Dissecting the Decision:

Investigators Discuss Available and Emerging Data on the Use of PARP Inhibitors in Ovarian Cancer and Other Novel Systemic Strategies Under Development for Gynecologic Cancers

A special audio supplement to a CME symposia series held during the Society of Gynecologic Oncology's 2017 Annual Meeting on Women's Cancer, featuring expert comments on the application of emerging research to patient care

Faculty Interviews

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Gynecologic Oncology™ UPDATE

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A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Gynecologic cancers comprise 5 primary cancers affecting the ovaries, uterine corpus (endometrial cancer), uterine cervix (cervical cancer), vulva and vagina. Despite many commonalities, each of these diseases is quite distinct, and management algorithms employed for each are consequently varied. Ovarian cancer (OC) is the fifth most common cause of cancer mortality in women, causing more deaths than any other gynecologic cancer. Given the significant number of clinical and research questions created by recent advances in the management of OC, including the introduction of PARP inhibitors, clinicians must be aware of emerging data and available protocols so that they may effectively counsel their patients. To bridge the gap between research and patient care, this program will feature special highlights from 2 satellite CME symposia presented during the 2017 Society of Gynecologic Oncology meeting. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to assist gynecologic oncologists, medical oncologists, gynecologists and other healthcare providers with the formulation of up-to-date clinical management strategies for various gynecologic cancers.

LEARNING OBJECTIVES

- Evaluate current and emerging treatment options for OC, and use this information to appropriately select and sequence systemic therapeutic approaches for patients with this disease.
- Appraise the efficacy and safety of approved and investigational PARP inhibitors as monotherapy for patients with BRCA-mutant advanced OC, and employ this information in the formulation of protocol and clinical treatment recommendations for these individuals.
- Appreciate the recent FDA approval of niraparib as maintenance therapy for patients with recurrent, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer, and safely integrate this agent into routine clinical practice.
- Consider the role of the anti-VEGF antibody bevacizumab in the initial and long-term treatment of advanced OC, cervical cancer and endometrial cancer.
- Recognize the mechanisms of action, emerging efficacy data and toxicity profiles of investigational agents in gynecologic cancers to effectively prioritize clinical trial opportunities for appropriate patients.

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CME INFORMATION

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Interview with Jonathan A Ledermann, MD

Tracks 1-13

Track 1	Biologic rationale for the use of PARP inhibitors in ovarian cancer (OC)
Track 2	Genetic alterations in OC and their sensitivity to PARP inhibition
Track 3	Incidence of homologous recombination deficiency (HRD) and identification of patients with OC who are most likely to benefit from PARP inhibitors
Track 4	Response to rucaparib in patients with BRCA-mutant and BRCA wild-type platinum-sensitive OC who have genomic loss of heterozygosity
Track 5	Efficacy and side-effect profiles of the PARP inhibitors olaparib, rucaparib and niraparib
Track 6	Activity of veliparib alone and in combination with chemotherapy for OC
Track 7	Results of the Phase III ENGOT-OV16/NOVA trial evaluating maintenance niraparib versus placebo for platinum-sensitive recurrent OC
Track 8	Study 19: Olaparib maintenance for platinum-sensitive, recurrent, serous OC
Track 9	Risk of myelodysplastic syndromes/ acute myeloid leukemia in patients receiving PARP inhibitors
Track 10	Potential use of PARP inhibitors as adjuvant therapy for patients with BRCA-mutated OC
Track 11	Results of SOLO2: Significant improvement in progression-free survival with olaparib maintenance in patients with platinum-sensitive, relapsed, BRCA mutation-positive OC
Track 12	Comparison of olaparib versus niraparib as maintenance therapy for patients with BRCA-mutated OC
Track 13	Incorporation of rucaparib into the treatment algorithm for patients with BRCA mutation-positive, recurrent OC

