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Scientific Plenary VII: Sinking or Swimming in the Gene Pool
Wednesday, March 15, 2017
Moderators: Michael A. Bookman, MD*, US Oncology Research and Arizona Oncology, Tucson, AZ, USA*
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41 - Scientific Plenary
Interim analysis of a phase I/IIA trial assessing E39+GM-CSF, a folate binding protein vaccine, to prevent recurrence in ovarian and endometrial cancer patients
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Objective: Folate-binding protein (FBP) is an immunogenic protein overexpressed in endometrial (EC) and ovarian cancer (OC). We are conducting a phase I/IIa trial of E39 (GALE 301)+GM-CSF, an HLA-A2-restricted, FBP-derived peptide vaccine, to prevent recurrences in disease-free EC and OC patients. This interim analysis summarizes toxicity, immunologic responses, and clinical outcomes to date.

Method: HLA-A2+ patients were vaccinated (VG), and HLA-A2- or –A2+ patients were followed as controls (CG). Six monthly intradermal inoculations of E39 + 250 mcg GM-CSF were administered to VG. Demographic, safety, immunologic, and recurrence rate (RR) data were collected and evaluated.

Results: This trial enrolled 51 patients: 29 in the VG group and 22 in the CG group. Fifteen patients received 1,000 mcg E39 and 14 received <1,000 mcg. There were no clinicopathologic differences between groups (all $P \geq 0.1$). E39 was well-tolerated regardless of dose. DTH increased pre- to postvaccination (5.7 ± 1.5 mm vs 10.3 ± 3.0 mm, $P = 0.06$) in the VG group, and increased more in the 1,000-mcg group (3.8 ± 2.0 mm vs 9.5 ± 3.5 mm, $P = 0.03$). With 12 months median follow-up, the RR was 41% (VG) versus 55% (CG) ($P = 0.41$). Among the 1,000-mcg patients, the RR was 13.3% versus 55% CG ($P = 0.01$). Estimated 2-year DFS was 85.7% in the 1,000-mcg group versus 33.6% in the CG group ($P = 0.021$).

Conclusion: This phase I/IIa trial reveals that E39+GM-CSF is well-tolerated and elicits a strong, dose-dependent in vivo immune response. Early efficacy results are promising in the 1,000-mcg-dose cohort. This study proves the safety and establishes the dose of E39 for a larger prospective, randomized, controlled trial in HLA-A2+ EC and OC patients to prevent recurrence.

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42 - Scientific Plenary
A description of women with the pathogenic variants in the ovarian cancer risk genes *BRIP1, RAD51C, RAD51D* identified through clinical testing by a hereditary cancer panel
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Objective: The National Comprehensive Cancer Network (NCCN) recommends that risk-reducing salpingo-oophorectomy (RRSO) be considered for women with pathogenic variants (PVs) in *BRCA1* and *BRCA2* and the mismatch repair (MMR) genes (*MLH1*, *MSH2*, *MSH6*, *PMS2*). Recently, *BRIP1*, *RAD51C,* and *RAD51D* have been shown to confer increased risk for ovarian cancer and have been added to NCCN guidelines. However, the ovarian cancer risk for these genes is less well studied, and there are no specific age recommendations for RRSO. Here, we investigate the clinical presentation of women who carry a PV in *BRIP1*, *RAD51C*, or *RAD51D*.

Method: Women who were found to carry a PV in *BRIP1*, *RAD51C*, or *RAD51D* via testing with a 25-gene hereditary cancer panel between September 2013 and July 2016 were assessed. Clinical information was obtained from the provider-completed test request form. Personal and family history of ovarian cancer and age-at-diagnosis were evaluated according to gene. Women with PVs in *BRCA1*, *BRCA2*, or the MMR genes were assessed for comparison.

