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Practice Guideline

Clinical practice guidelines for ovarian cancer: an update to the Korean Society of Gynecologic Oncology guidelines

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ABSTRACT

We updated the Korean Society of Gynecologic Oncology (KSGO) practice guideline for the management of ovarian cancer as version 5.1. The ovarian cancer guideline team of the KSGO published announced the fifth version (version 5.0) of its clinical practice guidelines for the management of ovarian cancer in December 2023. In version 5.0, the selection of the key questions and the systematic reviews were based on the data available up to December 2022. Therefore, we updated the guidelines version 5.0 with newly accumulated clinical data and added 5 new key questions reflecting the latest insights in the field of ovarian cancer between 2023 and 2024. For each question, recommendation was provided together with corresponding level of evidence and grade of recommendation, all established through expert consensus.

Keywords: Hyperthermic Intraperitoneal Chemotherapy; Risk-educing Salpingo-oophorectomy; Poly(ADP-ribose) Polymerase (PARP) Inhibitor; Mirvetuximab Soravtansine; Trastuzumab Deruxtecan; Practice Guideline; Ovarian Neoplasms

INTRODUCTION

Five key questions (KQs) were developed (**Table 1**), and levels of evidence and grades of recommendation were applied using the system shown in **Table 2** [1].

Table 1. KQs

#	Questions	Status
KQ1	Does hyperthermic intraperitoneal chemotherapy (HIPEC) improve survival in advanced epithelial ovarian cancer (EOC) patients who receive neoadjuvant chemotherapy and interval debulking surgery?	New
KQ2	Does poly (ADP-ribose) polymerase (PARP) inhibitor with bevacizumab maintenance therapy improve survival in advanced EOC patients with a response after first-line platinum-based chemotherapy including bevacizumab?	New
KQ3	Does risk-reducing salpingo-oophorectomy (RRSO) prevent the occurrence of ovarian cancer in asymptomatic carriers of BRCA pathogenic variants (PVs)?	New
KQ4	Does mirvetuximab soravtansine-gynx (MIRV) improve survival in patients with platinum-resistant ovarian cancer?	New
KQ5	Can trastuzumab deruxtecan be used in patients with locally advanced or metastatic gynecologic cancers?	New

KQ, key question.

Table 2. Levels of evidence and grades of recommendation (adapted from the Infectious Diseases Society of America—United States Public Health Service Grading System*)

Variables	Description
Levels of evidence	
Level I	Evidence from at least one large, randomized, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomized trials without heterogeneity
Level II	Small randomized trials or large randomized trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
Level III	Prospective cohort studies
Level IV	Retrospective cohort studies or case-control studies
Level V	Studies without a control group, case reports, expert opinions
Grades of recommendation	
Grade A	Strong evidence for efficacy with substantial clinical benefit, strongly recommended
Grade B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
Grade C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages, optional
Grade D	Moderate evidence against efficacy or for adverse outcomes, generally not recommended
Grade E	Strong evidence against efficacy or for adverse outcomes, never recommended

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Conflict of Interest
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CLINICAL CONSIDERATIONS AND RECOMMENDATIONS

1. KQ1. Does hyperthermic intraperitoneal chemotherapy (HIPEC) improve survival in advanced epithelial ovarian cancer (EOC) patients who receive neoadjuvant chemotherapy and interval debulking surgery?

P (population): EOC patients receiving neoadjuvant chemotherapy and interval debulking surgery
I (intervention): Cytoreductive surgery with HIPEC and postoperative chemotherapy
C (comparison): Cytoreductive surgery with postoperative chemotherapy
O (outcome): Survival (progression-free survival [PFS] and overall survival [OS])

The following recommendation was made through consensus:

> HIPEC can be administered in advanced EOC patients receiving neoadjuvant chemotherapy and interval debulking surgery because it improves survival rates (Level of evidence: I, Grade of recommendation: B).

Evidence

The OVHIPEC-1 trial [2,3], an open-label, phase III, randomized controlled trial (RCT), enrolled newly diagnosed stage III EOC patients with extensive abdominal disease or incomplete primary cytoreductive surgery (>1-cm residual). Patients were eligible if they had not progressed during at least 3 cycles of neoadjuvant carboplatin plus paclitaxel and ≤1 cm of residual disease during interval cytoreductive surgery. Through central randomization (1:1), patients were

