CME/MOC

Chair's Take on Advances in Gynecologic Cancer Care: Exploring New Advances and Innovative Therapies in Endometrial and Cervical Cancers

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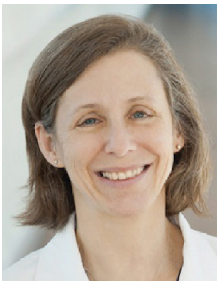
Chair



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Activity Information

Media: Enduring Material
Accredited Activity Release Date: June 16, 2020
Accredited Activity Expiration Date: June 15, 2021
Time to Complete Activity: 30 minutes

Activity Description
Watch Dr. Duska provide a brief recap of recent developments in endometrial and cervical cancer management, including evidence presented at the 2020 American Society of Clinical Oncology Annual Meeting. Dr. Duska comments on these findings and offers thoughts on new and emerging strategies, including targeted, immune checkpoint inhibitor, antibody-based, and combination therapies, in different patient populations with gynecologic cancer.

Target Audience
This activity has been designed to meet the educational needs of oncologists and other clinicians involved in the management of gynecologic cancers.

Educational Objectives
Upon completion of this activity, participants should be better able to:
- Summarize the current treatment role of novel therapeutics, including in conjunction with modern molecular diagnostic testing, in gynecologic cancers
- Describe updated evidence on new and emerging strategies, including targeted, immune checkpoint inhibitor, antibody-based, and combination therapies, in different patient populations with gynecologic cancers
- Integrate approved and emerging options in the management of endometrial and cervical cancer, including in the context of clinical trials, based on disease characteristics and latest recommendations
- Discuss the spectrum of unique safety considerations with novel targeted, antibody-based, and immunotherapy regimens in patients with gynecologic cancers

Providership, Credit, and Support
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Faculty Disclosures
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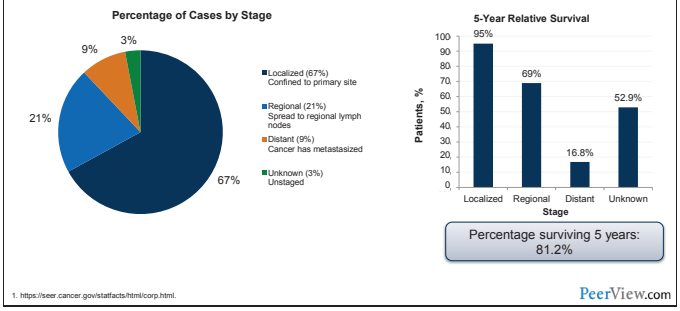
Dr. Duska: Hello, and welcome to "Exploring New Advances and Innovative Therapies in Endometrial and Cervical Cancers." I'm Linda Duska from the University of Virginia School of Medicine. During this presentation, I'll discuss some of the evidence that has recently made a difference in how we manage endometrial and cervical cancer patient populations, and also discuss some recent updates from the Virtual SGO and ASCO conferences 2020.

Endometrial Cancer:
One Size Does *NOT* Fit All

I'm going to start with endometrial cancer, and I hope by the end of this short presentation to convince you that we need to start using molecular classification of endometrial cancer to individualize therapy for women with advanced and recurrent disease. In fact, one size does not fit all.

Endometrial Cancer Stage and Survival: SEER Data[1]



1. https://seer.cancer.gov/statfacts/html/corp.html.

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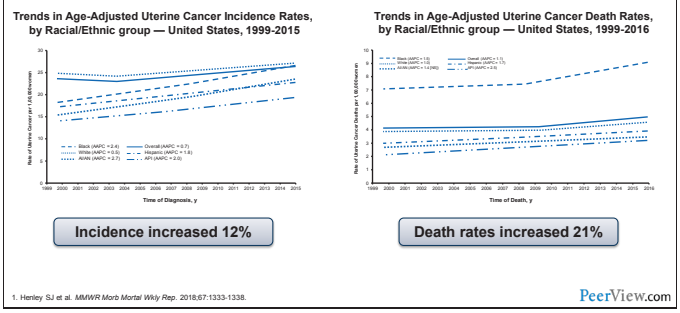
The overall survival for endometrial cancer in the United States is 81%. This is largely because, as demonstrated on this slide, the high 5-year survival is due to the large proportion of women who are diagnosed with early-stage disease. These women are often completely treated with surgery, with or without adjuvant therapy, and enjoy an excellent 5-year survival.

However, while less frequent, patients with distant or metastatic disease have a very low rate of survival. In the case of women with distant metastases, this rate is less than 20%. Additionally, patients with recurrent disease have few treatment options with low response rates, and it is for these populations of patients that novel treatments are needed.

Endometrial Cancer Stage and Survival[1]



1. Henley SJ et al. *MMWR Morb Mortal Wkly Rep.* 2018;67:1333-1338.

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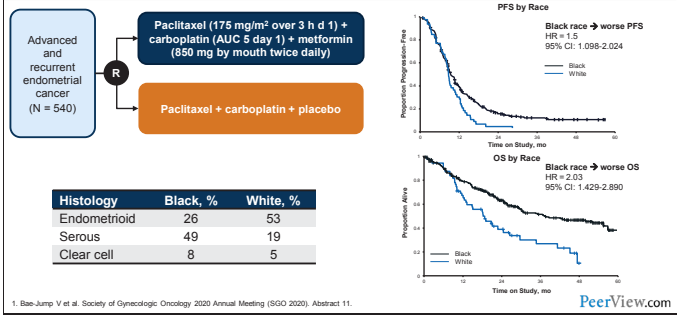
It is also of note that, unlike with other solid tumors, we've seen an alarming increase in both incidence of and death rates from endometrial cancer in the United States. As shown on this slide, both incidence and death rates have increased, by 12% for incidence and 21% for death rates, in the United States between 1999 and 2015.

Additionally, the rate of increase of both incidence and death rates and the overall death rates hav significantly increased in women of color, as shown in the heavy dashed line, particularly in the death rate portion of this slide.

Phase 2/3 GOG 286B Trial: Paclitaxel + Carboplatin ± Metformin[1]



Histology	Black, %	White, %
Endometrioid	26	53
Serous	49	19
Clear cell	8	5

1. Bae-Jump V et al. Society of Gynecologic Oncology 2020 Annual Meeting (SGO 2020). Abstract 11.

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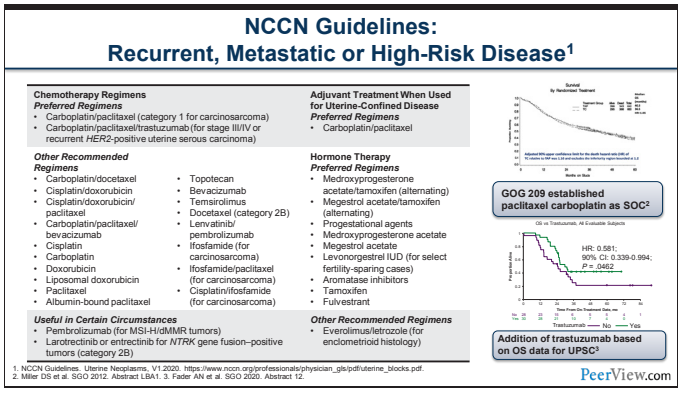
In further support of these data, this slide shows results regarding race from the study GOG 286B. Dr. Bae-Jump and her colleagues presented these results at SGO in 2020. The study was actually closed in 2018 for futility, and not surprisingly, this was a negative trial.

