Highlights: 2019 Annual Meeting on Women's Cancer
Society of Gynecologic Oncology (SGO)

Submitted April 1, 2019 by
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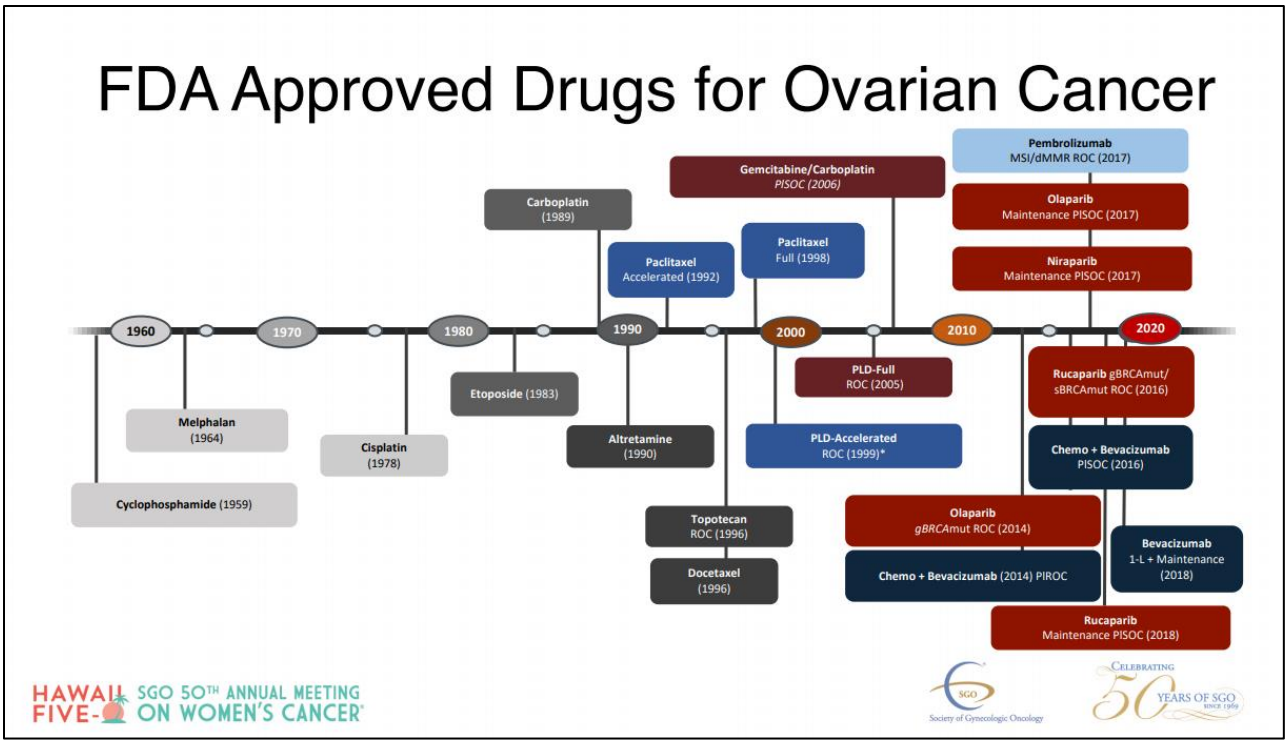
50 YEARS OF PROGRESS

This year's SGO annual meeting held in Honolulu, Hawaii March 15-19 celebrated the 50th anniversary of the society and broke previous records with 2,548 attendees. It was also the first meeting that I attended as an associate member since SGO recently opened membership to Patient Advocates. Here are my highlights from the survivor perspective of the sessions.

While dialogue continues on best use and timing of several interventions (such as neoadjuvant therapy, intraperitoneal therapy, and HIPEC), recent progress is clear in the number of treatments approved for ovarian cancer, including PARP inhibitors (PARPi).



EVERY WOMAN STUDY

The World Ovarian Cancer Coalition's Every Woman Study which was released late last year was presented during the International Session. This study identified challenges and opportunities to improve survival and quality of life for all women impacted with ovarian cancer.

CLINICAL TRIAL RESULTS

- **Phase III Avelumab with or without pegylated liposomal doxorubicin (PLD) or PLD alone (JAVELIN)**

During the late breaking abstract session, Dr. Eric Pujade Lauraine of ARCAGY-GINECO, Paris, France presented results of "Avelumab alone or in combination with PLD versus PLD alone in platinum-resistant or refractory epithelial ovarian cancer: Primary and biomarker analysis of the phase III JAVELIN Ovarian 200 trial" in platinum-resistant or refractive ovarian cancer. The trial did not show improvement in overall survival (OS) or progression free survival (PFS) objectives. Subgroup analysis indicated that patients with PD-L1–positive tumors had a trend to a higher overall response rate (ORR).

NCT02580058 study details can be found on ClinicalTrials.gov.

- **Phase I Oral lenvatinib and weekly paclitaxel**

During the late breaking abstract session, Dr. Floor Backes of Ohio State University, James Cancer Hospital, presented the results of a Phase I clinical trial of oral lenvatinib and weekly paclitaxel for recurrent ovarian and endometrial cancers. In this small dose-finding study, the ORR for platinum resistant ovarian cancer patients was 71% with median PFS of 14 months. Further studies to confirm these results and other combinations with oral lenvatinib are being planned.

