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Practice Guideline

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Clinical practice guidelines for cervical cancer: an update of the Korean Society of Gynecologic Oncology Guidelines

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ABSTRACT

We describe the updated Korean Society of Gynecologic Oncology (KSGO) practice guideline for the management of cervical cancer, version 5.1. The KSGO announced the fifth version of its clinical practice guidelines for the management of cervical cancer in March 2024. The selection of the key questions and the systematic reviews were based on data available up to December 2022. Between 2023 and 2024, substantial findings from large-scale clinical trials and new advancements in cervical cancer research remarkably emerged. Therefore, based on the existing version 5.0, we updated the guidelines with newly accumulated clinical data and added 4 new key questions reflecting the latest insights in the field of cervical cancer. For each question, recommendation was formulated with corresponding level of evidence and grade of recommendation, all established through expert consensus.

Keywords: Chemoradiotherapy; Immune Checkpoint Inhibitors; Minimally Invasive Surgical Procedures; Practice Guideline; Uterine Cervical Neoplasms

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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INTRODUCTION

The Korean Society of Gynecologic Oncology (KSGO) announced the fifth version of its clinical practice guidelines for the management of cervical cancer in March 2024. These guidelines were developed to reflect the latest insights and address critical contemporary issues in cervical cancer care, focusing on 5 key clinical questions. Each question was explored through systematic reviews and meta-analyses, forming the basis for drafting evidence-based recommendations with clearly defined levels and grades of evidence. These drafts underwent further refinement through consultations with relevant academic societies and public hearings, culminating in the release of the final version.

The selection of the key questions and the systematic reviews were based on data available up to December 2022. However, between 2023 and 2024, substantial findings from large-scale clinical trials and new advancements in cervical cancer research emerged. To incorporate these developments, the KSGO has released the Clinical Practice Guidelines for Cervical Cancer version 5.1, an updated edition that builds on the foundational work of version 5.0. The updated guidelines integrate newly published studies and reassess existing evidence to provide the most up-to-date recommendations.

Among the original 5 key questions, 3 have been updated, 1 remains unchanged, and 1 has been removed due to insufficient clinical evidence. In addition, 4 new key questions have been introduced. These changes are summarized in **Tables 1** and **2**. For each question, recommendation was formulated with corresponding level of evidence and grade of recommendation, all established through expert consensus (**Table 3**).

Table 1. Changes in guidelines version 5.1 compared to version 5.0

#	Item	Detail	Status
KQ1	Key question	Does the addition of immune checkpoint inhibitors to primary treatment (chemotherapy +/− bevacizumab) improve the survival of patients with persistent, recurrentor metastatic cervical cancer?	Updated
	Recommendation	Adding immune checkpoint inhibitors to chemotherapy +/− bevacizumab is recommended for patients with persistent, recurrent or metastatic cervical cancer. (Level of evidence: I, Grade of recommendation: A, Consensus)	
KQ2	Key question	Do immune checkpoint inhibitors improve the survival of patients with recurrent or metastatic cervical cancer in whom primary treatment has failed?	Maintained
	Recommendation	Immune checkpoint inhibitor monotherapy can be used for patients with recurrent or metastatic cervical cancer that has failed primary treatment. (Level of evidence: I, Grade of recommendation: B, Consensus)	
KQ3	Key question	Does minimally invasive radical hysterectomy result in survival outcomes similar to those of open radical hysterectomy in patients with cervical cancer?	Updated
	Recommendation	In patients with cervical cancer, minimally invasive radical hysterectomy has shown shorter disease-free survival and overall survival compared to open radical hysterectomy. Therefore, open radical hysterectomy is recommended as the standard treatment. However, the choice of surgical method can be made after discussing the benefits and risks of each approach with the patient. (Level of evidence: I, Grade of recommendation: D, Consensus)	
KQ4	Key question	Does adjuvant chemotherapyafter chemoradiotherapy and brachytherapy improve the survival of patients with locally advanced cervical cancer?	Updated
	Recommendation	Consideration should be given to not administering chemotherapy after concurrent chemoradiotherapy for patients with locally advanced cervical cancer. (Level of evidence: I, Grade of recommendation: D, Consensus)	
KQ5	Key question Recommendation		Removed

KQ, key question.