However, Dr. Bae-Jump's study demonstrated worse outcomes for black women when compared with white women with respect to progression-free survival and overall survival, as shown on the right-hand side of this slide, further substantiating the disparities I just showed you.

Black women were also more likely to have high-risk histologies. For example, if you look on the table in the left-hand bottom of the slide, black women had 49% serous cancers compared with 19% for white women.

The disparities with respect to black women were also confirmed in the database trial presented as an abstract at ASCO by Dr. Abel and colleagues, who found that black women were more likely to be diagnosed with high-risk histologies and more advanced stages of disease. These disparities are worthy of further study, and we look forward to Dr. Bae-Jump's translational work from GOG 286B.

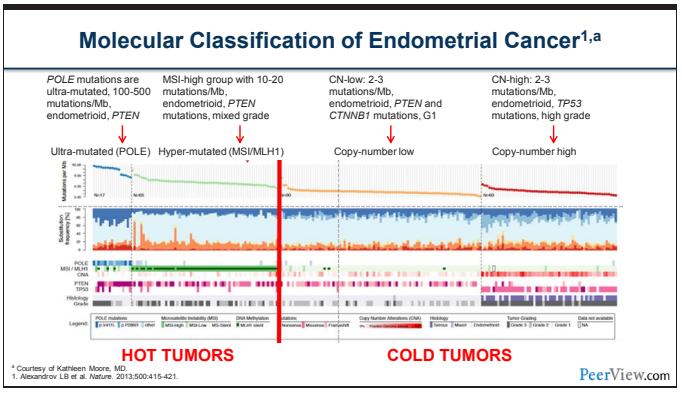


This slide shows the current NCCN guidelines for advanced or recurrent endometrial cancer, and I'm just going to take a moment to walk you through it. Up in the top left-hand corner, you'll see the preferred chemotherapy regimens. Carboplatin and paclitaxel is the preferred standard-of-care regimen for recurrent metastatic or high-risk disease, as established by GOG 209, the survival curves of which are shown in the upper right-hand corner. Median overall survival of the combination in GOG 209 was 30 months.

The guidelines also include the addition of trastuzumab to the carboplatin/paclitaxel backbone in women with stage III/IV or recurrent *HER2*-positive uterine serous carcinoma.

This addition to the NCCN guidelines was made following the publication of a preliminary analysis by Dr. Fader and colleagues in 2018 of a clinical trial with uterine papillary serious carcinoma. Dr. Fader updated these data at SGO in 2020, and the overall survival results are shown in the right-hand bottom corner of the slide. Her group confirmed the preliminary PFS findings and also demonstrated an overall survival advantage with a hazard ratio of 0.58 and an improvement in overall survival of 5 months.

In the left bottom corner of this slide, you'll note the addition of pembrolizumab for MMR-deficient tumors, and we'll talk about that in a few moments. And then I just want to draw your attention for a moment to the middle of the slide and remind you that hormonal therapy remains a viable and relatively nontoxic option for many women with advanced and recurrent endometrial cancer.



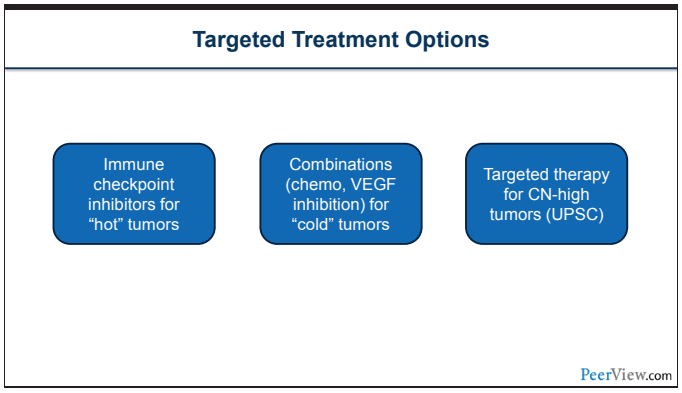
So, in the next portion of this presentation, I'm going to move on to recent treatment updates, and we're going to focus on immunotherapy and targeted options. But we need to set the stage with this idea of molecular classification of endometrial cancer, as shown on this slide. These data represent a comprehensive multiplatform analysis of almost 400 cases of endometrial cancer, and this new molecular classification is changing the way we think about this disease.

We're moving from a traditional type 1 and type 2 dichotomy to a molecular classification that is more reproducible than traditional histology, more predictive of response to therapy, and potentially more predictive of prognosis. The red vertical line in the slide divides the tumors into the hot tumors on the left and the cold tumors on the right.

The hot tumors are the ultra-mutated *POLE* tumors and the hyper-mutated microsatellite-unstable tumors. These tumors have a high mutational burden and are expected to be responsive to immunotherapy.

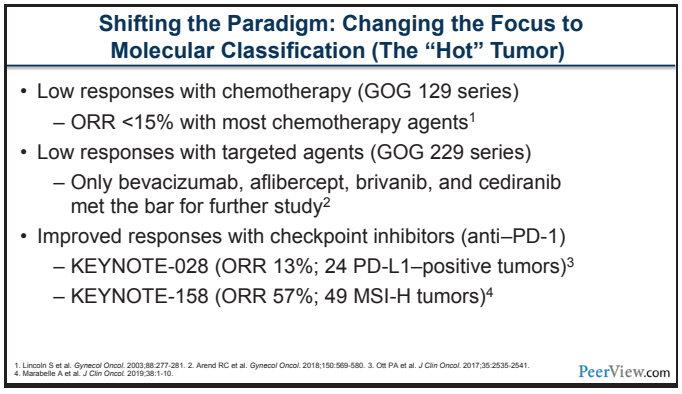
On the right hand of the slide are those tumors with a low mutational burden, so-called *cold tumors*. The copy number–low tumors, which include the majority of the endometrioid adenocarcinomas, and then the copy number–high tumors, which include the *TP53*-mutated tumors, the serous tumors, and about 25% of the grade 3 endometrioid cancers.

Just to give you a sense of proportions here, the *POLE*-mutation tumors represent 5% to 7% of all endometrial cancers; MSI-high tumors, 25% to 30%; copy number–low, about 40%; and the remainder, 25%, will be copy number high.



For the rest of this section on endometrial cancer, I'm going to focus on updates in the three categories that you see on this slide. First, we'll talk about immune checkpoint inhibitors for hot tumors, but I'm also going to show you some provocative data with respect to cold tumors and immune checkpoint inhibitors.

Second, we'll talk about using combinations with immune therapy to make immune therapy more effective in cold tumors. And finally, we'll end with targeted therapy for copy number–high tumors, specifically uterine papillary serous carcinomas.

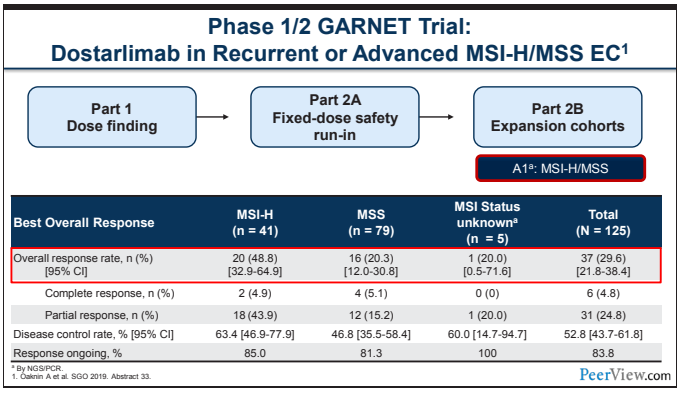


Let's begin by talking about immunotherapy as a single agent in this disease. So, the patient has endometrial cancer. She's already had frontline therapy with carboplatin/paclitaxel, and now, unfortunately, her cancer has progressed or recurred. This is now second-line therapy.