NCT02788708 study details can be found on ClinicalTrials.gov.

- **Phase II Pembrolizumab with bevacizumab and oral cyclophosphamide**

During the late breaking abstract session, Dr. Emese Zsiros from Roswell Park Comprehensive Cancer Center presented the findings of a phase II clinical trial of pembrolizumab in combination with bevacizumab and oral cyclophosphamide for recurrent platinum resistant ovarian cancer. In this heavily pre-treated group, the ORR was almost 40% with about 30% of the patients having durable responses of 12 months or more. This trial included Quality of Life (QoL) questionnaires to assess patient experiences beyond disease status.

NCT02853318 study details can be found on ClinicalTrials.gov.

- **Phase III Trabectedin and pegylated doxorubicin liposomal (PLD)**

During a plenary on clinical trials, Dr. Bradley Monk of Arizona Oncology presented results of the ET743-OVC-3006 trial, comparing trabectedin and PLD with PLD alone for recurrent platinum sensitive ovarian cancer. The study completed enrollment but was discontinued in early 2018, after an interim analysis showed the futility threshold for OS was exceeded and more toxicity was observed with the combination. Subgroup analysis revealed gBRCA mutation carriers saw an OS benefit of 34.2 months with the combination compared to 20.9 months with PLD alone, with longer benefit seen for patients with platinum-free intervals of 6 to 12 months. The efficacy of this combination after PARP inhibitor use is unclear since participants had not received prior treatment with PARP inhibitors.

Study results can be found on ClinicalTrials.gov at NCT01846611 results

IMMUNOTHERAPY

- **Phase II SOV02: Dendritic Cell Vaccine**

Dr. David Cibula of Charles University in Prague, Czech Republic presented final analysis of a Dendritic cell vaccine (DDCVAC) combined with second line of chemotherapy in recurrent platinum-sensitive ovarian cancer. PFS was increased by 1.2 months and OS was increased by 13.4 months. A phase III clinical trial will open later this year.

NCT02107950 study details can be found on ClinicalTrials.gov.

- **Phase II Pembrolizumab with cisplatin and gemcitabine (PemCiGem)**

Dr. Christine Walsh from Cedars-Sinai Medical Center provided interesting observations of an ongoing phase II study of pembrolizumab with cisplatin and gemcitabine in recurrent platinum resistant ovarian cancer in which palliative radiation is permitted to tumors causing symptoms. A few participants have had exceptional durable responses and the team is working to identify biomarkers of response. Dr. Walsh dedicated this work to a patient who inspired her to conduct this trial.

NCT02608684 study details can be found on ClinicalTrials.gov.

PARP INHIBITORS (PARPi)

- **Niraparib dosing based on baseline platelet count and body weight**

Dr. Ursula Matulonis from Dana-Farber Cancer Institute presented analysis from QUADRA data revealing that baseline platelet count and body weight predicts dose modifications. Most dose reductions for maintenance niraparib occurred in the first few months of treatment. Individualized dosing based on baseline body weight of less than 77 kilograms (about 170 pounds) or platelet count of less than 150,000/µL did not compromise efficacy. This individualized dosing approach will be utilized in the frontline phase III PRIMA study.

Dr. Bradley Monk of Arizona Oncology presented "A prospective evaluation of tolerability of niraparib dosing based upon baseline body weight and platelet count: Blinded pooled interim safety data from the ENGOT-OV26/PRIMA study." In this frontline maintenance study, each participant's niraparib dose was determined by baseline platelet count and body weight. The interim safety data show that the personalized starting dose improves tolerability.

- **PARPi after PARPi**

Dr. Kathleen Essel of the University of Oklahoma Health Sciences Center presented the results of a multi-institution retrospective review of ovarian cancer patients who received at least 2 lines of therapy that included PARP inhibition. Treatment with a second PARPi showed activity in this small study. More research and data are needed regarding optimal sequential treatment with PARP inhibitors as well as understanding and predicting resistance.

- **TWiST (Time WIthout Symptoms or Toxicity) Analysis**

Dr. Ursula Matulonis of Dana-Farber Cancer Institute presented: "Time without symptoms or toxicity in patients with recurrent ovarian cancer receiving niraparib maintenance treatment versus placebo: A TWIST analysis of the ENGOT24-OV16/NOVA trial." This retrospective study focused on grade 2 and above adverse events of nausea, vomiting, and fatigue. TWiST is the estimate of the difference between mean PFS and mean toxicity time (the number of days a patient experienced an adverse event prior to disease progression). Patients treated with niraparib in the ENGOT-OV16/NOVA trial experienced more TWiST compared with placebo.