Table 2. Key questions and recommendations newly developed in guidelines version 5.1

#	Item	Detail	Status
KQ5	Key question	Does simple hysterectomy result in recurrence rates comparable to those of radical hysterectomy in patients with early-stage, low-risk cervical cancer?	New
	Recommendation	In patients with early-stage, low-risk cervical cancer, simple hysterectomy has shown non-inferior recurrence rates compared to type II radical hysterectomy. Therefore, the choice of surgical method can be made after discussing the benefits and risks of each approach with the patient (Level of Evidence: I, Grade of Recommendation: B, Consensus)	
KQ6	Key question	Does neoadjuvant chemotherapy before chemoradiotherapy improve the survival of patients with locally advanced cervical cancer?	New
	Recommendation	Neoadjuvant chemotherapy can be administered prior to chemoradiotherapy for patients with locally advanced cervical cancer. (Level of Evidence: I, Grade of Recommendation: B, Consensus)	
KQ7	Key question	Does the addition of immune checkpoint inhibitors to chemoradiotherapy improve the survival of patients with locally advanced cervical cancer?	New
	Recommendation	Immune checkpoint inhibitor can be added to chemoradiotherapy for patients with locally advanced cervical cancer. (Level of Evidence: I, Grade of Recommendation: B, Consensus)	
KQ8	Key question	Do antibody-drug conjugates improve the survival of patients with recurrent or metastatic cervical cancer in whom primary treatment has failed?	New
	Recommendation	Antibody-drug conjugate tisotumab vedotintftv monotherapy can be used for patients with recurrent or metastatic cervical cancer that has failed primary treatment. (Level of Evidence: I, Grade of Recommendation: B, Consensus)	

KQ, key question.

Table 3. Level of evidence and grades of recommendation (adapted from the Infectious Diseases Society of America—United States Public Health Service Grading System*)

Variables	Description
Level 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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CLINICAL CONSIDERATIONS AND RECOMMENDATIONS

1. KQ1. Does the addition of immune checkpoint inhibitors to primary treatment (chemotherapy +/– bevacizumab) improve the survival of patients with persistent, recurrent or metastatic cervical cancer?

P (population): Recurrent or metastatic cervical cancer
I (intervention): Chemotherapy +/– angiogenesis inhibitor + immune checkpoint inhibitor
C (comparison): Chemotherapy +/– angiogenesis inhibitor
O (outcome): Survival

The following recommendation was made through consensus:

> Adding immune checkpoint inhibitors to chemotherapy +/– bevacizumab is recommended for patients with persistent, recurrent or metastatic cervical cancer (Level of evidence: I, Grade of recommendation: A).

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Evidence

In the KSGO Clinical Practice Guidelines for Cervical Cancer version 5.0, we provided a recommendation for this key question based on the randomized phase III study, KEYNOTE-826 [1]. In version 5.1, we have reanalyzed this key question by incorporating the results of the BEATcc study, a phase III randomized, open-label, multicenter trial that investigated whether adding atezolizumab to the standard carboplatin, paclitaxel, and bevacizumab treatment regimen provides enhanced efficacy [2]. Key characteristics of this study include its open-label design and the mandatory administration of bevacizumab. A total of 410 patients were randomized, and the atezolizumab group demonstrated significantly improved progression-free survival (PFS; hazard ratio [HR]=0.62; 95% confidence interval [CI]=0.49–0.78) and overall survival (OS; HR=0.68; 95% CI=0.52–0.88) compared to the control group.

We performed a meta-analysis of these 2 studies, confirming that the addition of immune checkpoint inhibitors to the existing standard chemotherapy regimen significantly improved PFS (HR=0.64; 95% CI=0.55–0.74) and OS (HR=0.67; 95% CI=0.57–0.80) (**Data S1**). However, grade 3 or higher adverse events were also increased compared to standard therapy alone (HR=1.37; 95% CI=1.02–1.85).