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assigned into interval cytoreductive surgery without HIPEC (surgery group; n=123) or with HIPEC (100 mg/m^2 cisplatin; surgery-plus-HIPEC group; n=122). Three additional cycles of carboplatin and paclitaxel were administered postoperatively. After a median follow-up of 4.7 years, recurrence-free survival significantly increased in the surgery-plus-HIPEC group compared to the surgery group (median, 10.7 vs. 14.2 months; hazard ratio [HR]=0.66; 95% confidence interval [CI]=0.50–0.87; p=0.003). OS also significantly increased in the surgery-plus-HIPEC group compared to the surgery group (median, 33.9 vs. 45.7 months; HR=0.67; 95% CI=0.48–0.94; p=0.02) [2]. After a median follow-up of 10.1 years in the surgery group and 10.4 years in the surgery-plus-HIPEC group, PFS significantly increased in the surgery-plus-HIPEC group compared to the surgery group (median, 10.7 vs. 14.3 months; HR=0.63; 95% CI=0.48–0.83; p=0.0008). OS also significantly increased in the surgery-plus-HIPEC group compared to the surgery group (median, 33.3 vs. 44.9 months; HR=0.70; 95% CI=0.53–0.92; p=0.011). Rates of grade 3–4 adverse events (AEs) were similar between the 2 groups (25% in the surgery group vs. 27% in the surgery-plus-HIPEC group, p=0.76) [3].

Currently, only a few hospitals in our country administer HIPEC because it is less preferred than intravenous chemotherapy. Therefore, we assigned the grade of recommendation of KQ1 as B.

2. KQ2. Does poly(ADP-ribose) polymerase (PARP) inhibitor with bevacizumab maintenance therapy improve survival in advanced EOC patients with a response after first-line platinum-based chemotherapy including bevacizumab?

P: Newly diagnosed advanced EOC patients with a response after first-line platinum-taxane chemotherapy with bevacizumab
I: PARP inhibitor with bevacizumab maintenance therapy
C: No PARP inhibitor with bevacizumab maintenance therapy
O: Survival (PFS and OS)

The following recommendation was made through consensus:

> PARP inhibitor with bevacizumab maintenance therapy* is recommended in advanced EOC patients with homologous recombination deficiency (HRD)-positive tumors or BRCA mutations showing a response to first-line platinum-based chemotherapy with bevacizumab after surgery because it improves survival (Level of evidence: I, Grade of recommendation: A).
>
> *Olaparib + bevacizumab is recommended. However, niraparib + bevacizumab may be used if the patient is unable to tolerate olaparib + bevacizumab.

Evidence

The PAOLA-1 trial [4,5], a double-blind, international, phase III RCT, enrolled patients (n=806) who had newly diagnosed, advanced, high-grade ovarian cancer and showed a response after first-line platinum-taxane chemotherapy plus bevacizumab. Patients were randomly assigned at a 2:1 ratio to receive olaparib tablets (300 mg twice daily) plus bevacizumab (n=537) or placebo plus bevacizumab (n=269) for up to 24 months. After a median follow-up of 22.9 months, PFS significantly increased in the olaparib group compared to the placebo group (median, 22.1 vs. 16.6 months; HR=0.59; 95% CI=0.49–0.72; p<0.001) [4]. The updated PFS at 5 years was significantly increased in the olaparib group

compared to the placebo group as follows: patients with HRD-positive tumors (median, 46.8 vs. 17.6 months; HR=0.41; 95% CI=0.32–0.54; 5-year PFS rate, 46.1% vs. 19.2%); patients with tumor BRCA mutations (median, 60.7 vs. 21.7 months; HR=0.45; 95% CI=0.32–0.64; 5-year PFS rate, 50.0% vs. 25.1%); and patients with HRD-positive tumors without BRCA mutations (median, 30.0 vs. 16.6 months; HR=0.47; 95% CI=0.32–0.7; 5-year PFS rate, 41.1% vs. 14.6%) [4]. After a median follow-up of 61.7 and 61.9 months in the olaparib and placebo groups, respectively, the OS was not different between the groups [5]. However, in subgroup analyses, OS was significantly increased in the olaparib group compared to the placebo group (patients with tumor BRCA mutations: median, 75.2 vs. 57.3 months; HR=0.62; 95% CI=0.45–0.85; 5-year OS rate, 65.5% vs. 48.4%) (patients with HRD-positive tumors without BRCA mutations: median, 75.2 vs. 66.9 months; HR=0.60; 95% CI=0.39–0.93; 5-year OS rate, 73.2% vs. 53.8%) [5]. AEs were similar to those attributed to olaparib and bevacizumab as monotherapy [4]. Myelodysplastic syndrome, acute myeloid leukemia, aplastic anemia, and new primary malignancy incidence were low and similar between groups [5].

