Highlights in gynaecological cancers

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SUMMARY

In the field of gynaecologic oncology, numerous studies were presented at the 2024 ASCO Annual Meeting. Several therapeutic de-escalation strategies were discussed, including the lack of benefits from lymphadenectomy in advanced ovarian cancer and from adjuvant chemotherapy in early high-risk cervical cancer. Neoadjuvant combined with adjuvant PARP inhibitors for patients with resectable recurrent ovarian tumours is a promising approach to avoid chemotherapy and enhance quality of life. Among the new treatments, mirvetuximab soravtansine for platinum-resistant ovarian cancers and selinexor for advanced or recurrent TP53 wild-type endometrial tumours are particularly promising. Additionally, several trials have explored the impact of obesity and its management in gynaecological cancers.

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INTRODUCTION

When diagnosed at an early stage, prognosis of gynaecological cancers is generally good, whereas advanced and recurrent diseases present a therapeutic challenge with typically low overall survival (OS). While surgery, chemotherapy, and radiotherapy have been key parts of treatment for many years, the management of gynaecological cancers continues to evolve, particularly with researches into treatment de-escalation, use of targeted therapies, and efficacy analyses based on molecular subgroups. In this article, we review the most promising and discussed studies presented at the 2024 ASCO Annual Meeting.

OVARIAN CANCER

In Belgium, ovarian cancer ranks as the sixth most prevalent cancer among women. It is mostly diagnosed at advanced stages due to aspecific symptoms, making it the most lethal. Patients with high-grade serous ovarian cancer (HGSOC) have generally a very high response to first-line chemotherapy with carboplatin and paclitaxel. Unfortunately, most patients will relapse, leading to a 5-year OS rate of 47.5%, requiring second and subsequent lines of systemic therapies.

CLEAR CELL CARCINOMA

Clear cell carcinoma (CCC) accounts for around 5% of ovarian cancers. These tumours are typically found at an early stage in younger women; however, beyond FIGO (International Federation of Gynaecology and Obstetrics) stage 1, patients usually have a worse prognosis than high-grade serous subtype due to intrinsic chemoresistance. Unfortunately, current treatments do not consider their specific histological and molecular characteristics. **BrUOG 354** is a randomised phase II trial (1:2) including 44 patients with non-renal CCC (81.2%/36 patients with ovarian cancer) progressing after at least one prior treatment. This study compares nivolumab (every two weeks) with or without ipilimumab (every six weeks). The median follow-up is 11.3 months. A complete response (CR) was observed in 16.7% of patients receiving the combination, while no CR was

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reported in the monotherapy group. Moreover, partial responses (PRs) were reported in 16.7% *versus* 14.3%, respectively. The median progression-free survival (mPFS) was 5.6 months for the combination and 2.2 months for nivolumab alone group; the median OS was 24.7 months compared to 17.3 months.[1] Of note, the phase II randomised **NRG-Y003** study published by *Zamarin et al.* in 2020, also evaluated this combination but in persistent and/or recurrent ovarian cancers, regardless of histological subtype. A clinical response (CR+PR) was observed in 31.4 % of patients receiving the combination (33.3% in BrUOG354 trial) with higher benefit in CCC subtype. In conclusion, combination of immune checkpoint inhibitors appears especially effective for ovarian CCC.[2]