Based on these updated results, the KSGO guideline development committee has agreed to revise the recommendation for this key question to its current form.

2. KQ2. Do immune checkpoint inhibitors improve the survival of patients with recurrent or metastatic cervical cancer in whom primary treatment has failed?

P: Recurrent or metastatic cervical cancer
I: Immune checkpoint inhibitor
C: Conventional chemotherapy
O: Survival

The following recommendation was made through consensus:

> Immune checkpoint inhibitor monotherapy can be used for patients with recurrent or metastatic cervical cancer that has failed primary treatment (Level of evidence: I, Grade of recommendation: B).

Evidence

The recommendation for this key question was based on the clinical outcomes of the EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9, a randomized multicenter phase III clinical trial [3]. No new clinical research data was available for this key question. Therefore, the guideline development committee has agreed to maintain the existing recommendation for this key question. Detailed evidence supporting this recommendation has been published [4].

3. KQ3. Does minimally invasive radical hysterectomy result in survival outcomes similar to those of open radical hysterectomy in patients with cervical cancer?

P: Cervical cancer
I: Minimally invasive radical hysterectomy

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C: Open radical hysterectomy
O: Survival

The following recommendation was made through consensus:

> In patients with cervical cancer, minimally invasive radical hysterectomy has shown shorter disease-free survival (DFS) and OS compared to open radical hysterectomy. Therefore, open radical hysterectomy is recommended as the standard treatment. Considering the clinical environment and situation in Korea, the choice of surgical method can be made after discussing the benefits and risks of each approach with the patient (Level of evidence: I, Grade of recommendation: D).

Evidence
The recommendation for this key question was based on the Laparoscopic Approach to Cervical Cancer (LACC) trial [5]. In the final survival analysis of the LACC trial published in 2024, Both DFS and OS remained significantly lower in the minimally invasive radical hysterectomy group than in the open radical hysterectomy group (DFS; HR=3.91; 95% CI=2.02–7.58; OS; HR=2.71; 95% CI=1.32–5.59) [6].

Based on these findings, the recommendation in version 5.0 was stated as: "Consideration should be given to not performing minimally invasive radical hysterectomy in patients with cervical cancer." Subsequently, expert opinions from various fields were gathered through multiple public hearings. Considering the introduction of various efforts and surgical techniques to prevent tumor cell spillage [7,8], and the fact that the recurrence rate for minimally invasive radical hysterectomy was not lower in the subgroup of patients with prior conization in the LACC trial [6,9], many expressed the opinion that the recommendation against performing minimally invasive surgery for all cases of cervical cancer may not be appropriate. Agreeing with this opinion, the KSGO guideline development committee decided to revise the recommendation to its current form.

4. KQ4. Does adjuvant chemotherapy after chemoradiotherapy and brachytherapy improve the survival of patients with locally advanced cervical cancer?

P: Locally advanced cervical cancer
I: Adjuvant chemotherapy after chemoradiation
C: Chemoradiation
O: Survival

The following recommendation was made through consensus:

> Consideration should be given to not administering chemotherapy after concurrent chemoradiotherapy (CCRT) for patients with locally advanced cervical cancer (Level of evidence: I, Grade of recommendation: D).

Evidence
In version 5.0, the intervention group for this key question included both chemotherapy and immune checkpoint inhibitors in the analysis. However, in version 5.1, chemotherapy and immune checkpoint inhibitors were separated, and the recommendation was revised

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accordingly. As a result, KQ4 was modified to include only adjuvant chemotherapy, and a new key question, KQ7, was added to address the addition of immune checkpoint inhibitors during and after chemoradiotherapy for locally advanced cervical cancer.