The GOG, Gynecology Oncology Group, has two series of studies that looked at second-line chemotherapy in endometrial cancer—the 129 series, which looked specifically at chemotherapy agents, and the 229 series, which looked at targeted agents—without particularly encouraging results in both cases. With chemotherapy, the majority of agents gave an overall response rate of less than 15%, and with targeted therapy, in most cases, less than 5%.

Now, let's look at the improved responses seen with checkpoint inhibitors, specifically in this case, pembrolizumab. When tumors were selected for PD-L1 positivity, as in KEYNOTE-028, the overall response rates were 13%, so, similar to what we had seen with chemotherapy. However, when tumors were selected for microsatellite deficiency, as in KEYNOTE-158, the overall response rate was 57%.

The results of these studies led to the approval of pembrolizumab for all MMR-deficient tumors in 2017, as well as the inclusion of pembrolizumab in the NCCN guidelines for endometrial cancer.



This slide shows the early results of GARNET. This is another study of a PD-1 inhibitor in women with recurrent or advanced endometrial cancer. This time, the PD-1 inhibitor is dostarlimab. Once again, we're looking at it in the second line, following frontline platinum therapy.

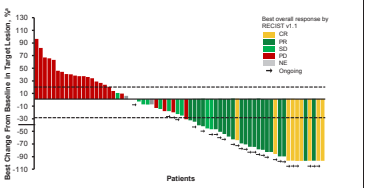
The data on this slide were presented at SGO in 2019. And in this study, both microsatellite-stable and microsatellite-deficient tumors were allowed to go on trial. In this analysis that I'm showing you on this slide, the MMR-deficient state was determined by next-generation sequencing.

In this analysis, you'll note 125 total patients were included, and that there were 41 microsatellite-deficient tumors and 79 microsatellite-stable tumors. The overall response rate in the microsatellite-high tumors was 49%. Remarkably, in the microsatellite-stable population, the response rate was 20%. Additionally, the responses were durable, and you'll note, at the bottom of this slide, that at the time of this presentation, the majority of patients were still responding.

The drug was tolerable, and also, the infusion schedule was favorable. The first four cycles were given every 3 weeks, but subsequently every 6 weeks.

GARNET: Updated Efficacy Results[1]

Variable	Dostarlimab dMMR EC (N = 71)
ORR, n (%) [95% CI]	30 (42) [31-55]
CR, n (%)	9 (13)
PR, n (%)	21 (30)
SD, n (%)	11 (16)
PD, n (%)	27 (38)
NE	3 (4)
DCR, n (%) [95% CI]	41 (58) [45-69]
Median follow-up, mo	11.2



- Median DOR not reached (1.87 to 19.61 months)
- 25/30 (83%) of responders remain in response at data cutoff

The ongoing phase 3 RUBY trial is directly comparing carboplatin + paclitaxel with placebo or dostarlimab in patients with recurrent or primary advanced EC (NCT03981796)

[a] Maximum percentage change in target lesions from baseline is indicated by bar length. Best overall response is indicated by color coding of bars and includes assessment of target, non-target, and new lesions.
1. Oaknin A et al. SGO 2020. Abstract 9.

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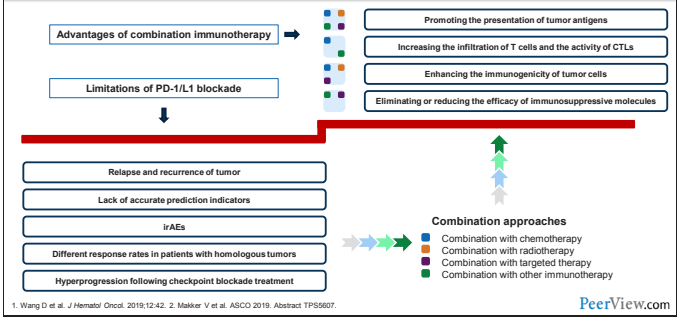
The data specific to the MMR-deficient tumors were presented by Dr. Sabatier at SGO in 2020 and are shown on this slide. In this analysis, in contrast to the slide I showed you from 2019, the MMR-deficient status was established by immunohistochemistry. The overall response rate of these 71 patients in this analysis was 42%, with nine complete responses and 21 partial responses.

As shown in the waterfall plot on the right-hand side of the slide, these responses were deep and durable. Additionally, as we saw before, the therapy was tolerable with rare high-grade adverse events. We look forward to the updated data regarding the microsatellite-stable tumors.

Similar to the situation with pembrolizumab, the ongoing RUBY trial will add dostarlimab to upfront carboplatin and paclitaxel in the first-line setting.

Rationale for Combinations: Make the Cold Tumor "Hot"[1,2]



1. Wang D et al. *J Hematol Oncol.* 2019;12:42. 2. Makker V et al. ASCO 2019. Abstract TPS5607.

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Second-line therapy options are limited for those patients who have microsatellite-stable tumors and who represent the majority. What options do we have for the tumor that is not hot and might not be expected to respond well to immunotherapy as a single agent?

As shown on this slide, adapted from a paper written by Wang and colleagues and published in 2019, combination strategies may allow us to make the cold tumor more susceptible to immunotherapy. This can be done with combinations with chemotherapy, radiotherapy, targeted therapies such as antiangiogenesis agents, or combination with other immunotherapy agents to make the microenvironment and the tumor more immunogenic.

KEYNOTE-146: Phase 1b/2 Trial of Lenvatinib Plus Pembrolizumab in Patients With EC[1-3]

- Age ≥18 y
- Metastatic EC (unselected for MSI or PD-L1)
- ECOG PS 0-1
- ≤2 previous systemic therapies
- Measurable disease according to irRECIST
- Life expectancy of ≥12 wk

N = 357

→ **Lenvatinib[a] 20 mg/d orally + pembrolizumab 200 mg IV every 3 wk** → Until disease progression, development of unacceptable toxicity or withdrawal of consent

- In September 2019, the FDA approved lenvatinib + pembrolizumab for the treatment of patients with advanced EC that is not MSI-H or dMMR who have disease progression following prior systemic therapy

- **Primary endpoint:** ORR at week 24
- **Secondary endpoints:** Overall ORR, DOR, PFS, OS, DCR, CBR, DSDR, no. of patients with TEAEs and treatment-emergent SAEs, AUC of lenvatinib, and apparent clearance of lenvatinib

[a] oral multikinase inhibitor that targets: VEGFR 1-3, FGFR 1-4, PDGFRα, RET, KIT
1. https://www.clinicaltrials.gov/ct2/show/NCT02501096. 2. Makker V et al. *Lancet Oncol.* 2019;20:711-718.
3. Makker V et al. *J Clin Oncol.* 2020 Mar 13 [Epub ahead of print.]

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KEYNOTE-146 is an example of the successful combination of an antiangiogenic drug with a PD-1 inhibitor. This study combined lenvatinib, on oral multikinase inhibitor, with pembrolizumab in unselected patients with recurrent or advanced endometrial cancer.