The OVARIO trial [6], a multicenter, phase II, single-arm, open-label study, was developed to assess the safety and efficacy of niraparib plus bevacizumab as a first-line maintenance therapy in newly diagnosed stage IIIB–IV EOC patients. Eligible patients (n=105) received debulking surgery and had a complete response, partial response, or no evidence of disease following first-line, platinum-based chemotherapy with at least 3 cycles of bevacizumab. The PFS rate at 18 months was 62% in the overall population and 76% in the HRD (n=49) as well as 47% in the $HR_{proficient}$ (HRP) (n = 38), and 56% in the $HR_{not\ determined}$ (HRnd) (n=18) subgroups, respectively. After a median follow-up time of 28.7 months, the median PFS was 19.6 months in the overall population and 28.3, 14.2, and 12.1 months in the HRD, HRP, and HRnd subgroups, respectively. AEs were consistent with those already known to exist with olaparib and bevacizumab, respectively.

3. KQ3. Does risk-reducing salpingo-oophorectomy (RRSO) prevent the occurrence of ovarian cancer in asymptomatic carriers of BRCA pathogenic variants (PVs)?

P: Asymptomatic carriers of BRCA1/2 PVs
I: RRSO
C: No RRSO
O: Incidence of ovarian cancer

The following recommendation was made through consensus:

> RRSO can be performed in asymptomatic carriers of BRCA PVs because it prevents occurrence of ovarian cancer (Level of evidence: III, Grade of recommendation: A).

Evidence

A prospective international cohort study (n=2,482) [7] reported that RRSO was associated with a lower risk of ovarian cancer; first breast cancer; and overall, breast cancer-specific, and ovarian cancer-specific mortality in BRCA PV carriers. Moreover, in another prospective international cohort study (n=5,783) [8], preventive oophorectomy in BRCA PV carriers was associated with an 80% reduction in the risk of EOC and a 77% reduction in all-cause mortality. A meta-analysis of 3 prospective cohort studies (n=9,192) [9] showed that RRSO in BRCA PV carriers reduced the ovarian cancer risk (HR=0.19; 95% CI=0.13–0.27; p<0.00001)

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and all-cause mortality (HR=0.32; 95% CI=0.27–0.38; p<0.00001). A recent prospective cohort study (n=2,557) [10] reported that, in asymptomatic BRCA PV carriers, high-grade serous carcinoma (HGSC) was detected from 1.5% (BRCA1 PV) and 0.6% (BRCA2 PV) of RRSO specimens. The fallopian tube was identified as the primary site in 73% of all tumors. The prevalence of HGSC in women who received RRSO at the recommended age (35–40 years for BRCA1 PV carriers and generally 40–45 years for BRCA2 PV carriers) was 0.4%. In BRCA PV carriers, older age at RRSO increased the risk of HGSC (odds ratio [OR]=1.070; 95% CI=1.021–1.122; p<0.01). The National Comprehensive Cancer Network (NCCN) guideline provides the RRSO protocol [11].

Only prospective studies have evaluated the impact of RRSO on the risk of ovarian cancer. However, it is very difficult to conduct RCTs to investigate the effects of RRSO on the risk of ovarian cancer because of ethical issues. Therefore, we decided the grade of recommendation of KQ3 to be A with consideration for this situation, although KQ3 is supported by only prospective studies.

4. KQ4. Does mirvetuximab soravtansine-gynx (MIRV) improve survival in patients with platinum-resistant ovarian cancer?

P: Platinum-resistant, high-grade serous ovarian cancer with high folate receptor α (FRα) expression
I: MIRV
C: Chemotherapy
O: Survival (PFS and OS)

The following recommendation was made through consensus:

> MIRV is recommended in patients with platinum-resistant HGSC with high FRα expression because it improves survival rates (Level of evidence: I, Grade of recommendation: A).

Evidence

MIRV, a first-in-class antibody-drug conjugate targeting FRα, was recently approved for the treatment of platinum-resistant ovarian cancer from the U.S. Food and Drug Administration (FDA) based on the results of the MIRASOL trial [12].

The MIRASOL trial [13], a phase III, global, confirmatory, open-label RCT, was conducted in patients with platinum-resistant HGSC. Eligible patients (n=453) had previously received one to 3 lines of chemotherapy and had high FRα tumor expression (≥75% of cells with ≥2+ staining intensity in immunohistochemistry [IHC]). Patients were randomly assigned at a 1:1 ratio to receive MIRV (6 mg/kg of adjusted ideal body weight every 3 weeks) (n=227) or chemotherapy (paclitaxel, pegylated liposomal doxorubicin, or topotecan) (n=226). PFS significantly increased in the MIRV group compared to the chemotherapy group (median, 5.62 vs. 3.98 months; p<0.001). Objective responses were 42.3% in the MIRV group and 15.9% in the chemotherapy group (OR=3.81; 95% CI=2.44–5.94; p<0.001). OS significantly increased in the MIRV group compared to the chemotherapy group (median, 16.46 vs. 12.75 months; HR=0.67; 95% CI=0.50–0.89; p=0.005). AEs of grade ≥3 occurred in 41.7% of the MIRV group and 54.1% of the chemotherapy group. AEs leading to discontinuation occurred in 9.2% of the MIRV group and 15.9% of the chemotherapy group.