PARP INHIBITORS

PARP inhibitors (PARPi) are widely used as maintenance therapy for advanced ovarian cancers. The phase II **NEO** trial is investigating olaparib as neoadjuvant therapy for platinum sensitive recurrent PARPi-naïve HGSOC patients suitable for secondary surgery. All participants received olaparib for 6 ± 2 weeks prior to surgery and after were randomised 1:1 between two arms. In arm A (n=19), patients received post-surgery platinum-based chemotherapy (four to six cycles) followed by olaparib, while in arm B (n=17) they received olaparib alone. Patients progressing during neoadjuvant olaparib treatment were included in arm A without randomisation. Patient characteristics were well-balanced between groups, except for germline *BRCA* wild-type status: 26.32% in arm A (with unknown status in 37%) compared to 70.59% in arm B (with unknown status in 6%). Olaparib alone after surgery has been proven as effective as chemotherapy followed by olaparib, showing an objective response rate (ORR) of 29% with lower toxicity (no grade 3 or higher adverse events reported). The 3-year OS rates were 84.2% and 75.1% [HR: 0.90; 95% CI 0.28-2.83], and the 3-year PFS were 46.8% and 46.3% [HR: 1.31; 95% CI 0.54-3.15] for arms A and B, respectively. No impact of germline *BRCA* status was described in OS analysis. This study suggests that a chemotherapy-free approach may be feasible for resectable recurrences.[3]

PLATINUM-RESISTANT OVARIAN CANCERS

Platinum-resistant ovarian cancers (PROC) represent a significant clinical challenge due to their poor prognosis and limited effective treatment options. Folate receptor α (FRα), which is highly expressed (around 90%) in ovarian cancers and minimally expressed in normal tissues, represents a promising target for PROC patients.

Mirvetuximab soravtansine (MIRV), an innovative antibody-drug conjugate (ADC) targeting FRα linked to DM4 (a potent anti-microtubule), was evaluated in the phase III randomised MIRASOL trial. This study assessed the efficacy and safety of MIRV compared to investigator's choice chemotherapy (ICC) in 453 women with FRα-high PROC (maximum one to three prior lines of treatment). Compared to ICC, MIRV demonstrated a 35% improvement in PFS [HR: 0.65; p<0.0001], more than doubled the ORR (42% *vs.* 16%) and provided a 33% improvement in OS [HR: 0.67; p=0.0046].[4] During this 2024 ASCO meeting, results regarding the subgroup of 199 older patients (≥ 65) were presented. The authors demonstrated that MIRV significantly outperformed ICC in terms of PFS [HR: 0.62; 95% CI 0.45-0.86], ORR (39.3% *vs.* 17.4%), and OS [HR: 0.57; 95% CI 0.37-0.87]. Additionally, patients experienced fewer grade ≥3 treatment-related adverse events with MIRV.[5] Furthermore, a pooled retrospective and exploratory study, combining data from four clinical (one first-in-human phase I, one phase II-**SORAYA**, and two phase III-**MIRASOL** and **FORWARD**) trials characterised recurrent FRα-positive ovarian cancer patients with extended survival following MIRV monotherapy. The population included 682 patients with a range of FRα expression; 1% had low, 20% had medium, and 79% had high expression.[6] Long-term survival was observed in 34% of patients, with a median OS of 28.35 months and an ORR of 55.7% (9.1% CR and 46.5% PR). In conclusion, data from these two studies support the use of MIRV as a new standard of care for women of all ages with FRα-high PROC.

LYMPHADENECTOMY

The phase III **LION** study found no benefit from systematic lymphadenectomy during primary cytoreduction for advanced ovarian cancer without suspicious lymph nodes.[7] Consequently, the phase III randomised **CARACO** study continues to investigate the role of lymphadenectomy during primary or interval cytoreductive surgery. The required sample size (n=450) was not achieved due to the premature closure of fourteen centres and the patient recruitment suspension following the LION trial's publication. Patients with advanced ovarian cancer (FIGO III-IVa) without suspicious lymph nodes (no nodes >2 cm described in imaging; no nodes palpated during surgery) were randomised 1:1 between two groups: one receiving pelvic and para-aortic lymphadenectomy (186 patients) and the other undergoing surgery without lymphadenectomy (193 patients). The median number of lymph nodes removed was 27. After a median follow-up of nine years, the median PFS was 14.8 months in the no-lymphadenectomy and 18.6 months in the lymphadenectomy groups [HR: 0.98; 95% CI 0.77-1.20]. The me-

dian OS was also not significantly different: 48.9 and 58.8 months in the no- and lymphadenectomy group [HR: 0.92; 95% CI 0.72-1.17], respectively. PFS and OS were comparable between the two arms even in the subgroup of patients undergoing interval debulking surgery. Serious postoperative complications were logically more frequent in the lymphadenectomy arm (including transfusions, reoperations, and urinary injuries). All these data suggest the omission of systematic pelvic and para-aortic lymphadenectomy in advanced ovarian cancer.[8]