The preliminary results of this study, published in the *Lancet Oncology* in 2019, showed an overall response rate of almost 40% in patients regardless of microsatellite-unstable status, and the results of this study led to the accelerated FDA approval of the combination in 2019 for women with advanced endometrial cancer who have disease progression following prior systemic therapy and microsatellite-stable tumors.

KEYNOTE-146: Final Efficacy Results[1]

Tumor Response[a]

Response Category	Total (n = 108)	Not MSI-H or dMMR (n = 94)	MSI-H/dMMR (n = 11)
	Week 24		
ORR (CR + PR), n (%)	41 (38.0)	34 (36.2)	7 (63.6)
95% CI	28.8 to 47.8	26.5 to 46.7	30.8 to 89.1
Response Category		At data cutoff	
Best overall response, n (%)			
CR	8 (7.4)	7 (7.4)	1 (9.1)
PR	34 (31.5)	28 (29.8)	6 (54.5)
SD	49 (45.4)	44 (46.8)	3 (27.3)
PD	12 (11.1)	10 (10.6)	1 (9.1)
Not evaluable	5 (4.6)	5 (5.3)	0
ORR (CR + PR), n (%)	42 (38.9)	35 (37.2)	7 (63.6)
95% CI	29.7 to 48.7	27.5 to 47.8	30.8 to 89.1
Median DOR, mo (range)	21.2 (1.2+ to 35.6+)	NE (1.2+ to 33.8+)	21.2 (6.1+ to 35.6+)

Tumor Response by Histology[b]

Response Category	Previously Treated Not MSI-H or dMMR			
	Adenocarcinoma Type			
	Endometrioid (n = 48)	Not Endometrioid (n = 48)	Serous (n = 33)	Clear Cell (n = 5)
Best overall response, n (%)				
CR	1 (2.2)	9 (18.8)	7 (21.2)	2 (40.0)
PR	11 (23.9)	15 (31.3)	7 (21.2)	2 (40.0)
SD	22 (47.8)	16 (33.3)	15 (45.5)	0
PD	6 (13.0)	6 (12.5)	3 (9.1)	0
Not evaluable	6 (13.0)	2 (4.2)	1 (3.0)	1 (20.0)
ORR (CR + PR), n (%)	12 (26.1)	24 (50.0)	14 (42.4)	4 (80.0)
95% CI	14.3 to 41.1	35.2 to 64.8	25.5 to 60.8	28.4 to 99.5
Median DOR, mo (range)	NE (1.2+ to 33.1+)	11.2 (1.9+ to 29.3+)	NE (1.9+ to 29.3+)	NE (6.3 to 19.5+)

[a] Investigator Assessment; irRECIST. [b] Independent Imaging Review; RECIST v1.1.
1. Makker V et al. SGO 2020. Abstract 10.

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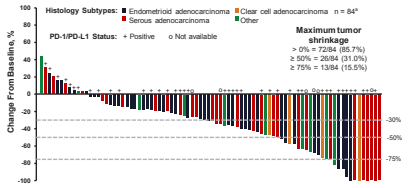
The final efficacy results were presented at SGO this year by Dr. Makker and are shown on this slide. You'll notice, on the left, that the responses are divided by microsatellite-stable or -unstable tumors, and on the right, by histology. Let me draw to your attention that the majority of patients in this trial, 94 of them, had microsatellite-stable tumors, and only 11 patients had microsatellite-deficient tumors.

On the left side of the slide, you'll note that the overall response rate for the entire group was 38%. The response rate was 64% for microsatellite-deficient patients, and 36% were patients with microsatellite-stable tumors.

If you look at tumor response by histology on the right, you'll note that the overall response rate for nonendometrioid tumors was 50%. This is pretty remarkable, given that these are generally considered to be nonresponsive to therapy.
The overall response rate was 42% in serous tumors and 80% in clear-cell tumors, and the median duration of response was not reached in any of these histologies.

KEYNOTE-146: Percentage Change in Sum of Diameters of Target Lesions[1,2]



- A randomized phase 3 trial of lenvatinib and pembrolizumab (Study 309/KEYNOTE-775 [NCT03517449]) for patients who have received ≤1 prior therapies is currently enrolling[2]

Per independent imaging review; RECIST v1.1
* n = the number of previously treated not-MSI-H or dMMR patients with both baseline and at least 1 post-baseline target lesion assessment.
1. Makker V et al. *Ann Oncol.* 2019;30:v403-v434. 2. Makker V et al. SGO 2020. Abstract 10.

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This waterfall plot shows percentage change in sum of diameters of target lesions in 84 microsatellite-stable patients by histologic subtype and PD-L1 status. Histologic subtype is color coded, and the red represents the serous cancers. PD-1 status is indicated by the plus signs that are along the zero horizontal axis in the waterfall plot.

Responses in these microsatellite-stable patients were deep, with 31% having tumor shrinkage of 50% or greater, and 16% having tumor shrinkage of 75% or greater. Additionally, responses were seen across all histologic subtypes and regardless of PD-L1 status.

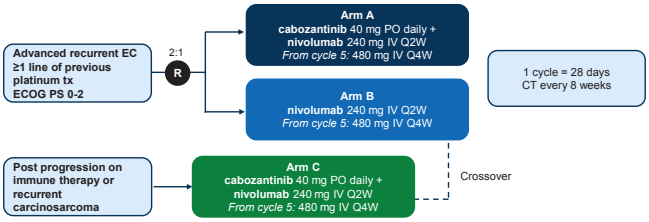
And I'll point your attention, again, to the red all the way over on the right-hand side of the waterfall plot, where we see deep and durable responses in those women with serous cancers, traditionally believed to be difficult to treat.

It must be noted, however, that this is a relatively toxic regimen. Treatment-related adverse events occurred in virtually all patients, and grade 3 or 4 adverse events in almost 70%, the most common of which were hypertension, fatigue, and diarrhea. Two deaths were deemed to be treatment related by individual study investigators, and 13% of patients experienced grade 3 or greater immune-related adverse events.

Nevertheless, these results are very encouraging, particularly in these difficult-to-treat histologies and have led to a randomized trial of lenvatinib plus pembrolizumab versus physician's choice chemotherapy in the second-line setting.

Additionally, given these excellent response rates, pembrolizumab and lenvatinib are being moved into the first-line therapy in a randomized trial against the standard-of-care chemotherapy doublet carboplatin and paclitaxel.

Phase 2 Trial: Cabozantinib Plus Nivolumab Versus Nivolumab in Metastatic EC[1]



- **Stratification:** By MSI status assessed by CT every 8 wk
- **Primary endpoint:** PFS
- **Secondary endpoints:** ORR; OS; incidence of AEs; and PD-L1 expression, CD3, CD4 and CD8 analysis

1. Lheureux S et al. 2020 American Society of Clinical Oncology Virtual Scientific Program (ASCO 2020) Abstract 6010.

PeerView.com

On this slide is another example of a combination of a tyrosine kinase inhibitor plus a PD-1 inhibitor, presented by Stéphanie Lheureux and colleagues at ASCO this year. You'll see that, in this study, women with advanced recurrent endometrial cancers who had had at least one platinum-based regimen were stratified by microsatellite status and randomized 2:1 to the combination arm of cabozantinib and nivolumab in arm A or single-agent nivolumab in arm B.

There was no prior line limit in this study. Patients were allowed to enter the trial with as many prior lines as necessary.

Arm C was an exploratory arm that included women with carcinosarcomas as well as those with prior progression on immune therapy. Those in arm B was allowed to cross over to this arm.