Results: Overall, 1,312 tested women had a PV in *BRIP1* ($n = 771$), *RAD51C* ($n = 375$), or *RAD51D* ($n = 166$). The incidence of ovarian cancer among women with a PV in *BRIP1* (16.3%) and *RAD51D* (18.7%) was similar to *BRCA1* (16.2%) and higher than *BRCA2* (11.4%) (Table 1). Women with a PV in *RAD51C* had the highest incidence of ovarian cancer (21.6%) of the genes

evaluated here. There was a similar incidence of ovarian cancer in ≥1 first or second degree relative among women with a PV in *BRIP1*, *RAD51C*, *RAD51D*, or *BRCA1* (34.9%–40.4%) (Table 1). Among women with ovarian cancer, the age at diagnosis for those with a PV in *BRIP1* (63.7 years), *RAD51C* (60.7 years), and *RAD51D* (56.6 years) was similar to women with a PV in *BRCA2* (59.3 years) (Table 1). This was slightly older than the average age-at-diagnosis of women with a PV in *BRCA1* (53.3 years) or in one of the MMR genes (45.2–51.3 years).

Conclusion: Here, we found that personal and family history of ovarian cancer among women with a PV in *BRIP1*, *RAD51C,* or *RAD51D* was similar to or higher than that observed for *BRCA1* and *BRCA2*. Fewer than half of women with a PV in *BRIP1*, *RAD51C,* or *RAD51D* had a personal or family history of ovarian cancer, and their average age of ovarian cancer diagnosis was similar to *BRCA2*. Collectively, this may aid clinical decisions regarding the medical management for women with PVs in these three genes.

Table 1. Personal and Family History and Age-at-Diagnosis.

Gene	PHx of Ovarian Cancer N (%)	Age at Ovarian Cancer Diagnosis* Mean (SD)	FHx of Ovarian Cancer** N (%)
BRIP1 (n=771)	126 (16.3)	63.7 (11.65)	287 (37.2)
RAD51C (n=375)	81 (21.6)	60.7 (10.57)	131 (34.9)
BRCA2 (n=3731)	425 (11.4)	59.33 (10.11)	1103 (29.6)
RAD51D (n=166)	31 (18.7)	56.6 (9.19)	67 (40.4)
BRCA1 (n=3458)	567 (16.4)	53.5 (9.73)	1206 (34.9)
MSH6	73 (n/a)	51.3 (10.77)	–
PMS2	51 (n/a)	50.8 (14.45)	–
MLH1	16 (n/a)	47.3 (10.20)	–
MSH2	45 (n/a)	45.2 (9.89)	–
No Mutation	13,683 (n/a)	57.1 (14.87)	–
*Individuals who were missing age data on the test request form are not included **Ovarian cancer was reported in one or more first or second degree relative			

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43 - Scientific Plenary

Overall survival in *BRCA1* or *RAD51C* methylated vs mutated ovarian carcinoma following primary treatment with platinum chemotherapy

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Objective: In ovarian carcinoma, mutations in genes in the homologous recombination DNA repair (HRR) pathway, including *BRCA1* and *RAD51C*, are associated with increased survival and specific clinicopathologic features. Promoter hypermethylation is an alternative mechanism of reducing gene expression. This study evaluated whether methylation of *BRCA1* and *RAD51C* is similar in terms of survival outcomes and clinicopathologic phenotypes.

Method: A series of 332 primary ovarian carcinomas were assessed for methylation of *BRCA1* and *RAD51C* using methylation-sensitive PCR and for damaging germline and somatic mutations in 16 genes associated with HRR: *ATM, ATR, BARD1, BLM, BRCA1, BRCA2, BRIP1, CDK12, CHEK2, MRE11A, NBN, PALB2, RAD51C, RAD51D, RBBP8, SLX4,* or *XRCC2*.

Results: *BRCA1* methylation was detected in 22 carcinomas (6.6%) and *RAD51C* methylation in 9 carcinomas (2.7%). Germline or somatic mutations in one or more HRR genes were found in 95 carcinomas (29%). Methylation of *BRCA1* and *RAD51C* was mutually exclusive with mutations in these genes ($P = 0.001$). Women with cancers with *BRCA1* methylation (57.7 years ± 2.5) or *BRCA1* mutations (mean 54.1 years ± 1.4) were younger than those without (63.3 years ± 0.8; $P = 0.029$, $P < 0.0001$). *BRCA1* methylation and germline *BRCA1* mutation were both associated with high-grade serous histology ($P = 0.045$, $P = 0.001$) and *TP53* mutations ($P = 0.012$, $P = 0.004$). *BRCA1* mutations were associated with increased sensitivity to platinum chemotherapy, while *BRCA1*methylation was not ($P = 0.034$, $P = 0.803$). Unlike HRR mutations, methylation was not associated with an improved overall survival compared to cases with neither methylation nor mutation. Median overall survival was 41 months in methylated, 43 months in neither mutated nor methylated, and 63 months in mutated cases.

