RTP ONDEMAND

Current and Future Role of PARP Inhibitors in the Management of Ovarian Cancer

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

Faculty Interviews

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CME Certified

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RTP ONDEMAND

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RTP On Demand: Current and Future Role of PARP Inhibitors in the Management of Ovarian Cancer

OVERVIEW OF ACTIVITY

The American Cancer Society estimates that 22,280 new cases of ovarian cancer (OC) will be diagnosed in the United States in 2016 and 14,240 individuals will die of the disease. Significant resources have been invested over the past few decades in attempts to better understand the natural history of the disease, identify genetic and other factors responsible for its proliferation and develop novel therapies with the potential to significantly improve outcomes for patients. One such avenue, investigating PARP inhibition as a mechanism to combat OC development and progression, ultimately led to the 2014 FDA approval of the PARP inhibitor olaparib. Given the significant number of clinical and research questions created by this recent introduction and the rapidly expanding database surrounding PARP inhibition in general, it is clear that additional educational resources are needed to keep practicing clinicians up to date and informed. To that end, this special *RTP On Demand* program uses one-on-one discussion with leading investigators in the field to assist practicing clinicians with the formulation of up-to-date management strategies.

LEARNING OBJECTIVES

- Use available guidelines and consensus statements to develop an evidence-based algorithm for conducting genetic screening for patients with OC.
- Understand the rationale for the investigation of PARP inhibition as monotherapy or in combination with other novel agents for patients with BRCA mutation-positive and BRCA wild-type advanced OC, and use this information to inform protocol and nonresearch treatment options for these individuals.
- Appreciate the recent approval of olaparib for patients with highly refractory advanced OC, and appropriately integrate this agent into the clinical management of such cases.
- Develop an understanding of the available efficacy data and toxicity profiles of investigational PARP inhibitors to effectively prioritize clinical trial opportunities for appropriate patients with OC.
- Educate patients about the side effects associated with approved and investigational PARP inhibitors, and provide preventive and emergent strategies to reduce or ameliorate these toxicities.

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CME INFORMATION

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Matulonis** — Advisory Committee: AstraZeneca Pharmaceuticals LP, Genentech BioOncology, ImmunoGen Inc, Merck. **Dr Herzog** — Advisory Committee: Amgen Inc, AstraZeneca Pharmaceuticals LP, Caris Life Sciences, Pfizer Inc, Roche Laboratories Inc. **Dr Birrer** — Advisory Committee: Acceleron Pharma, AstraZeneca Pharmaceuticals LP, ImmunoGen Inc, Merrimack Pharmaceuticals Inc, OXiGENE Inc, Roche Laboratories Inc, Sanofi, Threshold Pharmaceuticals Inc.

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Interview with Ursula A Matulonis, MD

Tracks 1-20

Track 1	**Case discussion:** A 55-year-old woman with recurrent ovarian cancer (OC) is found to harbor a germline BRCA1 mutation and receives olaparib on a clinical trial
Track 2	Activity and ongoing investigation of cediranib in platinum-sensitive and platinum-resistant OC
Track 3	Antitumor activity of olaparib and management of associated side effects
Track 4	Importance of BRCA testing in OC
Track 5	Identification of factors predictive of benefit from PARP inhibition
Track 6	Role of PARP in DNA repair
Track 7	Background of the Phase III ENGOT-OV16/NOVA trial evaluating maintenance niraparib versus placebo for platinum-sensitive recurrent OC
Track 8	Results of Study 19: Olaparib maintenance therapy for platinum-sensitive relapsed OC
Track 9	Perspective on the failure of olaparib to receive FDA approval as maintenance therapy
Track 10	Results of the ENGOT-OV16/NOVA trial: Niraparib significantly improves progression-free survival in platinum-sensitive recurrent OC irrespective of BRCA mutation or homologous recombination deficiency (HRD) status
Track 11	Somatic versus germline testing and identification of other genomic signatures that may predict benefit from PARP inhibition
Track 12	**Second opinion:** A 45-year-old woman with optimally debulked Stage IIIA serous OC with a germline BRCA2 mutation and no evidence of disease after adjuvant chemotherapy
Track 13	Clinical trials evaluating the use of PARP inhibitors alone and in combination in earlier-line settings
Track 14	KEYNOTE-162: A Phase I/II study of niraparib with the anti-PD-1 antibody pembrolizumab for patients with recurrent OC or triple-negative breast cancer
Track 15	**Second opinion:** Monitoring blood counts in patients receiving olaparib and the use of erythropoiesis-stimulating agents
Track 16	**Second opinion:** Therapeutic options for patients experiencing disease progression on olaparib
Track 17	Efficacy and side-effect profiles of the novel PARP inhibitors rucaparib, niraparib and veliparib
Track 18	Continuation or switching of PARP inhibitor therapy for patients experiencing disease progression
Track 19	Management of gastrointestinal toxicity in patients receiving olaparib
Track 20	Differences in form, strength and number of pills or capsules administered per day among approved and investigational PARP inhibitors