Cabozantinib + Nivolumab vs Nivolumab in Metastatic EC: Results[1]

Endpoint/Outcome	Arm A (Cabo + Nivo; n = 36)	Arm B (Nivo; n = 18)
Median PFS, mo (95% CI)	5.3 (3.5-9.2)	1.9 (1.6-3.4)
	P = .09[a]	
ORR, %	25	11.1
SD as best response, %	44.4	11.1

Arm C
Carcinosarcoma (n = 9):
PR: n = 1; SD: n = 4
Prior IO (n = 21):
PR: n = 5; SD: n = 12

Preliminary CyTOF analysis across treatment arms identified multiple immune subsets for further interrogation, including activated CD8+ and CD4+ T cells

[a] Met the significance level of 0.1.
1. Lheureux S et al. ASCO 2020. Abstract 6010.

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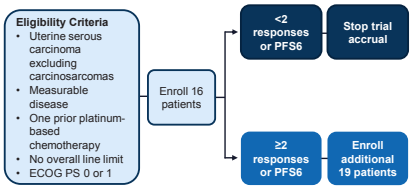
This was a heavily pretreated patient population, with more than half of patients receiving three or more prior regimens. The primary endpoint was progression-free survival, and the study met the statistical endpoint, as shown on this slide, with a median PFS in the combination arm of 5.3 months compared with 1.9 months in arm B. And you'll also note the overall response rates.

Arm C also had some responses, with one PR in carcinosarcoma, and several responses in the crossover arm.

Overall survival data and translational data have not completed, but this study shows interesting activity, and we look forward to study maturity and further translational work.

Phase 2 WEE1 Trial: Checkpoint Inhibitor Adavosertib (AZD1775) in Recurrent Uterine Serous Carcinoma[1]



Best Overall Response	Overall N = 34
Complete response[a]	1 (2.9%)
Partial response[a]	8 (23.5%)
Stable disease ≥ 6 months < 6 months	 7 (20.6%) 9 (26.5%)
Progressive disease	7 (20.6%)
Unevaluable	1 (2.9%)
ORR[b]	10 (29.4%)
Clinical benefit rate[c]	17 (50.0%)
mPFS, mo (95% CI)	6.14 (4.21, 9.92)
PFS rate at 6 mo (95% CI)	59.6% (40.6-74.3)
mDOR, mo (95% CI)	9.03 (5.29-NA)

Data cutoff: November 14, 2019. [a]Confirmed. [b]Confirmed and unconfirmed. [c]CR + PR + SD ≥ 6 months.
1. Liu JF et al. ASCO 2020. Abstract 6009.

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Now I'm going to move from combinations with immunotherapy to a focus on the copy number–high tumors and, specifically, the serous cancers. We already discussed the results of Dr. Fader's trial, which confirmed the overall survival advantage of adding trastuzumab to the carboplatin/paclitaxel backbone for advanced and recurrent uterine papillary serous carcinomas that express *HER2*.

In this study on this slide, presented by Dr. Liu, we see the results of a WEE1 inhibitor as a single agent in patients with serous carcinoma. Again, similar to the prior trial, there was no prior-line limit in this study.

Patients were older, with a median age of 70 years, and heavily pretreated, with a median of three prior lines of therapy. Despite this, there was one complete response and eight partial responses seen in this study, with an overall response rate of 29%.

Dr. Liu also showed examples of impressive individual radiologic responses to this single-agent therapy in two heavily pretreated patients during her presentation at SGO. This is a difficult-to-treat population. These are very interesting results, and further study of this agent is warranted.

Ongoing Phase 3 Trials: Immunotherapy Combinations in Advanced/Recurrent Endometrial Cancer[1]

Trial Name	Setting	Treatment Arms	Primary Endpoint(s)	NCT Number
RUBY	1L	Dostarlimab + carboplatin-paclitaxel vs placebo + carboplatin-paclitaxel	PFS	NCT03981796
AtTEnd/ ENGOT-en7	1L	Atezolizumab + carboplatin-paclitaxel vs placebo + carboplatin-paclitaxel	PFS, OS	NCT03603184
DUO-E/ GOG-3041/ ENGOT-EN10	1L	Durvalumab + carboplatin-paclitaxel, followed by durvalumab (± olaparib) maintenance	PFS	NCT04269200
ENGOT-en9/ MK-7902-001/ LEAP-001	1L	Lenvatinib + pembrolizumab vs carboplatin-paclitaxel	PFS, OS	NCT03884101
KEYNOTE-775	2L	Lenvatinib + pembrolizumab vs physician's choice chemo	PFS, OS	NCT03517449

1. https://clinicaltrials.gov.

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This slide shows examples of ongoing phase 3 trials in advanced and recurrent endometrial cancer and in combination with immunotherapy.

AtEnd and DUO are very similar, with the use of different PD-1 inhibitors and the addition of olaparib in the DUO study.

I want to point your attention to the ENGOT study, which I already alluded to earlier. This is the only trial that does not use chemotherapy in the frontline. And remarkably, we're moving these targeted-agent combinations into the frontline versus standard-of-care chemotherapy.

Take-Home Thoughts on New Developments in Advanced and Recurrent Endometrial Cancer

- These patients have limited treatment options, representing a high unmet need
- TCGA classification better reflects tumor behavior and potential therapeutic response
- Checkpoint inhibitor monotherapy is promising in dMMR tumors
  - Pembrolizumab is approved for second-line therapy in dMMR tumors
  - Dostarlimab resulted in a robust ORR in patients with recurrent or advanced dMMR EC that had progressed on prior therapy, with durable responses
- Adavosertib showed promising clinical activity in uterine serous carcinoma
- Trastuzumab in HER2 positive UPSC tumors give an OS advantage
- Combination therapy with PD1 inhibitors may be successful
- Racial disparities persist and need to be better understood at multiple levels

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Here are some take-home thoughts on the new developments that I've just shown you. First, I want to remind you that these patients have limited treatment options, representing a high unmet need. The TCGA classification better reflects tumor behavior and potential therapeutic response than does the traditional type 1 and type 2 dichotomy that we've used in the past.

Checkpoint inhibitor monotherapy is promising in MMR-deficient tumors, and dostarlimab may show a response in MMR-stable tumors, results pending.

WEE1 inhibitors showed promising clinical activity as a single agent in uterine serous carcinoma, and trastuzumab gives an overall survival advantage when added to the carboplatin/ paclitaxel backbone in serous tumors that are *HER2* positive.

Combination therapy with PD-1 inhibitors is very promising in microsatellite-stable tumors and could potentially be brought to the first line to take the place of the standard of care, carboplatin/ paclitaxel. And finally, racial disparities persist and need to be better understood at multiple levels.

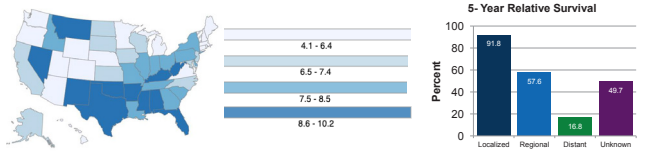
Where Newer Therapeutic Options Fit in Cervical Cancer

Navigating the Way Past Chemotherapy

All right, now I'm going to move on to where newer therapeutic options fit into cervical cancer. And we're going to talk about some ways to navigate the way past chemotherapy once again.