CERVICAL CANCER

Cervical cancer ranks as the fourth most common cancer among women worldwide, following breast, colorectal, and lung cancers, with an estimated 604,000 new cases diagnosed annually and resulting in 342,000 deaths. It is the second most prevalent cancer in developing countries, accounting for 85% of cases. In developed nations, the incidence has significantly decreased due to screening programs and HPV vaccination. In Belgium, about 650 new cases are reported each year, making cervical cancer the fourth most common cancer among women aged 25 to 44. The 5-year OS rate is 60%, varying by stage to 92%, 65%, and 17% for early-stage, locally advanced, and metastatic cases, respectively.[9]

The therapeutic management of early-stage cervical cancer is based on hysterectomy with or without lymph nodes assessment according to stage. A phase III **GOG-0724** study including 232 patients evaluates the effectiveness of adjuvant chemotherapy following chemoradiation ± brachytherapy. Patients with high-risk of recurrence after radical hysterectomy [FIGO stage IA, IB, or IIA (positive lymph nodes and/or positive parametria)] were randomised into arms with or without adjuvant chemotherapy. Patients were stratified based on various factors (brachytherapy, radiotherapy modalities, and radiation dose). The addition of chemotherapy after chemoradiation did not improve survival, neither PFS [HR: 1.05; 95% CI 0.65-1.68] nor OS [HR: 0.91; 95% CI 0.49-1.69] but increased the risk of grade ≥3 adverse events, with 59% of patients developing an adverse effect (compared to 37% in the absence of adjuvant chemotherapy).[10] Of note, a meta-analysis (published in 2022) including eight studies (2,150 patients) assessed the efficacy of adjuvant chemotherapy in patients with locally advanced cervical cancer. *Horeweg et al.* demonstrated that the addition of adjuvant chemotherapy did not improve either OS [HR: 0.78, 95% CI 0.45-1.33; p=0.36] or PFS [HR: 0.85; 95% CI 0.65-1.10; p=0.22].[11] The results of the GOGG-0724 trial and this meta-analysis definitively close the question on the adjuvant chemotherapy benefit whatever the stage.

ENDOMETRIAL CANCER

Endometrial cancer (EC) is the most common gynaecological malignancy in developed countries, with 1,420 new cases reported in 2021 in Belgium. For localised disease, the standard treatment is total hysterectomy, with or without adjuvant therapy, based on clinicopathological and molecular factors affecting recurrence risk. While localised tumours have generally a good prognosis, with a 5-year OS rate of 95%, 15-25% of cases are considered to be at high risk of relapse, resulting in unfavourable outcomes despite receiving adjuvant therapy.

TP53 WILD-TYPE EC

Selinexor is an inhibitor of exportin 1 (XPO1), a protein responsible for the trafficking of nuclear proteins (including tumour suppressor proteins such as p53, p21, p27, and FOXO) to the cytoplasm. By inhibiting XPO1, these proteins are sequestered in the nucleus, where they remain active.