Conclusion: Patients with *BRCA1* methylation share some clinical characteristics with patients with *BRCA1* mutations including younger age, predominantly high-grade serous histology, and frequent *TP53* mutations. However, unlike mutation, *RAD51C* and *BRCA1* methylation was not associated with improved survival or increased sensitivity to platinum

chemotherapy. Possibly, methylation is more readily reversed than mutation allowing more rapid development of platinum resistance and negating any impact on overall survival.

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44 - Scientific Plenary

Detection of tumor-derived DNA with combination Pap smear and plasma testing in women with primary ovarian cancer: A potential screening test on the horizon?

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Objective: Most women with ovarian cancer (OC) will be diagnosed with advanced-stage disease. Early detection of this lethal malignancy at earlier, more curable stages is desirable. A recent pilot study demonstrated that liquid-based Pap tests detect tumor-derived DNA mutations in approximiately 40% of OC patients. Subsequent studies have also examined cancer detection strategies using cell-free tumor DNA (CT-DNA) from patient plasma. Our study purpose was to determine whether the combination of liquid Pap and CT-DNA plasma testing increases the detection of tumor-derived DNA driver mutations in patients with OC.

Method: Patients undergoing surgery for primary OC as well as controls without OC were enrolled in this institutional review board-approved, prospective study. DNA from liquid-based Pap tests was purified, and 139 pairs were designed to amplify 110 to 142 bp segments containing regions of interest from the following 18 genes known to be driver mutations in OC: *AKT1*, *APC*, *BRAF*, *CDKN2A*, *CTNNB1*, *EGFR*, *FBXW7*, *FGFR2*, *KRAS*, *MAPK1*, *NRAS*, *PIK3CA*, *PIK3R1*, *POLE*, *PPP2R1A*, *PTEN*, *RN F43*, and *TP53*. In addition, DNA from plasma was purified and 61 primer pairs were designed to amplify 67 to 81 bp segments containing regions of interest from 16 genes: *AKT1, APC, BRAF, CDKN2A, CTNNB1, EGFR, FBXW7, FGFR2, GNAS, HRAS, KRAS, NRAS, PIK3CA, PPP2R1A, PTEN,* and *TP53*. A Pap or plasma test was considered "positive" if it harbored at least 1 driver mutation noted above.

Results: In total, 88 OC patients underwent both Pap and plasma testing at the time of primary surgery and were compared with 97 controls. Overall, 33% of OC patients had stage I-II, and the remainder had stage III-IV disease. The majority (80%) had high-grade serous carcinoma. The overall detection rate of a driver gene mutation was 76.1%. Specifically, 63.6% of those with stage I-II disease and 97.1% of those with stage III-IV disease had either a positive Pap and/or CT-DNA plasma test. Conversely, in the control population, the false positive rate was 1.5% (specificity 98.5%)

Conclusion: Combination liquid-based Pap and CT-DNA plasma testing detected a substantial number of tumor-derived driver DNA mutations (76.1%) with high specificity in patients with primary OC. In those with early-stage disease, approximately two-thirds of patients (63.6%) had tumoral DNA mutations detected by these techniques. A prospective validation trial is underway at our institution to define the utility of combination Pap and plasma testing in OC screening.

Scientific Plenary VIII: Personalizing Healthcare Decisions: Primum Non Nocere
Wednesday, March 15, 2017

Moderators: John V. Brown, MD*, Gynecologic Oncology Associates, Newport Beach, CA, USA*
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45A - Scientific Plenary

Defining priority symptoms in recurrent ovarian cancer: A comparison of four different criteria from a Gynecologic Oncology Group study (GOG 259)

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Objective: Systematic assessment of a core set of priority symptoms for women with cancer has been recommended by NCI and the National Academy of Sciences. How symptoms are classified as priority has not been well established. The purpose of this study is to (1) demonstrate how designation of "priority" differs based on the defined criteria, and (2) recommend a core set of priority symptoms to be assessed for all women with recurrent ovarian cancers.