The meta-analysis conducted for the revised KQ4 included 4 randomized phase 3 clinical trials (**Data S1**) [10-13]. The analysis revealed that both PFS (HR=0.88; 95% CI=0.73–1.08) and OS (HR=0.93; 95% CI=0.72–1.19) did not differ significantly between the CCRT plus adjuvant chemotherapy group and the CCRT group. On the other hand, analysis of 3 studies that reported adverse events showed that the incidence of grade 3 or higher adverse events was significantly higher in the CCRT plus adjuvant chemotherapy group (HR=3.01; 95% CI=1.41–6.45). Since there was heterogeneity in the survival outcomes of the studies included in the meta-analysis, we assigned the grade of recommendation as D.

5. KQ5. Does simple hysterectomy result in recurrence rates comparable to those of radical hysterectomy in patients with early-stage, low-risk cervical cancer?

P: Early-stage, low-risk cervical cancer
I: Simple hysterectomy
C: Radical hysterectomy
O: Survival

The following recommendation was made through consensus:

> In patients with early-stage, low-risk cervical cancer, simple hysterectomy has shown non-inferior recurrence rates compared to type II radical hysterectomy. Therefore, the choice of surgical method can be made after discussing the benefits and risks of each approach with the patient (Level of evidence: I, Grade of recommendation: B).

Evidence

In the phase III multicenter randomized noninferior SHAPE trial [14], patients who underwent simple hysterectomy for early-stage low-risk cervical cancer showed noninferiority in pelvic recurrence rate compared to the patients who underwent type II radical hysterectomy (2.52% vs. 2.17%; HR=1.12; 95% CI=0.47–2.67). No difference was observed between the 2 groups for OS (HR=1.09; 95% CI=0.38-3.14). The incidence of surgery-related adverse events within 4 weeks after surgery was lower in the simple hysterectomy group (42.6% vs. 50.6%, p=0.04). And the incidence of urinary incontinence and urinary retention within and beyond 4 weeks after surgery was significantly lower in the simple hysterectomy group than in the radical hysterectomy group. The patients included in this study had cervical squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma, with tumor sizes ≤2 cm and invasion depths ≤10 mm.

However, several factors warrant caution in interpreting the results of the SHAPE trial. Notably, 75% of the patients underwent minimally invasive surgery, about 80% had prior conization, and fewer than 50% of patients had residual disease in the hysterectomy specimen. Additionally, type III radical hysterectomy was not performed as the control intervention. Considering these factors, the guideline development committee agreed to assign a grade of recommendation as B for this recommendation.

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6. KQ6. Does induction chemotherapy before chemoradiotherapy improve the survival of patients with locally advanced cervical cancer?

P: Locally advanced cervical cancer
I: Neoadjuvant chemotherapy prior to chemoradiation
C: Chemoradiation
O: Survival

The following recommendation was made through consensus:

> Induction chemotherapy can be administered prior to chemoradiotherapy for patients with locally advanced cervical cancer (Level of evidence: I, Grade of recommendation: B).

Evidence
In the phase III, multicenter randomized, open-label INTERLACE trial, patients with locally advanced cervical cancer were randomly assigned to receive induction chemotherapy before definitive chemoradiotherapy or not [15]. The induction chemotherapy regimen consisted of weekly paclitaxel 80 mg/m^2 and carboplatin area under the curve 2 for 6 weeks. Patients who received induction chemotherapy showed significantly improved PFS (HR=0.65; 95% CI=0.46–0.91) and OS (HR=0.60; 95% CI=0.40–0.91). In terms of relapse patterns, local relapse rates were similar in both groups (16%), but distant relapse was lower in the induction chemotherapy group (12%) compared to the control group (20%). However, the induction chemotherapy group had more frequent grade 3 or higher adverse events: 59% vs. 48%, and hematologic grade 3 or higher adverse events occurred in 30% vs. 13%, respectively.

Induction chemotherapy with a short course of carboplatin and paclitaxel has advantages in its low cost and wide availability. However, considering that the short course carboplatin and paclitaxel regimen is not yet approved in South Korea, and that applying induction chemotherapy to all patients with locally advanced cervical cancer is not appropriate, the guideline development committee decided to assign the grade of recommendation as B.