For more information: https://www.cancernetwork.com/sgo/sgo-2019-twist-backs-benefits-parp-inhibitor-ovarian-cancer

RISK REDUCING STRATEGIES FOR MUTATION CARRIERS: Worry, Regret and Distress

One area being studied is whether hereditary mutation carriers who are at high risk for ovarian cancer and choose risk reducing surgery should (1) have one risk-reducing surgery to remove both the ovaries and fallopian tubes (risk reducing salpingo-oophorectomy or RRSO) or (2) first have a surgery to remove the fallopian tubes followed by a second surgery later to remove the ovaries (salpingectomy with delayed oophorectomy or SDO) to retain the benefits of natural estrogen. During the Late Break Abstract session, early results of two studies were presented.

- **TUBA Study**

Dr. Miranda Steenbeek of Radboud University Medical Center, Nijmegen, Netherlands presented "Worry and regret in the prospective multicentre TUBA study in BRCA1/2 mutation carriers." This study concluded that cancer worry declines after either option, with only low levels of decision regret. There was a higher level of regret after RRSO without hormone replacement therapy, which might be caused by more severe menopausal symptoms.

- **WISP Study**

Dr. Karen Lu of MD Anderson presented "WISP: A prospective, multi-center trial of salpingectomy with delayed oophorectomy (SDO) versus risk reducing salpingo-oophorectomy (RRSO) in women at increased risk for hereditary ovarian cancer." Women at high risk of ovarian cancer who undergo RRSO or SDO have a significant decrease in cancer distress. Women choosing RRSO have significant worsening of menopausal symptoms and higher decision regret, compared to women undergoing SDO. At present, none of the participants in the WISP have been diagnosed with ovarian cancer.

The WISP study is part of the Stand up to Cancer Ovarian Dream Team funded by ORCA.

Further information regarding these two studies can be found here: https://www.medscape.com/viewarticle/910898?src=soc_tw_190330_mscpedt_news_mdscp_ovarian&faf=1

RARE OVARIAN SUBTYPES

Here is a list of some of the scientific posters on rare ovarian cancer subtypes. Please note that these reflect early preliminary work or single-institution retrospective observational studies:

- Dr. Vasily Yakovlev, et al, VCU Massey Cancer Center, "ARID1A: A new synthetic lethality partner to PARP inhibitors in the treatment of ovarian cancer ***clear cell***."
- Dr. Paulina Cybulska, et al, Memorial Sloan Kettering Cancer Center, "Molecular profiling and classification of ***endometrioid*** ovarian carcinomas."
- Dr. Paulina Cybulska, et al, Memorial Sloan Kettering Cancer Center, "Clinical Outcomes of Patients with ***endometrioid*** ovarian cancer."
- Dr. Nathaniel Jones, et al, Precision Oncology Alliance, "Comprehensive molecular profiles of ***low grade serous*** ovarian cancer."
- Dr. Marrufa Rumman, et al, Wayne State Karmanos Cancer Institute, "ONC201 induces the unfolded protein response UUPR) in high- and ***low-grade ovarian*** carcinoma cell lines and leads to cell death regardless of platinum sensitivity."
- Dr. Nathaniel Jones, et al, Precision Oncology Alliance, "Comprehensive genomic profiling of ***mucinous*** ovarian carcinoma with comparisons to mucinous colorectal carcinoma."

ADVOCATES AND SURVIVORS AT SGO

Fallopian tube cancer survivor Terry Jannuzo provided the patient perspective during Medscape's Education Session Maintenance Therapy for Ovarian Cancer: Practical Considerations for Community Practice moderated by Dr. Ursula Matulonis. Terry's powerful presentation can be watched via SHARE Cancer Support's Facebook Video.

During her SGO Presidential Address, Dr. Carol Brown recognized ovarian cancer survivor advocate Mary Scroggins for her courage and intelligence during Gynecologic Oncology Group's

Patient Advocate Committee in 2005 and beyond to incorporate meaningful patient advocate participation with researchers. Mary Scroggins also provided the patient perspective on disparities in clinical trial participation during a plenary session on clinical trials.

Ovarian cancer survivor and Olympic gymnast Shannon Miller was the guest speaker at Cure Magazine's Ovarian Cancer Heroes event honoring committed individuals in the field of ovarian cancer, including Dr. Shannon Westin of MD Anderson.

Other awards: Awards for Distinguished Service for raising awareness of gynecologic cancers were presented to N.E.D. (No Evidence of Disease) the band, and Karen Carlson, Executive Director of Foundation for Women's Cancer (FWC) which hosts survivor education courses and provides informational material to survivors and caregivers.

ADDITIONAL SGO COVERAGE

OncLive: https://www.onclive.com/conference-coverage/sgo-2019

Medscape: https://www.medscape.com/viewcollection/34848

MDedge: https://www.mdedge.com/hematology-oncology/conferences/sgo-womens-cancer-meeting

Targeted Oncology: https://www.targetedonc.com/conference/sgo-2019

The Cancer Therapy Advisor:
https://www.cancertherapyadvisor.com/home/news/conference-coverage/society-of-gynecologic-oncology-sgo/sgo-2019/

ABSTRACTS and LATE BREAKING ABSTRACTS

https://www.sgo50.org/wp-content/uploads/2019/02/SGO-2019-Annual-Meeting-Abstracts.pdf

https://www.sgo50.org/wp-content/uploads/2019/03/SGO-2019-Late-Breaking-Abstracts.pdf