Method: Baseline data from 497 women with recurrent ovarian, fallopian, or primary peritoneal cancer participating in GOG-0259 were used to identify a core index of patient-reported priority symptoms. We used the Symptom Representation

Questionnaire to assess priority rankings of 28 symptoms based on four criteria: (1) symptom prevalence, (2) symptom severity, (3) percentage of women identifying each symptom as 1 of top 3 symptoms "I would like to get better control over," and (4) the association between symptom severity and functional well-being as measured by the Functional Assessment of Cancer Therapy–Ovarian. Final priority ranking included all symptoms that were ranked in the top 10 for any of the 4 criteria.

Results: A set of 18 symptoms is proposed as the core symptoms that should be systematically assessed among women with recurrent ovarian cancer: fatigue, sleep disturbance, pain, anxiety, peripheral neuropathy, constipation, hair loss, memory problems, abdominal bloating, nausea, drowsiness, depression, lack of appetite, mood swings, weight gain, sexuality concerns, PPE, and lymphedema. Fatigue, sleep disturbance, and pain were ranked in the top 10 symptoms for all 4 criteria. Anxiety, peripheral neuropathy, constipation, and memory problems each appeared in 3 of the top 10 symptom rankings.

Conclusion: The set of 18 core patient-reported symptoms recommended for systematic assessment among patients with recurrent ovarian cancer are common, severe, poorly managed, and/or interfere with survivors' functioning and can be efficiently assessed in 1–2 minutes. Systematic assessment in clinical and research settings could advance understanding about the predictors and consequences of poorly managed symptoms and could lead to more proactive, personalized interventions to improve functional well-being in this at-risk patient population.

45B - Scientific Plenary

Effects of the WRITE Symptoms interventions on symptom and quality-of-life outcomes for women with recurrent ovarian cancer. GOG-259: An NRG Oncology/Gynecologic Oncology Group study

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Objective: GOG-259 was a 3-arm randomized controlled trial of 2 web-based symptom management interventions (WRITE Symptoms) for women with recurrent ovarian cancer. The primary aims of the study were to compare the efficacy of nurse-guided (ND) WRITE and self-directed (SD) WRITE to enhanced usual care (EUC) in improving symptoms and quality of life (QOL).

Method: Women with recurrent/persistent ovarian, fallopian, or primary peritoneal cancer with 3 or more symptoms were eligible. Women (n = 497) were randomized after completing baseline measures including symptom burden and controllability (SRQ) and QOL (FACT-O). WRITE interventions were 8 weeks in duration helping women to develop, implement, and refine symptom management plans for up to 3 target symptoms. All women received the EUC protocol: monthly online assessment of symptom representations, communication, and management with symptom severity reports sent to providers; online access to resources; and emails once every 2 weeks. Outcomes were evaluated at 8 and 12 weeks post baseline. Repeated measures modeling with linear contrasts was used to evaluate groups by time effects on symptoms and QOL controlling for key covariates.

Results: At baseline 84% of women were receiving chemotherapy, and 58.8% had received 3+ previous treatment regimens. Mean age was 59.3 + 9.2 years with 14.7 + 2.7 years of formal education. Women had a mean of 14.2 + 4.9 concurrent symptoms; fatigue, constipation, and peripheral neuropathy were most often selected for intervention. See Figures 1, 2, and 3 for changes over time in (unadjusted) outcomes by group assignment. Symptom burden and QOL improved significantly over time ($P < .001$) for patients in all 3 groups. There was a group–time interaction ($P < .001$) for symptom controllability: women receiving WRITE interventions improved from baseline to 8 and 12 weeks; EUC participants did not change. Personal and clinical predictors of improved outcomes will be presented.

Conclusion: Women in all 3 groups experienced statistically and clinically significant improvements in symptoms and QOL. Symptom controllability improved only for women receiving WRITE interventions. Unanticipated improvements in the EUC group raise the question of whether the EUC protocol served as a low-dose but effective symptom management intervention.