Editor's note: On December 19, 2016, the FDA granted accelerated approval to rucaparib for the treatment of advanced OC associated with deleterious BRCA mutations (germline and/or somatic) in patients who have received 2 or more chemotherapies.

Interview with Thomas J Herzog, MD

Tracks 1-15

Track 1	**Case discussion:** A 54-year-old woman with recurrent, platinum-resistant OC who is found to harbor a BRCA1 germline mutation
Track 2	Perspective on the importance of up-front BRCA testing for patients with epithelial OC
Track 3	Benefits and limitations of genetic counseling and currently available genetic tests
Track 4	Clinical experience with gastrointestinal toxicity and anemia with PARP inhibitors in OC
Track 5	Risk of second cancers with olaparib

Interview with Dr Herzog (continued)

Track 6	Synthetic lethality in PARP inhibition for patients with OC lacking BRCA1/2 mutations
Track 7	Somatic versus germline BRCA mutations and correlation with response to PARP inhibitors
Track 8	Niraparib maintenance therapy for platinum-sensitive, recurrent OC
Track 9	Tolerability and side-effect profile of niraparib maintenance therapy
Track 10	Investigation of PARP inhibitors as front-line therapy for BRCA mutation-positive OC
Track 11	Ongoing Phase III trials of olaparib, rucaparib and niraparib
Track 12	Current US and European approvals for olaparib
Track 13	Results of the Phase III MITO8 trial evaluating the effect on survival of prolonging the platinum-free interval for patients with OC experiencing disease recurrence 6 to 12 months after platinum-based chemotherapy
Track 14	OV21/PETROC: Results of a Phase II study of intraperitoneal versus intravenous chemotherapy after neoadjuvant chemotherapy and optimal debulking surgery for epithelial OC
Track 15	Novel immunotherapies under investigation for advanced OC, including checkpoint inhibitors and antibody-drug conjugates

Interview with Michael Birrer, MD, PhD

Tracks 1-2

Track 1	Perspective on clinical implications of the ENGOT-OV16/NOVA trial results: Niraparib maintenance therapy for platinum-sensitive, recurrent OC
Track 2	Evolving landscape of PARP inhibition in the treatment of OC

Related Video Program

Visit www.ResearchToPractice.com/RTPODOvarian116/Video to view video highlights of the interviews with (from left) Drs Matulonis, Herzog and Birrer by Dr Love and earn up to 1 additional *AMA PRA Category 1 Credit™*.

Topics covered include:

- Genetic assessment for women with OC
- Biologic rationale for the use of PARP inhibitors
- Niraparib maintenance therapy for platinum-sensitive, recurrent OC
- Efficacy and side-effect profiles of the various PARP inhibitors
- Management of PARP inhibitor-associated side effects
- Therapeutic options for patients experiencing disease progression on olaparib

SELECT PUBLICATIONS

A phase 2, open-label, single-arm study to evaluate the safety and efficacy of niraparib in patients with advanced, relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received three or four previous chemotherapy regimens. NCT02354586

A phase 2, open-label study of rucaparib in patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer (ARIEL2). NCT01891344

A phase III, open label, randomised, controlled, multi-centre study to assess the efficacy and safety of olaparib monotherapy versus physician's choice single agent chemotherapy in the treatment of platinum sensitive relapsed ovarian cancer in patients carrying germline BRCA1/2 mutations. NCT02282020

A phase III, randomised, double blind, placebo controlled, multicentre study of olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO Stage III-IV) ovarian cancer following first line platinum based chemotherapy. NCT01844986

Banerjee S et al. **Management of nausea and vomiting during treatment with the capsule (CAP) and tablet (TAB) formulations of the PARP inhibitor olaparib.** *Proc ECCO* 2015;**Abstract 2759**.