Cervical Cancer Stage and Survival[1,2]

- Cervical cancer is the fourth most common cancer among women worldwide
- 5-year OS is 66%
- Limited treatment options for advanced/recurrent disease



1. https://seer.cancer.gov/statfacts/html/cervix.html.
2. Rate per 100,000 of new cervical cancer in the United States (2016); https://gis.cdc.gov/Cancer/USCS/DataViz.html.

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So, cervical cancer continues to be a significant problem in the world. It's the fourth most common cancer among women worldwide. And in the United States, as you'll see on this graph, it continues to disproportionately affect women in certain states. The ones that are dark blue in color have higher numbers of women with cervical cancer. The 5-year overall survival rate is 66%, and there are limited treatment options for women with advanced or recurrent disease.

Chemoradiation for Early Stage/Locally Advanced Disease[1]

Chemoradiation

Preferred Regimens
- Cisplatin
- Carboplatin if patient is cisplatin intolerant

Other Recommended Regimens
- Cisplatin + fluorouracil

1. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf.

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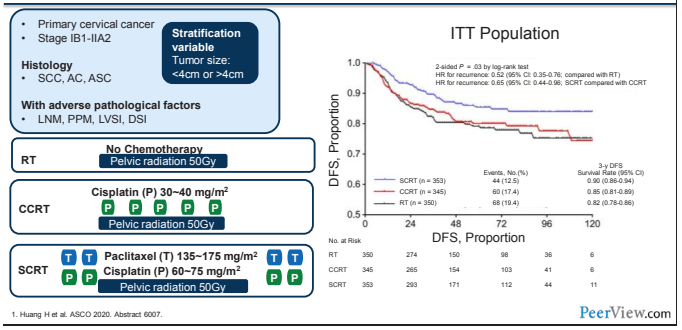
This slide shows the NCCN guidelines for chemoradiation for early-stage and locally advanced disease, and I'm going to start this portion of the presentation by talking to you about one study regarding women with early-stage disease.

Post-Operative Adjuvant Treatment: Phase 3 STARS[1]



1. Huang H et al. ASCO 2020. Abstract 6007.

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This study, the STARS trial, was presented at ASCO this year by Dr. Huang and colleagues. And let me just walk you through the study schema. Patients who had early-stage cervical cancer and underwent radical hysterectomy who had adverse pathologic risk factors that are shown on this slide were randomized to three different arms.

One arm was radiation therapy alone. One arm was traditional concurrent radiation and chemotherapy with weekly cisplatin. And then the last arm, the one on the bottom, was sequential chemoradiation therapy. In this arm, the patients received two cycles of paclitaxel and cisplatin followed by radiation therapy with two more cycles of paclitaxel and cisplatin.

As shown on the right side of the slide, there was an advantage to sequential treatment in the entire population in an intent-to-treat analysis. However, only 60% of the patients on this trial were able to complete traditional chemoradiation, the middle arm, due to toxicity, and patients were not stratified by intermediate- and high-risk factors. These data are interesting and need to be validated in further studies.

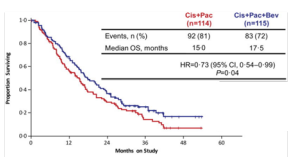
NCCN Guidelines: Cervical Cancer[1,2]

Systemic Therapy Regimens for Recurrent or Metastatic Cervical Cancer

First-Line Combination Therapy:
Preferred Regimens
- Cisplatin + paclitaxel + bevacizumab (category 1)
- Carboplatin + paclitaxel + bevacizumab

Possible First-Line Single-Agent Therapy:
Preferred Regimens
- Cisplatin

Second-Line Therapy:
Preferred Regimens
- Pembrolizumab for PD-L 1+ or MSI-H/dMMR tumors



Consider MMR/MSI, or PD-L1, and/or *NRTK* gene fusion testing for patients with recurrent, progressive, or metastatic disease

1. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. 2. Tewari KS et al. *Lancet.* 2017;390:1654-1663.

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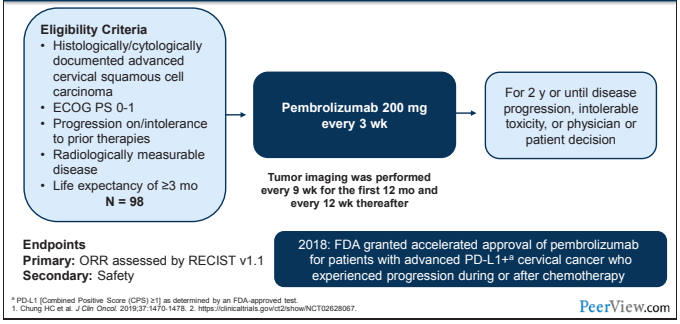
This slide shows the NCCN guidelines for recurrent advanced or metastatic cervical cancer. The standard-of-care treatment is

based on results from GOG 240, which establishes standard of care as paclitaxel plus a platinum plus bevacizumab as first-line therapy, with the survival curves shown on the right side of the slide.

In second-line therapy, pembrolizumab received FDA approval in 2018, and I'm going to show you those data in a moment. But similar to the data that I showed you for endometrial cancer, treatment following first-line therapy for cervical cancer has very low response rates, and this remains a very significant unmet need.

KEYNOTE-158: Phase 2 Trial of Pembrolizumab in Previously Treated Advanced Cervical Cancer[1,2]



[a] PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test.
1. Chung HC et al. *J Clin Oncol.* 2019;37:1470-1478. 2. https://clinicaltrials.gov/ct2/show/NCT02628067.

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We've already talked about KEYNOTE-158. Here are the inclusion criteria for patients with advanced or recurrent cervical cancer who progressed after primary therapy. The primary endpoint for this study was overall response rate.

KEYNOTE-158: Efficacy Results[1]

Endpoint/Outcome	Total population (N = 98)
Median follow-up, mo (range)	10.2 (0.6-22.7)
ORR, n (%) [95% CI][a]	12 (12.2) [6.5-20.4]
PD-L1–positive tumors[b,c]	12 (14.6) [7.8-24.2]
DCR n (%) [95% CI]	30 (30.6) [21.7-40.7]
Median DOR, mo (range)	NR (≥3.7 to ≥18.6)

[a] 3 CR and 9 PR; all were in pts with PD-L1–positive pts. [b] n = 82. [c] 14.3 % (95% CI, 7.4%-24.1%) of these responses were in pts who had received ≥1 lines of chemotherapy for recurrent or metastatic disease.
1. Chung HC et al. *J Clin Oncol.* 2019;37:1470-1478.

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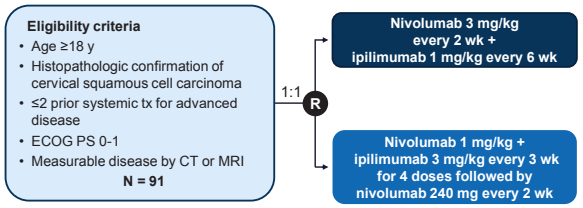
These are the efficacy results. The overall response rate was 12%, with a 14% overall response rate in women with PD-1–positive tumors. The measure of PD-L1 expression in this study was the combined positive score, or CPS, and PD-L1 positivity was defined as a CPS of 1 or greater.

Eighty-four percent of women in this trial were PD-L1 positive by this definition. No responses were observed in patients with PD-L1–negative tumors. So, by this definition, PD-L1 did appear to be a biomarker that, at least when absent, predicted no response. But clearly, given these low response rates, there is room for some improvement.