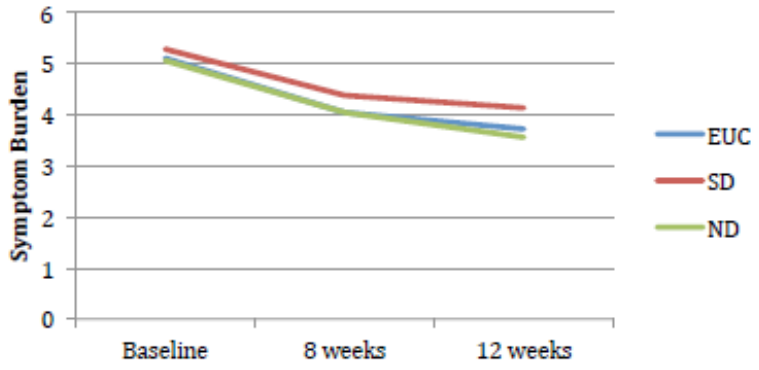

Fig. 1. Mean Symptom Burden Scores from Baseline to 12 Weeks by Group Assignment.

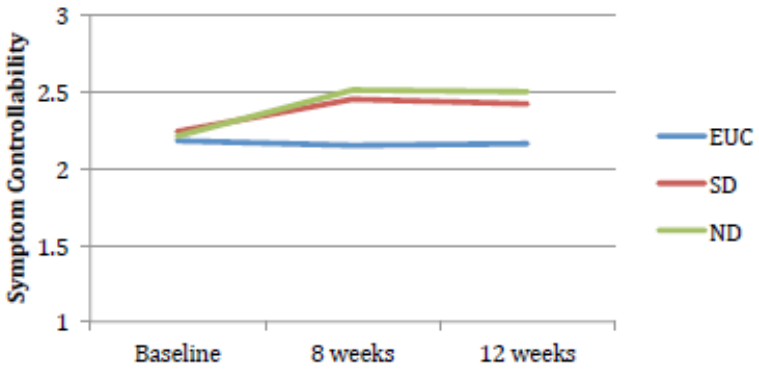

Fig. 2. Mean Symptom Controllability Scores from Baseline to 12 Weeks by Group Assignment.

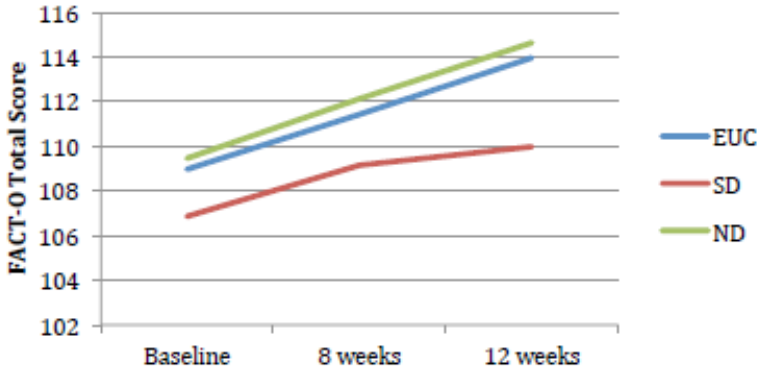

Fig. 3. Mean Quality of Life Scores (FACT-0 Total) from Baseline to 12 Weeks by Group Assignment.

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46 - Scientific Plenary

Early palliative care is associated with improved quality of end-of-life care for women with high risk gynecologic malignancies

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Objective: Early palliative care has been demonstrated to improve quality and duration of life in patients with metastatic non-small cell lung cancer. Historically, 49% of women received palliative care at our institution before dying from gynecologic malignancies. The primary objective of our study was to evaluate the feasiblity of increasing early access to palliative care by universal screening of women with high-risk malignancies and its association with aggressive care at the end of life (ACE).

Method: After institutional review board approval, all women with high-risk gynecologic malignancies (defined as 5-year prognosis <30%) were offered a palliative care consultation within 12 weeks of cancer diagnosis at a single institution. Patients who died were assigned an ACE score measured as 1 point for each of 8 aggressive measures at the end of life: (1) <3 days of hospice enrollment, (2) death in intensive care unit (ICU)/intubated, (3) chemotherapy within 14 days of death, (4) new chemotherapy, (5) >14 days hospitalized, (6) >1 hospital admission, (7) >1 emergency department admission, or (8) ICU admission, within 30 days of death. ACE scores were compared using Mann Whitney testing and SPSS software.

Results: Of 115 patients screened, 96 were eligible for study enrollment over a 12-month time period. Sicty-five women (68%) had a palliative medicine consultation as compared to an historical rate of 49% of women who died from gynecologic malignancies ($P = 0.014$). At the time of analysis 28 (29%) were deceased and 24 (25%) had enrolled in hospice. ACE scores were significantly higher, indicating more aggressive measures at the end of life, for women who did not participate in early palliative care (median 2.5, range 0-4, vs median 0, range 0–3, $P < 0.05$).

