

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

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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

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SOX2 EXPRESSION IN OVARIAN SEROUS EPITHELIAL CANCER

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Introduction/Background The transcription factor Sox2 is highly expressed in embryonic stem cells and is considered to act as a key driver of stem-like properties of cancer cells.

Methodology This study aimed to investigate the immunohistochemical expression profile of Sox2 in ovarian serous epithelial cancer, to determine its potential significance in disease prognosis, association with clinical and pathological parameters, as well as with patient survival.

Results A total of 270 patients were enrolled in the study. In FIGO stage I tumors Sox2 expression was absent in 28.9% of the tumors, while high Sox2 expression was significantly less frequent (7.0%, $p < 0.01$). Significantly higher Sox2 expression compared with low expression was found in the third FIGO stage (65% vs.43.2%; $p < 0.01$). Disease progression was recorded in 23.1% of patients with high Sox2 expression, which is significantly higher in comparison to patients without

Sox2 expression (11.4%; $p < 0.05$). Partial remission was observed in 14.1% with high Sox2 expression and this was significantly lower than in subjects with low Sox2 expression (28.8%; $p < 0.05$) or without Sox2 expression (34.3%; $p < 0.01$). Overall survival was the longest in the group without Sox2 expression, while the mortality was more prevalent in the group with high expression, but without statistical significance.

Conclusion The study showed that Sox2 overexpression in ovarian serous epithelial cancer was associated with the unfavorable clinical course of the disease.

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FERTILITY AND PREGNANCY OUTCOMES AFTER FERTILITY-SPARING TREATMENT IN OVARIAN CANCER PATIENTS

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Introduction/Background Incidence of ovarian cancer (OC) among reproductive-aged women has increased. Unlike cervical cancer, there are scanty recommendations on fertility-sparing treatment for OC.

The aim of this study is to evaluate fertility and obstetrics outcomes in patients with history of OC after fertility-sparing surgical treatment.

Methodology A prospective single-center study was performed on patients with stage I OC diagnosis made between January 2013 and December 2016 at the Careggi University Hospital in Florence. Data were collected with a telephone questionnaire in order to analyze not only oncological outcomes but also fertility and pregnancy outcomes.

Results A total of sixteen patients with OC were enrolled. The average age of patients at diagnosis was 29 years, and twelve patients were nulliparous. Most of them (11 pts, 68,75%) had serous low-grade OC (LGOC), 12,5% high grade serous OC, 12,5% juvenile granulosa cell cancer and one patient (6,25%) had mucinous LGCOS. These patients (18,5%) underwent adjuvant chemotherapy as their stage was IC. Mean follow-up was 63 months, OS rate was 100%, PFS at three year was 72,5%. Pregnancy outcomes were better among those patients who underwent ART (n=10), with 100% of pregnancy rate vs 75% the other six patients ($p < 0.05$), 4,10% of miscarriage rate vs 6,8% in no-ART group ($p < 0.05$), and birth rate of 100% vs 83% in no-ART group ($p < 0.01$). Concerning ovarian hormonal function, an FSH value > 40 mUI/ml was found in only one patient (6,25%) and an estradiol values < 20 pg/ml in a percentage of 18,5%. Turning to AMH value: all patients had AMH above 0,1 ng/ml, 3 patients (18,75%) had AMH between 0.1 and 1 ng/ml, 13 (81,25) patients had AMH values > 1 ng/ml.

Conclusion Our study represents an analysis of the globally fertility in patients with OC. Pregnancy and fertility results following ART seems to be promising, though the reproductive outcome are significantly better when patients are sent to ART.

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