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5. KQ5. Can trastuzumab deruxtecan (T-DXd) be used in patients with locally advanced or metastatic gynecologic cancers?

P: Patients with human epidermal growth factor 2 (HER2)-expressing locally advanced or metastatic ovarian, endometrial, or cervical cancers after at least one systemic treatment or without alternative treatments
I: T-DXd
C: Conventional chemotherapy
O: Overall response rate (ORR)

The following recommendation was made through consensus:

> T-DXd can be administered in patients with HER2-expressing locally advanced or metastatic ovarian, endometrial or cervical cancers after ≥1 systemic treatment or without alternative treatments because it has high ORRs (Level of evidence: III, Grade of recommendation: C).

Evidence

T-DXd, a HER2-directed antibody-drug conjugate, is used for the treatment of HER2-expressing breast and gastric cancers and HER2-mutant non-small-cell lung cancer [14]. Recently, the FDA granted accelerated approval to fam-trastuzumab deruxtecan-nxki (Enhertu®; Daiichi Sankyo, Inc., Tokyo, Japan) for adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options [15]. The treatment for nine different types of HER2-positive (IHC 3+) solid tumors were approved based on 3 clinical trials. The treatment for ovarian, endometrial, and cervical cancers were approved based on the results of DESTINY-PanTumor02 (NCT04482309) among those clinical trials [15,16].

The DESTINY-PanTumor02 trial [14], a phase II, global, open-label, single-arm study, was done in patients with HER2-expressing (IHC 3+/2+) locally advanced or metastatic disease after at least one systemic treatment or without alternative treatments. A total of 267 patients across 7 tumor cohorts (ovarian, endometrial, cervical, bladder, biliary tract, pancreatic, and other) were treated with T-DXd (5.4 mg/kg once every 3 weeks). The median follow-up time was 12.75 months, and the ORR was the primary endpoint. In patients with ovarian cancer (n=40), outcomes were as follows: ORR, 45% (36.8% in IHC 2+, 63.6% in IHC 3+); median PFS, 5.9 months (4.1 months for IHC 2+, 12.5 months for IHC 3+); median OS, 13.2 months (13.0 months for IHC 2+, 20.0 months for IHC 3+); and AEs of grade ≥3, 52.5%. Patients with endometrial cancer (n=40) showed the following outcomes: ORR, 57.5% (47.1% in IHC 2+, 84.6% in IHC 3+); median PFS, 11.1 months (8.5 months for IHC 2+, not reached [NR] for IHC 3+); median OS, 26.0 months (16.4 months for IHC 2+, 26.0 months for IHC 3+); and AEs of grade ≥3, 47.5%. Patients with cervical cancer (n=40) showed the following outcomes: ORR, 50.0% (40.0% in IHC 2+, 75.0% in IHC 3+); median PFS, 7.0 months (4.8 months for IHC 2+, NR for IHC 3+); median OS, 13.6 months (11.5 months for IHC 2+, NR for IHC 3+); and AEs of grade ≥3, 35.0%. Eleven ovarian cancer patients, 13 endometrial cancer patients, and 8 cervical cancer patients were identified as having HER2 IHC 3+ expression.

In KQ5, conventional chemotherapy was considered as “the comparison” because DESTINY-PanTumor02 was a single-arm study without a control group. Moreover, ORR was considered to be “the outcome” because the primary endpoint of DESTINY-PanTumor02 was ORR.

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Therefore, the ORR of conventional chemotherapy in gynecologic cancer was searched. In patients with recurrent EOC who received single agents or combination chemotherapy, the ORR ranged between 3% and 53% [17,18]. In patients with metastatic, advanced, or recurrent endometrial cancer, ORRs were 0%–62% (platinum-based chemotherapy, 34%–62%; non-platinum-based chemotherapy, 0%–37%) [19]. In patients with metastatic, persistent, or recurrent cervical cancer, ORRs were 0%–62.6% (single agents, 0%–33%; phase II trials of cisplatin-based doublets, 22%–54%; phase III trials of cisplatin-based chemotherapy, 13%–62.6%) [20].

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