

Visiting Professors

Clinical Investigators Review Key Publications and Current Cases in Gynecologic Oncology

CME INFORMATION

TARGET AUDIENCE

This activity is intended for gynecologic and medical oncologists, gynecologists and other healthcare providers involved in the treatment of gynecologic cancers.

OVERVIEW OF ACTIVITY

In 2015 it is anticipated that approximately 98,000 new cases of gynecologic cancer — which includes cancer of the ovaries, uterine corpus (endometrial cancer), uterine cervix (cervical cancer), vulva and vagina — will be documented in the United States and 30,000 individuals will succumb to these diseases. As with many other tumors, patient outcomes are critically dependent on effective multidisciplinary care. Despite many commonalities, each of these diseases is in fact quite distinct, and in this regard management algorithms employed for each are varied.

Existing and emerging multimodality treatment regimens used in the routine management of these diseases necessitate the physician's working knowledge of novel surgical, radiation and systemic therapeutic techniques. Ongoing clinical trials will continue to refine the optimal management of these tumors, and the introduction of innovative, targeted compounds may offer individualized treatment options that provide increased efficacy and improved tolerability. In order to offer optimal patient care — including the option of clinical trial participation — clinicians who care for patients with gynecologic cancers must be well informed of these advances.

These video proceedings from a CME symposium held during the Society of Gynecologic Oncology's 2015 Annual Meeting on Women's Cancer feature discussions with leading researchers with an expertise in gynecologic oncology regarding actual patient cases and related clinical research findings. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to assist gynecologic oncologists and other healthcare providers with the formulation of up-to-date clinical management strategies for various gynecologic cancers.

LEARNING OBJECTIVES

- Employ current clinical guidelines and available data in the selection of treatment options for patients with commonly diagnosed gynecologic cancers.

- Develop a treatment plan for advanced cervical cancer, incorporating recently approved and investigational agents, and understand and counsel patients about the risks of perforation and fistula associated with anti-angiogenic therapy.
- Consider clinical investigator perspectives regarding the indications for BRCA mutation testing, and use this information to appropriately select patients with ovarian cancer (OC) for this analysis.
- Develop an evidence-based algorithm for the initial and long-term treatment of advanced OC considering the role of the recently approved anti-VEGF antibody bevacizumab.
- Understand the rationale for the investigation of PARP inhibitors in OC, and recall the results of studies with olaparib and other similar agents under development for patients with advanced disease.
- Appreciate the recent approval of olaparib for patients with highly refractory advanced OC, and integrate this agent into the clinical care of appropriate individuals.
- Develop an understanding of the emerging efficacy data and toxicity profiles of investigational agents in OC to effectively prioritize clinical trial opportunities for appropriate patients.
- Counsel appropriately selected patients with gynecologic cancers about participation in ongoing clinical trials.
- Develop strategies for managing complex psychosocial issues affecting patients with advanced cancers, incorporating palliative care specialists and identifying special needs, such as minor children of patients with cancer.

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Hardware/Software Requirements:

A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later
Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

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SELECT PUBLICATIONS

Richard T Penson, MD, MRCP

A randomized phase III trial of cisplatin plus paclitaxel with and without NCI-supplied bevacizumab (NSC 704865) versus the non-platinum doublet, topotecan plus paclitaxel, with and without NCI-supplied bevacizumab, in Stage IVB, recurrent or persistent carcinoma of the cervix. [NCT00803062](#)

A single arm, single stage phase II trial of GSK1120212 and GSK2141795 in persistent or recurrent cervical cancer. [NCT01958112](#)

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Kitagawa R et al. **Paclitaxel plus carboplatin versus paclitaxel plus cisplatin in metastatic or recurrent cervical cancer: The open-label randomized phase III trial JCOG0505.** *J Clin Oncol* 2015;[Epub ahead of print].

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Paclitaxel in treating patients with advanced, refractory, or recurrent cervical or vaginal cancer. [NCT00002562](#)

Phase II evaluation of oxaliplatin in persistent or recurrent squamous cell carcinoma of the cervix. [NCT00005837](#)

Tewari KS et al. **Improved survival with bevacizumab in advanced cervical cancer.** *N Engl J Med* 2014;370(8):734-43.