Phase 1/2 CheckMate -358: Nivolumab + Ipilimumab in Metastatic Cervical Cancer[1,2]



Endpoints
Primary: Incidence of TRAEs and treatment-related SAEs, ORR, rate of surgery delay
Secondary: PFS, OS, DOR

1. Naumann RW et al. *Ann Oncol.* 2019;30(Suppl 5):v698-v899. Abstr LBA62. 2. https://clinicaltrials.gov/ct2/show/NCT02488759.

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This brings us to CheckMate -358. The CheckMate study takes advantage of the combination of a PD-1 inhibitor and a CTLA-4 inhibitor, nivolumab and ipilimumab, presented at ESMO in 2019.

Patients were allowed to go on trial if they had received less than or equal to two prior systemic therapies for advanced disease. But I want to make the point that a little less than half of patients in each arm had not received any prior chemotherapy and were receiving the combination of immune checkpoint inhibitors as their first line of therapy. Patients were randomized 1:1 to one of these two regimens.

CheckMate -358: Efficacy Results[1]

Outcomes in Women With Cervical Cancer Receiving Nivolumab Plus Ipilimumab in Two Dosing Schedules				
	Nivolumab (3 mg/kg) + Ipilimumab (1 mg/kg)		Nivolumab (1 mg/kg) + Ipilimumab (3 mg/kg)	
Endpoint	No Prior Treatment	Prior Treatment	No Prior Treatment	Prior Treatment
ORR	31.6%	23.1%	45.8%	36.4%
Clinical benefit rate	63.2%	53.8%	70.8%	72.7%
Median PFS	13.8 mo	3.6 mo	8.5 mo	5.8 mo
12-month PFS	52.6%	17.9%	43.5%	38.1%
OS	Not reached	10.3 mo	Not reached	25.4 mo
12-month OS	83.5%	37.5%	89.7%	78.0%

1. Naumann RW et al. *Ann Oncol.* 2019;30(suppl 5):v698-v899. Abstract LBA62.

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These are the results of CheckMate -358, and I want to draw your attention to two important aspects of these results. If you look at the two arms in the no-treatment column, you'll note that the overall response rates for both combinations, for patients who had not received prior treatment, were higher than for those patients who had received prior treatment.

And in fact, on the right side of the slide, in the right column, those patients who had not received prior treatment had an overall response rate of almost 46%. Additionally, the median PFS for both groups that had received no prior treatment, 13.8 months and 8.5 months, were comparable to the median PFS that we saw in the results of GOG 240.

The second important point about this trial is that PD-L1 positivity by immunohistochemistry was not a required eligibility criteria for entry into this trial. However, the investigators did perform

immunohistochemistry for PD-L1 and had access to those results. In this study, PD-L1 was not a biomarker for response—a little bit different than the results I showed you in the prior slide.

The really interesting results from this study suggest a possibility—again, similar to the case with endometrial cancer and pembrolizumab and lenvatinib—that we can move this combination therapy into the frontline and put it up against the standard-of-care chemotherapy.

Phase 2 Trial: Camrelizumab + Apatinib in Advanced Cervical Cancer in China[1,2]

Eligibility criteria
- Age 18-70 y
- ECOG PS 0-1
- Progressed on ≤1 previous systemic chemotherapy for metastatic, recurrent, or persistent cervical cancer
- Measurable disease

N = 45

→ **Apatinib 250 mg orally once daily + camrelizumab 200 mg IV every 2 wk**

→ **Until disease progression, development of unacceptable toxicity, or withdrawal of consent**

Primary endpoint: ORR assessed by RECIST v 1.1[a]

[a] An optimal Simon 2-stage design was employed to test the null hypothesis of a 17% ORR versus 35% alternative (1-sided alpha 0.10, 80% power), if more than 3 responses out of the first 16 patients were observed, then the study would continue to enroll a total of 44 patients.
1. Huang X et al. SGO 2020. Abstract 55. 2. Lan C et al. ASCO 2020. Abstract 6021.

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This phase 2 trial was also presented at ASCO this year (2020) and looks at a combination of an anti–PD-1 immune checkpoint inhibitor, camrelizumab, with apatinib, a tyrosine kinase inhibitor that selectively inhibits the vascular endothelial growth factor receptor 2. Patients in this study progressed on less than or equal to one prior systemic chemotherapy for metastatic recurrent or persistent cervical cancer, and the primary endpoint was overall survival.

Phase 2 Trial: Efficacy Results and Post-Hoc Analysis[1,2,a]

Endpoint/Outcome	Camrelizumab + Apatinib (N = 45)
Median follow-up, mo (range)	9.2 (2.4-12.2)
ORR, n (%) [95% CI][b]	12 (58.5) [44.7-74.4]
CR, n (%)	2 (4.8)
PR, n (%)	23 (54.8)
Median DOR, mo	NR
DCR, n/N (%)	37/42[b] (88.1)
Median PFS, mo (95% CI)	7.6 (5.8-NR)

Post Hoc Analysis	Camrelizumab + Apatinib (N = 45)
ORR, n/N (%)	
PD-L1–positive tumors	20/29 (69)
PD-L1–negative tumors	5/10 (50)
Chi-squared test P	.281
Median PFS, mo	
PD-L1–positive tumors	9.6
PD-L1–negative tumors	5.3
Log-rank test P	.017

[a] As of Jan 22, 2020. [b] Of 42 pts who had at least one post-baseline tumor assessment (efficacy evaluable population.
1. Huang X et al. SGO 2020. Abstract 55. 2. Lan C et al. ASCO 2020. Abstract 6021.

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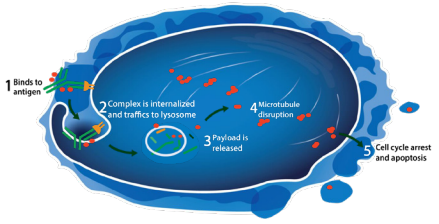
Here are the results of this study. The overall response rate for the combination was 58.5%, with two complete responses and 23 partial responses. You'll also note, on the right-hand side of the slide, that PD-L1 positivity was not a biomarker for overall response rate but was a biomarker for progression-free survival.

Patients who had PD-L1–positive tumors had a higher PFS of 9.6 compared with those who had PD-L1–negative tumors, which was 5.3. This combination shows promising activity and is worthy of further study.

Emerging Therapies: Antibody–Drug Conjugates



Tisotumab vedotin targets tissue factor, a protein often highly expressed in cervical cancer and associated with poor prognosis

Phase 1/2 innovaTV-201
(NCT02001623)[1]
- ORR: 22%
- mDOR: 6.0 months
- 6-month PFS: 40%

Phase 2 innovaTV-204
(NCT03438396)
- Results expected this year

Phase 1/2 innovaTV-205
(NCT03786081)
- In combination

1. Hong DS et al. *Clin Cancer Res*. 2020;26:1220-1228.

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Finally, I'm going to finish with some emerging therapies in cervical cancer that show promise for the future. The first is this antibody–drug conjugate. Tissue factor is aberrantly expressed in a broad range of solid tumors, including cervical cancer, and is associated with poor prognosis.

Tisotumab vedotin is an antibody–drug conjugate composed of a fully human monoclonal antibody specific for tissue factor conjugated to the microtubule-disrupting agent monomethyl auristatin E via protease cleavable linker.