The phase III **SIENDO** trial investigates the efficacy of selinexor as maintenance therapy in 263 patients with advanced or recurrent EC who have previously received paclitaxel-carboplatin chemotherapy for more than twelve weeks. Patients are randomised (2:1) between selinexor maintenance *versus* placebo. Patient characteristics are homogeneous between both groups, with over 80% diagnosed with endometrioid EC and 25% exhibiting Mismatch Repair (MMR) deficiency. The PFS among all patients (irrespective of tumour molecular subgroup), showed no improvement in the selinexor group [HR: 0.76; 95% CI 0.54-1.08; p=0.13]. In contrast, selinexor maintenance significantly improved survival, with a mPFS of 28.4 compared to 5.2 months with placebo [HR: 0.44; 95% CI 0.27-0.73; p=0.0005] in the TP53 wild-type (TP53wt) arm. In the TP53wt + MMR proficient group, the mPFS is 39.5 *versus* 4.9 months with placebo [HR: 0.36; 95% CI 0.19-0.71; p=0.0011]. In the TP53wt + MMR deficient group, the efficacy of selinexor is less pronounced, with a mPFS of 13.1 compared to 3.7 months with placebo [HR 0.49; 95% CI 0.18-1.34; p=0.0825].[12] The ongoing and actively enrolling phase III **ENGOT-EN20/GOG-3083/xport-EC-042** study is evaluating selinexor as maintenance therapy specifically in this TP53wt population.[13]

BRCA MUTATED EC

DUO-E is a double-blind, phase III study evaluating the efficacy and safety of addition of durvalumab to chemotherapy followed by durvalumab with or without olaparib in newly diagnosed advanced or recurrent EC. This trial randomised (1:1:1) patients between three groups: Arm A (chemotherapy alone, n=241), Arm B (chemotherapy plus durvalum-

ab followed by maintenance with durvalumab and placebo, n=238), and Arm C (chemotherapy plus durvalumab followed by durvalumab and olaparib, n=239). The authors show a statistically significant improvement in PFS for both Arm B [HR: 0.71, 95% CI: 0.57-0.89] and Arm C [HR: 0.55, 95% CI: 0.43-0.69] when compared to Arm A. The addition of olaparib to durvalumab appears to further enhance PFS in the MMRp group. However, the study was not designed to compare Arm B with Arm C. Similar to the findings observed in *BRCA*-mutated ovarian cancers, it is anticipated that the efficacy of olaparib might be more pronounced in *BRCA*-mutated ECs. During this 2024 ASCO meeting, a retrospective and descriptive (due to limited sample size) analysis based on *BRCA* somatic mutations was conducted. The prevalence of *BRCA* mutations was relatively low: 12.6% in MMRd and 4% in MMRp tumours. In the primary analysis, PFS benefit was observed in the intention-to-treat and pMMR populations irrespective of *BRCA*m status.[14]

HORMONE RECEPTORS POSITIVE EC

Hormonal therapy has long been the standard treatment for low-grade, indolent, hormone receptor-positive ECs. The enhanced effect of hormonal therapy by the addition of a cyclin-dependent kinase 4/6 (CDK 4/6) inhibitor, which reduce cell cycle progression is well described in breast cancer. A phase II mono-arm study conducted by Angela K. Green evaluates the combination of **fulvestrant** and **abemaciclib** in 27 patients with advanced or recurrent hormone receptor-positive EC. An ORR of 44% was observed, all patients achieving a PR according to RECIST v1.1. The median duration of response was 15.6 months, and the mPFS was nine months. A subgroup analysis revealed that patients with no specific molecular profile (NSMP) had a better ORR (59%) compared to other subgroups, including those with abnormal TP53, MMRd, and POLε (13%) (p=0.042). In terms of toxicity, ten patients needed reduced doses of abemaciclib, and the majority of grade ≥3 adverse events were hematological abnormalities (anaemia and neutropenia).[15] Of note, three previous other phase II studies evaluated the combination of hormonal therapy and a CDK 4/6 inhibitor in advanced or recurrent EC. Letrozole was combined with palbociclib (n=72 patients, ORR 63%, mPFS 8.3 months), abemaciclib (n=30 patients, ORR 30 %, mPFS 9.1 months) or ribociclib (n=20 patients, mPFS 5.4 months); the only phase III trial with lerociclib, was withdrawn.