Interview with Bradley J Monk, MD

Tracks 1-11

Track 1	Management of platinum-sensitive, recurrent OC
Track 2	Choice of maintenance treatment with bevacizumab versus a PARP inhibitor for platinum-sensitive, relapsed OC in the second-line setting
Track 3	Activity of bevacizumab for platinum-resistant, recurrent OC
Track 4	Importance of genetic testing for all patients with OC
Track 5	Integration of bevacizumab into the clinical management of OC
Track 6	Role of neoadjuvant systemic therapy and intraperitoneal chemotherapy for patients with OC
Track 7	Mechanism of action, efficacy and tolerability of the novel antibody-drug conjugate mirvetuximab soravtansine
Track 8	Efficacy of bevacizumab for patients with endometrial cancer
Track 9	GOG 240: Improvement in overall survival with the addition of bevacizumab to chemotherapy in patients with recurrent, metastatic cervical cancer
Track 10	Potential adverse events associated with bevacizumab
Track 11	Investigation of listeria-based human papillomavirus (HPV) immunotherapy for advanced cervical cancer

Related Video Program

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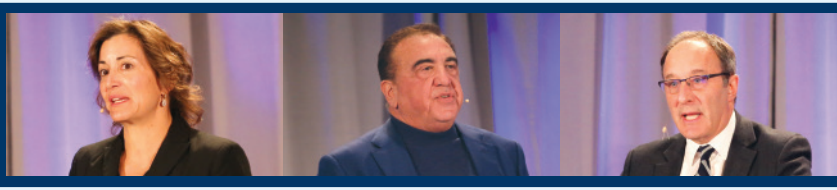

Topics covered include:

Part I: Emerging Treatment Strategies and Novel Approaches in Gynecologic Cancers

- Selection and Sequencing of Available Therapies for Patients with Ovarian Cancer
- Current Systemic Treatment of Advanced Cervical Cancer and Endometrial Cancer
- Novel Investigational Agents in Development and Emerging Role of Immunotherapy in Gynecologic Cancers

Part II: PARP Inhibition in the Management of Ovarian Cancer

- Genetic and Genomic Assessment in Women with Ovarian Cancer
- PARP Inhibitor Monotherapy in Advanced Disease
- Published and Emerging Research Data with PARP Inhibitor Maintenance Therapy
- Unique Tolerability Considerations Associated with PARP Inhibitors

SELECT PUBLICATIONS

A phase 3 placebo-controlled study of carboplatin/paclitaxel with or without concurrent and continuation maintenance veliparib (PARP inhibitor) in subjects with previously untreated stages III or IV high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer. NCT02470585

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POST-TEST

Dissecting the Decision: Investigators Discuss Available and Emerging Data on the Use of PARP Inhibitors in Ovarian Cancer and Other Novel Systemic Strategies Under Development for Gynecologic Cancers

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Current guidelines recommend that _____ undergo BRCA testing.**
   a. All patients with epithelial OC
   b. Only patients of Ashkenazi Jewish descent
   c. Only patients with a strong family history of breast cancer or OC at a young age

2. **The incidence of homologous recombination deficiency in patients with high-grade serous OC is estimated to be approximately _____.**
   a. 20%
   b. 30%
   c. 50%

3. **Study 19, investigating olaparib maintenance after platinum-based chemotherapy in patients with platinum-sensitive, recurrent, serous OC, reported a statistically significant improvement in overall survival for patients who received olaparib compared to placebo.**
   a. True
   b. False

4. **In which of the following subgroups of patients with platinum-sensitive recurrent OC did niraparib maintenance therapy provide a significant progression-free survival benefit compared to placebo on the Phase III ENGOT-OV16/NOVA trial?**
   a. Patients with germline BRCA mutations
   b. Patients without germline BRCA mutations
   c. Patients with HRD positivity and no germline BRCA mutations
   d. All of the above
   e. Both b and c

5. **Thrombocytopenia that occurs early (in the first 2 cycles) is a characteristic toxicity of _____.**
   a. Olaparib
   b. Niraparib
   c. Rucaparib