Three trials that include cervical cancer are shown on the right side of the slide. The top study has been published with an overall response rate of 22% as a single agent. The other two studies are ongoing.

innovaTV 204 is investigating the antitumor activity and safety of the antibody–drug conjugate in approximately 100 patients with previously treated recurrent or metastatic cervical cancer, and innovaTV 205 is investigating the combination of the antibody–drug conjugate in combination. And we look forward to the results of these trials.

Emerging Therapies: Adoptive Cell Therapy[1,2]

Phase 2: innovaTIL-04
Adoptive cell transfer with autologous infiltrating lymphocytes (LN-145)

Surgical resection of tumor → Fragment tumor and isolate TILs → Expand TILs *in vivo* → Lymphodepletion and infusion of TILs and IL-2

	LN-145
Patient Population	Advanced disease, PST
N	27
ORR, n (%)	12 (44.4)
CR, n (%)	3 (11.1)
PR, n (%)	9 (33.3)
SD, n (%)	11 (40.7)
DCR, %	85.2
Median DOR[a], mo	NR
Median PFS, mo	NR

Endpoints
Primary: ORR assessed by RECIST v1.1
Secondary: DOR, DCR, Safety

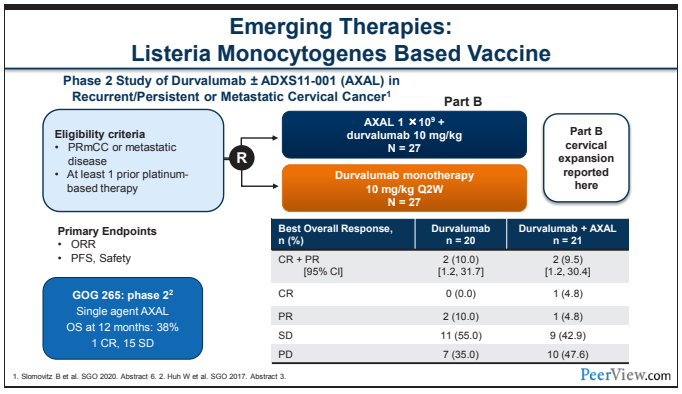
[a] Median follow-up: 7.4 months.
1. Jazaeri AA et al. *J Clin Oncol*. 2019;37:2538. 2. https://clinicaltrials.gov/ct2/show/NCT03108495.

PeerView.com

Here's another emerging therapy, adoptive cell therapy. This adoptive cell therapy study was presented at ASCO in 2019 by Dr. Jazaeri and also published in 2019.

In this study, the tumor was surgically resected and fragmented to isolate the tumor-infiltrating lymphocytes. The TILs were then expanded in vivo. Patient underwent lymphodepletion and infusion of the TILs with IL-2. The primary endpoint of this study was overall response rate.

On the right side of the slide, you'll see that the overall response rate in this study was 44%, with three CRs and nine PRs. This is a promising emerging therapy, and further study is needed.



Finally, I want to end with *Listeria monocytogenes*–based vaccine, or AXAL. This study shown this slide was presented by Dr. Slomovitz at SGO this year and was based on the results of GOG 265, shown in the bottom left corner.

GOG 265 was a phase 2 study of AXAL as a single agent in women with advanced or recurrent cervical cancer and more then met the bar, with an overall survival at 12 months of 38%. This was felt to be very promising and worthy of further study.

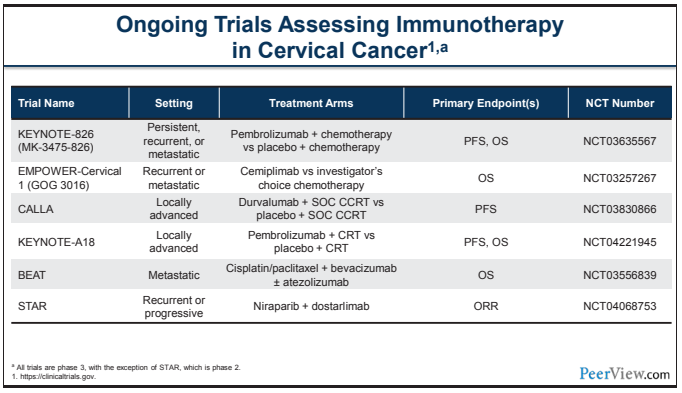
A subsequent randomized phase 2 study of AXAL with or without cisplatin in advanced cervical cancer was published in 2018 but did not show a difference between the combination and the single-agent AXAL, with a 12-month overall survival of 31% for AXAL alone versus 39% for the combination.

Dr. Slomovitz presented the results of this randomized phase 2 trial of durvalumab plus AXAL in the blue arm and durvalumab alone in the orange arm in patients with recurrent and persistent or metastatic cervical cancer.

As you can see on this slide, the CR plus PR rate was approximately 10% for both arms. Similarly, there was no difference in overall survival or best overall response between the arms.

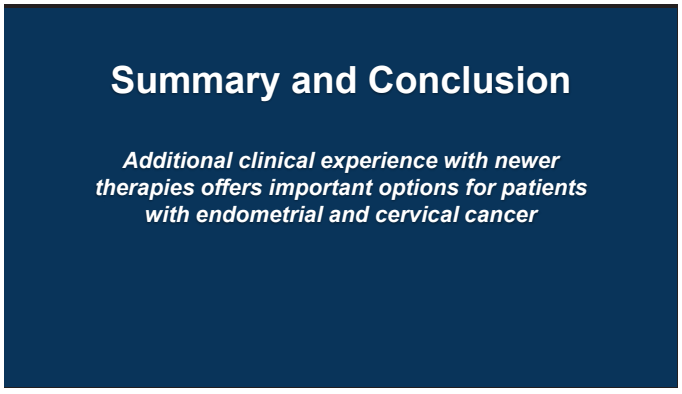
Interestingly, median progression-free survival in the durvalumab-only arm was 5 months, compared with only 2 months in the combination arm. However, as noted by Dr. Slomovitz during his presentation, more patients in the combination arm had greater than or equal to three prior lines of therapy, perhaps accounting for this PFS difference.

It is also notable that the adverse events in the combination arm were significantly higher than those in the single-agent arm, and there was one death in the combination arm. While AXAL shows promise as a single agent, this particular combination did not appear to provide a treatment advantage, and further combination studies are needed.



This slide shows examples of ongoing phase 3 trials assessing immunotherapy in cervical cancer. You'll note that CALLA and KEYNOTE-A18 add immunotherapy to chemoradiation in the frontline setting for early or locally advanced disease.

Here are some take-home thoughts on new developments in advanced and recurrent cervical cancer. Single-agent immunotherapy is approved for advanced cervical cancer in the second line. However, immunotherapy combination approaches show a lot of promise, and further study of these combinations is needed. Additional emerging therapies are on the horizon, and these include antibody–drug conjugates, adoptive cell transfer, and vaccine opportunities.



In summary, we've seen that additional experience with newer therapies offers new options for patient populations with advanced endometrial and cervical cancer and allows us to target and individualize therapy to those patients.

I thank you for joining me. I hope you found this program useful for your practice and also inspirational. And I hope that you'll continue to enter your patients onto clinical trials so that we can learn more about new therapies for these patients. I look forward—and I hope you do, too—to hearing future updates as some of these trials mature and we learn new data. Thank you very much.

Narrator: This activity has been jointly provided by Medical Learning Institute, Inc. and PVI, PeerView Institute for Medical Education.

CME/MOC

Chair's Take on Advances in Gynecologic Cancer Care: Exploring New Advances and Innovative Therapies in Endometrial and Cervical Cancers

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