Bradley J Monk, MD

A phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube, and primary peritoneal carcinoma NCI-supplied agent(s): Bevacizumab (NSC 704865). [NCT00951496](#)

Aghajanian C et al. **OCEANS: A randomized, double-blinded, placebo-controlled, phase III trial of chemotherapy with or without bevacizumab (BEV) in patients with platinum-sensitive recurrent epithelial ovarian (EOC), primary peritoneal (PPC), or fallopian tube cancer (FTC).** *Proc ASCO* 2011;[Abstract LBA5007](#).

AGO-Ovar 17: A prospective randomised phase III trial to evaluate optimal treatment duration of first-line bevacizumab in combination with carboplatin and paclitaxel in patients with primary epithelial ovarian, fallopian tube or peritoneal cancer. [NCT01462890](#)

AGO-Ovar 2.21: A prospective randomized phase III trial of carboplatin/gemcitabine/bevacizumab versus carboplatin/pegylated liposomal doxorubicin/bevacizumab in patients with platinum-sensitive recurrent ovarian cancer. [NCT01837251](#)

AURELIA: A multi-center, open-label, randomised, two-arm phase III trial of the effect on progression free survival of bevacizumab plus chemotherapy versus chemotherapy alone in patients with platinum-resistant, epithelial ovarian, fallopian tube or primary peritoneal cancer. [NCT00976911](#)

Bookman MA, Brady MF. **Intraperitoneal chemotherapy: Long-term outcomes revive a long-running debate.** *J Clin Oncol* 2015;33(13):1424-6.

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GOG-0213: A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab (NSC 704865) followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer. [NCT00565851](#)

GOG-0218: A phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC 704865) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, suboptimal advanced stage epithelial ovarian, primary peritoneal cancer, or fallopian tube cancer. [NCT00262847](#)

GOG-0262: A phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab (NSC 704865) in the treatment of primary stage II, III or IV epithelial ovarian, peritoneal or fallopian tube cancer and ACRIN 6695: Perfusion CT imaging to evaluate treatment response in patients participating in GOG-0262. [NCT01167712](#)

ICON7: A randomised, two-arm, multi-centre gynaecologic cancer InterGroup trial of adding bevacizumab to standard chemotherapy (carboplatin and paclitaxel) in patients with epithelial ovarian cancer. [NCT00483782](#)

Ledermann JA et al. Newly diagnosed and relapsed epithelial ovarian carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol* 2013;24(Suppl 6):24-32.

MITO16MANGO2b: Multicenter phase III randomized study with second line chemotherapy plus or minus bevacizumab in patients with platinum sensitive epithelial ovarian cancer recurrence after a bevacizumab/chemotherapy first line. [NCT01802749](#)

OCEANS: A phase III, multicenter, randomized, blinded, placebo-controlled trial of carboplatin and gemcitabine plus bevacizumab in patients with platinum-sensitive recurrent ovary, primary peritoneal, or fallopian tube carcinoma. [NCT00434642](#)

OCTAVIA: A single-arm phase II clinical study investigating the addition of bevacizumab to carboplatin and weekly paclitaxel as first-line treatment in patients with epithelial ovarian cancer. [NCT00937560](#)

Oza AM et al. **ICON7:** Final overall survival results in the GCIG phase III randomized trial of bevacizumab in women with newly diagnosed ovarian cancer. *Proc ECC* 2013; [Abstract 6](#).

Perren TJ et al. A phase 3 trial of bevacizumab in ovarian cancer. *N Engl J Med* 2011;365(26):2484-96.

Pfisterer J et al. Gemcitabine plus carboplatin compared with carboplatin in patients with platinum-sensitive recurrent ovarian cancer: An intergroup trial of the AGO-OVAR, the NCIC CTG, and the EORTC GCG. *J Clin Oncol* 2006;24(29):4699-707.