OBESITY AND GYNAECOLOGICAL CANCERS

One of the major challenges in gynaecologic oncology is the significant impact of obesity on the development and progression of cancer. A large-scale study was conducted in the United States between 2001 and 2018, including 586,742 women diagnosed with endometrioid EC. The majority of the patients were white (83%), older (61.7% over 60 years old), and diagnosed at an early stage (with localised disease in 68.3%). Most patients included were overweight (28.1%) or obese (42.4%), with no difference observed based on age. While the incidence of many cancers tends to remain stable or decrease, the global incidence of EC has risen by 21% since 2008, attributed to extended life expectancy and increasing obesity prevalence. In 2014, ovarian cancer was more prevalent, accounting for 5% of cancers in women, while EC represented 3%. By 2024, this trend has reversed, with EC becoming more frequent (5%). Since 2001, it is particularly observed in younger women, with a 137.5% and 71.8% increase among patients aged 0 to 29 years and 30 to 39 years, respectively. These incidence changes are primarily observed in the black (25.7% increase) and Hispanic (17.8%) populations.[16]

In this context, an increasing number of studies are focusing on obesity in cancer and the impact of its management. It has already been shown that bariatric surgery, with a 10-year follow-up, reduces the risk of developing obesity-related cancers by 32% [HR: 0.68; 95% CI 0.53-0.87].[17]

A comparative "big data" study evaluates the risk of developing obesity-related cancers among patients with a BMI of 35 or greater who underwent bariatric surgery or were treated with GLP-1 receptor agonists (GLP-1 RAs). This study included various obesity-related cancers: gastrointestinal, female reproductive organ (ovarian, endometrial, breast), and other cancers such as thyroid cancer, multiple myeloma, and renal cell carcinoma. The 334,675 patients were divided into three groups based on their obesity management: arm A compares bariatric surgery to GLP-1 RA treatment (n=14,504), arm B compares GLP-1 RA treatment to no treatment (n=21,768), and arm C compares bariatric surgery to no treatment (n=55,798).[18]

In arm A, after one to two years, patients lost more weight with bariatric surgery (-5.31 ± 6.05 kg/m²) than those on GLP-1 RA treatment (-1.57 ± 5.12 kg/m²). At fifteen years, 273 patients receiving GLP-1 RA therapy (8.75%) and 397 patients who underwent bariatric surgery (6.58%) developed obesity-related cancers, respectively [HR: 1.147; 95% CI 0.876-1.502; p=0.319]. Those treated with GLP-1 RAs showed a decreased risk of obesity-associated cancer [HR: 0.809; 95% CI 0.666 - 0.983]; bariatric surgery patients had also a reduced risk [HR: 0.78; 95% CI 0.67-0.91] compared to individuals with no treatment. GLP-1 RA and bariatric surgery were associated with lower mortality compared to control. Managing obesity is crucial for reducing the risk of developing cancer and associated mortality.

CONCLUSION AND KEY MESSAGES

The landscape of patient care is transforming with the rise of targeted and personalised therapies. These therapies not only enhance treatment efficacy but also prioritise quality of life. Indeed, studies on gynaecological cancers presented at the 2024 ASCO Annual Meeting also focus on treatment de-escalation in favour of patient well-being. CARACO study highlighted the lack of survival benefit from pelvic and para-aortic lymphadenectomy in advanced ovarian cancer, along with more frequent postoperative complications. NEO trial suggested a chemotherapy-free approach with PARPi in neo-adjuvant and maintenance setting for resectable recurrent platinum-sensitive ovarian tumours. For early and locally advanced cervical cancer, the addition of adjuvant chemotherapy does not improve survival but increases the risk of treatment-related side effects.
Targeted therapies were also presented, particularly the efficacy of dual immunotherapy (anti-PD-1 and anti-CTLA-4) in ovarian clear cell carcinoma. Molecular subgroup analyses are crucial, as seen with the use of selinexor in maintenance treatment for advanced or recurrent EC. In the overall population, selinexor showed no benefit, while in the TP53wt group, treatment significantly improved survival.
Endometrial cancer is significantly associated with obesity, which partly explains its increasing incidence over the last two decades. Treating obesity by surgical or pharmacological approaches may reduce the incidence of cancer and the mortality rates.

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