Coleman RL et al. **A phase II evaluation of the potent, highly selective PARP inhibitor veliparib in the treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who carry a germline BRCA1 or BRCA2 mutation — An NRG Oncology/Gynecologic Oncology Group study.** *Gynecol Oncol* 2015;137(3):386-91.

Helleday T. **The underlying mechanism for the PARP and BRCA synthetic lethality: Clearing up the misunderstandings.** *Mol Oncol* 2011;5(4):387-93.

Konecny GE, Kristeleit RS. **PARP inhibitors for BRCA1/2-mutated and sporadic ovarian cancer: Current practice and future directions.** *Br J Cancer* 2016;115(10):1157-73.

Kristeleit RS et al. **Clinical activity of the poly(ADP-ribose) polymerase (PARP) inhibitor rucaparib in patients (pts) with high-grade ovarian carcinoma (HGOC) and a BRCA mutation (BRCAmut): Analysis of pooled data from Study 10 (parts 1, 2a, and 3) and ARIEL2 (parts 1 and 2).** *Proc ESMO* 2016;**Abstract 8560**.

Kristeleit RS et al. **Gynecologic cancers: Emerging novel strategies for targeting DNA repair deficiency.** *Am Soc Clin Oncol Educ Book* 2016;35:e259-68.

Lancaster JM et al. **Society of Gynecologic Oncology statement on risk assessment for inherited gynecologic cancer predispositions.** *Gynecol Oncol* 2015;136(1):3-7.

Ledermann J et al. **Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer.** *N Engl J Med* 2012;366(15):1382-92.

Mackay HJ et al. **OV21/PETROC: A randomized Gynecologic Cancer Intergroup (CGIG) phase II study of intraperitoneal (IP) versus intravenous (IV) chemotherapy following neoadjuvant chemotherapy and optimal debulking surgery in epithelial ovarian cancer (EOC).** *Proc ASCO* 2016;**Abstract LBA5503**.

Mirza MR et al. **A randomized, double-blind phase 3 trial of maintenance therapy with niraparib vs placebo in patients with platinum-sensitive recurrent ovarian cancer (ENGOT-OV16/NOVA trial)**. *Proc ESMO* 2016;**Abstract LBA3_PR**.

Mirza MR et al. **Niraparib maintenance therapy in platinum-sensitive, recurrent ovarian cancer.** *N Engl J Med* 2016;375(22):2154-64.

Panagiotis K et al. **Phase I/II study of niraparib plus pembrolizumab in patients with triple-negative breast cancer or recurrent ovarian cancer (KEYNOTE-162).** *Proc ASCO* 2016;**Abstract TPS5599**.

Phase 3 study of rucaparib as switch maintenance after platinum in relapsed high grade serous and endometrioid ovarian cancer (ARIEL3). NCT01968213

Randomized, double-blind, phase III trial olaparib vs placebo patients with advanced FIGO Stage IIIB-IV high grade serous or endometrioid ovarian, fallopian tube, or peritoneal cancer treated standard first-line treatment. NCT02477644

Sandro P et al. **The MITO8 phase 3 international multicenter randomized study testing the effect on survival of prolonging platinum-free interval (PFI) in patients with ovarian cancer (OC) recurring between 6 and 12 months after previous platinum-based chemotherapy: A collaboration of MITO, MANGO, AGO, BGOG, ENGOT, and GCIG.** *Proc ASCO* 2016;**Abstract 5505**.