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Pujade-Lauraine E et al. **AURELIA:** A randomized phase III trial evaluating bevacizumab (BEV) plus chemotherapy (CT) for platinum (PT)-resistant recurrent ovarian cancer (OC). *Proc ASCO* 2012; [Abstract LBA5002](#).

ROSIA: Global study to assess the addition of bevacizumab to carboplatin and paclitaxel as front-line treatment of epithelial ovarian cancer, fallopian tube carcinoma or primary peritoneal carcinoma. [NCT01239732](#)

Tewari D et al. Long-term survival advantage and prognostic factors associated with intraperitoneal chemotherapy treatment in advanced ovarian cancer: A gynecologic oncology group study. *J Clin Oncol* 2015;33(13):1460-6.

Ursula A Matulonis, MD

A cancer research UK phase II proof of principle trial of the activity of the PARP-1 inhibitor, AG-014699, in known carriers of a BRCA 1 or BRCA 2 mutation with locally advanced or metastatic breast or advanced ovarian cancer. [NCT00664781](#)

A phase 1 dose-escalation study of intraperitoneal (IP) cisplatin, IV/IP paclitaxel, IV bevacizumab, and oral olaparib for newly diagnosed ovarian, primary peritoneal, and fallopian tube cancer. [NCT02121990](#)

A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent/CTEP-supplied agent ABT-888 (NSC 737664) and CTEP-supplied agent bevacizumab (NSC 704865) in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer. [NCT00989651](#)

A phase I trial of pegylated liposomal doxorubicin (PLD), carboplatin, and NCI supplied veliparib (ABT-888), and NCI supplied bevacizumab in recurrent platinum sensitive ovarian, primary peritoneal and fallopian tube cancer. [NCT01459380](#)

A phase I/II, open-label, safety, pharmacokinetic, and preliminary efficacy study of oral rucaparib in patients with gBRCA mutation ovarian cancer or other solid tumors. [NCT01482715](#)

A phase 2 pilot study of BMN 673 (talazoparib), an oral PARP inhibitor, in patients with deleterious BRCA1/2 mutation-associated ovarian cancer who have had prior PARP inhibitor treatment. [NCT02326844](#)

A phase 2 study of olaparib and cediranib for the treatment of recurrent ovarian cancer. [NCT02345265](#)

A phase 3 randomized double-blind trial of maintenance with niraparib versus placebo in patients with platinum sensitive ovarian cancer. [NCT01847274](#)

A phase III study comparing single-agent olaparib or the combination of cediranib and olaparib to standard platinum-based chemotherapy in women with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer. [NCT02446600](#)

A proof of concept clinical trial of the combination cediranib-olaparib at the time of disease progression on olaparib in ovarian cancer. [NCT02340611](#)

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

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Liu JF et al. **PARP inhibitors in ovarian cancer: Current status and future promise.** *Gynecol Oncol* 2014;133(2):362-9.

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Ramus SJ, Gayther SA. **The contribution of BRCA1 and BRCA2 to ovarian cancer.** *Mol Oncol* 2009;3(2):138-50.

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Deborah K Armstrong, MD

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bevacizumab, in women with newly diagnosed, previously untreated, suboptimal advanced stage epithelial ovarian, primary peritoneal cancer, or fallopian tube cancer. [NCT00262847](#)

GOG-0262: A phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab (NSC 704865) in the treatment of primary stage II, III or IV epithelial ovarian, peritoneal or fallopian tube cancer and ACRIN 6695: Perfusion CT imaging to evaluate treatment response in patients participating in GOG-0262. [NCT01167712](#)

Norquist BS et al. **Germline mutations in DNA repair genes in women with ovarian, peritoneal, or fallopian tube cancer treated on GOG protocols 218 and 262.** *Proc SGO 2014*;Abstract 10.

Rebbeck TR et al. **Breast cancer risk after bilateral prophylactic oophorectomy in BRCA1 mutation carriers.** *J Natl Cancer Inst* 1999;91(17):1475-9.

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