treated with platinum-based chemotherapy. Median PFS2I was 5.8 months for platinum sensitive disease and 3.5 months for platinum resistant disease.

Conclusion The real-world outcomes for niraparib treatment are worse than observed in the NOVA trial. Patients who meet NOVA trial eligibility criteria have better outcomes, however, these results are still inferior to those reported in the trial. Post PARP outcomes are poorer than expected in both platinum sensitive and platinum resistant settings. Strategies to effectively treat PARPi resistant disease are urgently needed.

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PHASE 1B TRIAL OF MONALIZUMAB (NKG2A INHIBITOR) PLUS DURVALUMAB: SAFETY AND EFFICACY IN PATIENTS WITH METASTATIC OVARIAN, CERVICAL, AND MICROSATELLITE-STABLE ENDOMETRIAL CANCERS

¹Susana Banerjee, ²Ana Oaknin, ³Inmaculada Sanchez-Simon, ⁴Alfonso Cortes Salgado, ⁵Sandip Pravin Patel, ⁶Amit Oza, ⁷Mayukh Das, ⁷Panagiotis Kourtesis, ⁷Maria Libera Ascierto, ⁸Jennifer R Diamond. ¹Royal Marsden NHS Foundation Trust and Institute of Cancer Research; ²Hospital Vall D'hebron, Vall D'hebron Institute of Oncology (Vhio); ³Hospital Universitario Virgen; ⁴Hospital Universitario Ramón; ⁵Ucsd Moore Cancer Center; ⁶Princess Margaret Cancer Centre; ⁷Astrazeneca; ⁸University of Colorado Cancer Center

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Introduction/Background The immune checkpoints NKG2A and programmed cell death-1 (PD-1) are expressed on both tumour-infiltrating natural killer (NK) and CD8+ T cells in several cancer types, and are implicated in reducing antitumor immune response. To evaluate whether dual targeting of non-redundant checkpoint pathways (NKG2A/HLA-E and PD-1/PD-L1) may enhance antitumour immunity, the combination of monalizumab and durvalumab is being assessed in a Phase 1b expansion study in multiple solid tumours

(NCT02671435). Here we report safety and efficacy results in patients with ovarian, cervical or microsatellite-stable (MSS) endometrial cancer.

Methodology Eligible patients had advanced recurrent or metastatic high-grade serous epithelial ovarian cancer or cervical cancer (patients in each cohort could have received up to 2 prior lines of systemic therapy) or MSS endometrial cancer (patients could have received up to 3 prior lines of systemic therapy), with Eastern Cooperative Oncology Group performance status 0–1. Patients received monalizumab 750 mg Q2W and durvalumab 1500 mg Q4W for up to 3 years until unacceptable toxicity or confirmed progression. The primary endpoint was safety and tolerability; secondary endpoints included antitumour activity.

Results Between March 2017 and March 2019, 40 patients with ovarian cancer (age range, 42–75 years), 16 patients with cervical cancer (age range, 32–79 years) and 40 patients with MSS endometrial cancer (age range, 45–79 years) were enrolled. Rates of treatment-related adverse events (AEs) were generally similar across cohorts (table 1). There were no grade 5 AEs and no events leading to discontinuation of monalizumab or durvalumab. Objective responses were seen only in ovarian cancer (table 2): among the 37 evaluable patients, 2 (5.4%) had confirmed partial responses and 10 (27.0%) had stable disease (SD) including 6 (16.2%) with disease control at 24 weeks (DCR24). Median progression-free survival (mPFS) was 1.8 months and median overall survival (mOS) was 16.7 months. Six (37.5%) of the 16 evaluable patients with cervical cancer had SD; mPFS was 2.0 months and mOS was 8.6 months. Fifteen (38.5%) of the 39 evaluable patients with MSS endometrial cancer had SD, including 5 (12.8%) with DCR24; mPFS was 1.8 months and mOS was 10.7 months.

Conclusion Monalizumab plus durvalumab treatment had manageable safety in all cohorts. Modest clinical activity was demonstrated in recurrent ovarian cancer, whereas activity in cervical and MSS endometrial cancers was minimal. Further understanding of dual immune-checkpoint targeting is required.

Abstract 518 Table 1 Safety in patients with ovarian, cervical or MSS endometrial cancer

	Ovarian cancer (N=40)	Cervical cancer (N=16)	MSS endometrial cancer (N=40)
Safety			
At least one monalizumab-related AE, n (%)	23 (57.5)	9 (56.3)	24 (60.0)
At least one durvalumab-related AE, n (%)	24 (60.0)	9 (56.3)	26 (65.0)
At least one monalizumab-related SAE, n (%)	3 (7.5)	2 (12.5)	3 (7.5)
At least one durvalumab-related SAE, n (%)	4 (10.0)	2 (12.5)	2 (5.0)
Death (grade 5 severity), n (%)	0	0	0
At least one event leading to monalizumab discontinuation, n (%)	0	0	0
At least one event leading to durvalumab discontinuation, n (%)	0	0	0

Abstract 518 Table 2 Efficacy in patients with ovarian, cervical or MSS endometrial cancer

	Ovarian cancer (N=37)	Cervical cancer (N=16)	MSS endometrial cancer (N=39)
Efficacy			
Complete response, n (%)	0	0	0
Partial response, n (%)	2 (5.4)	0	0
Stable disease, n (%)	10 (27.0)	6 (37.5)	15 (38.5)
Objective response rate, n (%)	2 (5.4)	0	0
Disease control rate at 24 weeks, n (%)	6 (16.2)	0	5 (12.8)
Median progression-free survival (months)	1.8	2.0	1.8
Median overall survival (months)	16.7	8.6	10.7