POST-TEST

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Olaparib monotherapy is FDA approved for patients with deleterious germline BRCA mutation-positive advanced OC previously treated with 3 or more lines of chemotherapy.**
   a. True
   b. False

2. **For which of the following patients with platinum-sensitive, recurrent OC did the use of niraparib maintenance therapy provide a significant progression-free survival benefit in comparison to placebo on the Phase III ENGOT-OV16/NOVA trial?**
   a. Patients with germline BRCA mutation
   b. Patients with no germline BRCA mutation
   c. Patients with no germline BRCA mutation but with HRD positivity
   d. All of the above
   e. Both a and b
   f. Both b and c

3. **For how long did patients on the Phase III ENGOT-OV16/NOVA trial receive niraparib maintenance therapy?**
   a. One year
   b. Two years
   c. Indefinitely (until either disease progression or toxicity)

4. **The most common cytopenia observed with niraparib on the Phase III ENGOT-OV16/NOVA trial was _____.**
   a. Anemia
   b. Neutropenia
   c. Thrombocytopenia
   d. All of the above

5. **The Phase III PAOLA-1 trial is evaluating olaparib in combination with _____ as first-line therapy for advanced OC.**
   a. Anti-PD-1/PD-L1 inhibition
   b. Bevacizumab
   c. Cediranib

6. **Side effects of olaparib therapy include _____.**
   a. Anemia
   b. Nausea
   c. Fatigue
   d. Vomiting
   e. All of the above

7. **The Phase III SOLO1 trial is evaluating olaparib monotherapy maintenance for patients with _____ advanced OC after first-line platinum-based chemotherapy.**
   a. BRCA wild-type
   b. Germline BRCA mutation-positive
   c. Both a and b

8. **Rucaparib is a novel PARP inhibitor with demonstrated single-agent activity in the treatment of patients with BRCA mutation-positive advanced OC.**
   a. True
   b. False

9. **The Phase I/II KEYNOTE-162 trial is evaluating niraparib in combination with _____ for patients with recurrent OC or triple-negative breast cancer.**
   a. Atezolizumab
   b. Nivolumab
   c. Pembrolizumab
   d. All of the above

10. **It is recommended that _____ undergo BRCA testing.**
    a. All patients with epithelial OC
    b. Patients with an Ashkenazi Jewish background
    c. Patients with a strong family history of breast cancer or OC at a young age

EDUCATIONAL ASSESSMENT AND CREDIT FORM

RTP On Demand: Current and Future Role of PARP Inhibitors in the Management of Ovarian Cancer

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 evaluating maintenance niraparib versus placebo for patients with platinum-sensitive recurrent OC	4 3 2 1	4 3 2 1
Appropriate use of BRCA testing for guidance in treatment selection for patients with OC	4 3 2 1	4 3 2 1
FDA approval of olaparib monotherapy and current integration into clinical practice	4 3 2 1	4 3 2 1
Investigation of PARP inhibitors as front-line therapy for BRCA mutation-positive OC	4 3 2 1	4 3 2 1
KEYNOTE-162: A Phase I/II study of niraparib with the anti-PD-1 antibody pembrolizumab for patients with recurrent OC or triple-negative breast cancer	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 ovarian cancer do you see per year? ..... patients

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
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☐ 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: .....

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

- Use available guidelines and consensus statements to develop an evidence-based algorithm for conducting genetic screening for patients with OC..... 4 3 2 1 N/M N/A
- Understand the rationale for the investigation of PARP inhibition as monotherapy or in combination with other novel agents for patients with BRCA mutation-positive and BRCA wild-type advanced OC, and use this information to inform protocol and nonresearch treatment options for these individuals..... 4 3 2 1 N/M N/A
- Appreciate the recent approval of olaparib for patients with highly refractory advanced OC, and appropriately integrate this agent into the clinical management of such cases..... 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:

- Develop an understanding of the available efficacy data and toxicity profiles of investigational PARP inhibitors to effectively prioritize clinical trial opportunities for appropriate patients with OC. . . . . 4 3 2 1 N/M N/A
- Educate patients about the side effects associated with approved and investigational PARP inhibitors, and provide preventive and emergent strategies to reduce or ameliorate these toxicities. . . . . 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:

. . . . . .

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Ursula A Matulonis, MD	4 3 2 1	4 3 2 1
Thomas J Herzog, MD	4 3 2 1	4 3 2 1
Michael Birrer, MD, PhD	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

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