7. KQ7. Does the addition of immune checkpoint inhibitors to chemoradiotherapy improve the survival of patients with locally advanced cervical cancer?

P: Locally advanced cervical cancer
I: Chemoradiation + immune checkpoint inhibitor
C: Chemoradiation
O: Survival

The following recommendation was made through consensus:

> Immune checkpoint inhibitor can be added to chemoradiotherapy for patients with locally advanced cervical cancer (Level of evidence: I, Grade of recommendation: B).

Evidence
In the phase III, multicenter randomized, double-blind CALLA trial published in 2023, patients with locally advanced cervical cancer received either the programmed death-ligand 1 (PD-L1) inhibitor durvalumab or a placebo every 4 weeks during and after definitive

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chemoradiotherapy [16]. A total of 770 patients participated in the study, and no statistically significant improvement in PFS was observed (HR=0.84; 95% CI=0.65–1.08; p=0.17).
On the other hand, the phase III randomized KEYNOTE-A18 trial, which included 1,060 patients with locally advanced cervical cancer, investigated the addition of the programmed cell death protein 1 (PD-1) inhibitor pembrolizumab or placebo every 3 weeks during chemoradiotherapy followed by maintenance therapy every 6 weeks for approximately 2 years. Pembrolizumab group showed statistically significant improvements in both PFS (HR=0.68; 95% CI=0.56–0.84) and OS (HR=0.67; 95% CI=0.50–0.90) compared to the control group [17,18].

A meta-analysis of these 2 studies showed that the addition of immune checkpoint inhibitors to chemoradiotherapy significantly improved both PFS (HR=0.76; 95% CI=0.64–0.91) and OS (HR=0.71; 95% CI=0.57–0.89) (**Data S1**). There was no significant difference in the incidence of grade 3 or higher adverse events between the 2 groups (HR=1.18; 95% CI=0.92–1.51).

Based on the results of these large-scale clinical trials, we developed the above recommendation through expert consensus. However, considering the heterogeneity in the results of the 2 studies included in the analysis and the potential differences in efficacy based on the mechanism of action between PD-1 and PD-L1 inhibitors, the grade of recommendation was assessed as B.

8. KQ8. Do antibody-drug conjugates improve the survival of patients with recurrent or metastatic cervical cancer in whom primary treatment has failed?

P: Recurrent or metastatic cervical cancer
I: Antibody-drug conjugate
C: Conventional chemotherapy
O: Survival

The following recommendation was made through consensus:

> Antibody-drug conjugate tisotumab vedotin-tftv monotherapy can be used for patients with recurrent or metastatic cervical cancer that has failed primary treatment (Level of evidence: I, Grade of recommendation: B).

Evidence
In the phase 3, randomized, open-label InnovaTV-301 trial, patients with cervical cancer who failed platinum-based first-line treatment were compared between tisotumab vedotin-tftv, an antibody-drug conjugate, and investigator's choice of chemotherapy [19]. A total of 502 patients participated, and tisotumab vedotin-tftv showed statistically significant improvements in OS (HR=0.70; 95% CI=0.54–0.89) and PFS (HR=0.67; 95% CI=0.54–0.82) compared to the investigator's choice of chemotherapy. Subgroup analysis confirmed that these survival benefits were observed regardless of prior use of immune checkpoint inhibitors. On the other hand, the incidence of any grade 3 or higher adverse events was lower in the tisotumab vedotin-tftv group (HR=0.65; 95% CI=0.46–0.94). Based on these findings, tisotumab vedotin-tftv may be a preferred treatment option over chemotherapy for patients with cervical cancer who have failed first-line treatment. However, for the same reason as KQ2, the grade of recommendation was assigned as B due to the current unavailability of tisotumab vedotin-tftv in South Korea.

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SUPPLEMENTARY MATERIAL

Data S1

Meta-analyses of each key questions

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