6. **Rucaparib was recently approved by the FDA for patients with deleterious BRCA-mutated advanced OC who have received _____.**
   a. Two or more lines of chemotherapy
   b. Three or more lines of chemotherapy
   c. No chemotherapy

7. **The Phase III SOLO2 trial evaluating olaparib monotherapy versus placebo as maintenance therapy for patients with platinum-sensitive, relapsed OC _____.**
   a. Demonstrated a statistically significant improvement in progression-free survival with olaparib
   b. Included only patients with BRCA-mutant disease
   c. Evaluated the capsule formulation of olaparib
   d. All of the above
   e. Both a and b

8. **Bevacizumab has been FDA approved for platinum-sensitive, recurrent OC in combination with which of the following chemotherapy options?**
   a. Carboplatin/paclitaxel
   b. Carboplatin/gemcitabine
   c. Topotecan hydrochloride
   d. All of the above
   e. Both a and b

9. **Mirvetuximab soravtansine (IMGN853) is _____.**
   a. An anti-angiogenic agent
   b. An antibody-drug conjugate
   c. A PARP inhibitor

10. **The Phase III AIM2CERV study is investigating listeria-based HPV immunotherapy as adjuvant treatment after chemoradiation therapy for patients with advanced _____.**
    a. Cervical cancer
    b. Endometrial cancer
    c. Ovarian cancer

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Dissecting the Decision: Investigators Discuss Available and Emerging Data on the Use of PARP Inhibitors in Ovarian Cancer and Other Novel Systemic Strategies Under Development for Gynecologic Cancers

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Results of the Phase III ENGOT-OV16/NOVA trial: Efficacy of niraparib as maintenance therapy for patients with BRCA mutation-positive and BRCA wild-type, platinum-sensitive, recurrent OC	4 3 2 1	4 3 2 1
Recent FDA approval of rucaparib and current integration into clinical practice	4 3 2 1	4 3 2 1
Major efficacy findings of the Phase III SOLO2 trial evaluating olaparib as maintenance therapy for patients with BRCA mutation-positive, platinum-sensitive, recurrent OC	4 3 2 1	4 3 2 1
FDA approval and optimal integration of bevacizumab in combination with chemotherapy for patients with platinum-sensitive recurrent OC	4 3 2 1	4 3 2 1
Mechanism of action and available research data on the efficacy of mirvetuximab soravtansine in platinum-resistant OC	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice
☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with the following do you see per year?

OC: ..... Endometrial cancer: ..... Cervical cancer: .....

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Evaluate current and emerging treatment options for OC, and use this information to appropriately select and sequence systemic therapeutic approaches for patients with this disease ..... 4 3 2 1 N/M N/A
- Appraise the efficacy and safety of approved and investigational PARP inhibitors as monotherapy for patients with BRCA-mutant advanced OC, and employ this information in the formulation of protocol and clinical treatment recommendations for these individuals ..... 4 3 2 1 N/M N/A
- Appreciate the recent FDA approval of niraparib as maintenance therapy for patients with recurrent, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer, and safely integrate this agent into routine clinical practice. ..... 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Consider the role of the anti-VEGF antibody bevacizumab in the initial and long-term treatment of advanced OC, cervical cancer and endometrial cancer . . . . . 4 3 2 1 N/M N/A
- Recognize the mechanisms of action, emerging efficacy data and toxicity profiles of investigational agents in gynecologic cancers to effectively prioritize clinical trial opportunities for appropriate patients . . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

. . . . . .

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain: . . . . . .

Additional comments about this activity:

. . . . . .

PART 2 — Please tell us about the faculty and editor for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter	Effectiveness as an educator
Jonathan A Ledermann, MD	4 3 2 1	4 3 2 1
Bradley J Monk, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

Please recommend additional faculty for future activities:

. . . . . .

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Gynecologic Oncology UPDATE

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