Conclusion: Early palliative care is feasible in an ethnically and racially diverse population of women with gynecologic malignancies. Universal screening rather than consultation-based referral was associated with increased access to palliative care. Palliative care at the time of cancer diagnosis was associated with decreased ACE scores at the time of death.

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47 - Scientific Plenary

Variations in patient preferences over side effects of treatments for ovarian cancer: Baseline results of a randomized controlled clinical trial

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Objective: Efforts to enhance shared decision making (SDM) are critical in improving cancer care. One important component of SDM regarding chemotherapy is patient preference regarding side effects. We set out to examine the variation in preferences over 4 side effects due to chemotherapy side effects as part of a clinical trial of a patient decision aid for SDM.

Method: As part of a randomized trial "Ovarian Cancer Patient-Centered Decision Aid" (PCOA, NCT02259699), newly diagnosed ovarian cancer patients facing a decision on the route of administration of adjuvant chemotherapy of either intravenous (IV) or intraperitoneal (IP)/IV were randomized to a computer-based decision aid (PCOA) versus standard-of-care discussion of IV versus IP/IV therapy. PCOA explained the major side effects likely to be experienced during chemotherapy: nausea and vomiting, neuropathy, fatigue, and abdominal pain. It also described 3 severity levels for each: mild, moderate, and severe. Patients ranked the 4 side effects and their 3 possible severity levels on a visual analog scale (VAS, 1-100, where 100 is least preferred). Quality of life (QOL) was assessed with FACT (Functional Assessment of Cancer Therapy)-O-TOI (general), FACT-fatigue, and FACT/GOG-AD (abdominal pain). "Optimism" was defined as a latent variable comprising all preferences for all side effects. PCOA and QOL surveys were administered to candidates for IV or IP/IV chemotherapy at the first visit after optimal cytoreduction.

Results: A total of 56 patients on PCOA had complete preference data. The average age was 58 years, and 93% were Caucasian. Over 80% were considered to be in good health. Mean TOI score was 66 (SD = 17), fatigue score 33 (SD = 9), and abdominal discomfort 11 (SD = 4). Mean preference ranking (as VAS) was 90 for severe quality nausea (SD = 14), 84 for pain (SD =13), 74 for neuropathy (SD = 22), and 65 for fatigue (SD = 25), indicating that patients were most concerned about nausea over other toxicities. In a multivariable analysis, "optimism" (lower preferences for all side effects) was significantly associated with higher QOL and was independent of insurance status or socioeconomic status.

Conclusions: Understanding patient preferences regarding toxicities is critical to enhancing shared decision making. The finding of a correlation between "optimism" and QOL deserves additional study.

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48 - Scientific Plenary

Observed toxicities in elderly gynecologic cancer patients treated on phase I clinical trials: The University of Oklahoma Health Sciences Center experience

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Objective: While it is documented that older patients are less able to tolerate primary therapy and less likely to be enrolled in primary treatment trials for gynecologic cancers, little is known about their ability to participate and tolerate treatment in clinical trials for recurrent or refractory disease. This study sought to examine baseline characteristics, treatment-related toxicities, and outcomes of older versus younger patients participating in phase 1 clinical trials.

Method: A retrospective analysis of patients enrolled in phase 1 clinical trials for gynecologic malignancies at a single center during 2010–2016 was performed. Demographic and clinicopathologic data were abstracted and analyzed. Older was defined as ≥70 years. Toxicities (hematologic and nonhematologic) were defined as either grade III or IV by Common Termminology Criteria for Adverse Events criteria. Best response was calculated using Response Evaluation Crteria in Solid Tumors criteria. Associations between categorical variables were determined using the Fisher exact test and continuous variables using the Wilcoxon rank sum test. Survival was estimated using the Kaplan-Meier method.

Result: A total of 267 patients were included with 20% (n = 41) composing the older cohort. No differences were observed in baseline demographics. The vast majority (98%) were treated for recurrent disease, with no difference between the groups in number of cycles or duration of treatment. Older patients incurred similar grade III-IV hematologic (22% vs 24%, P = 0.89) and nonhematologic toxicities (26% vs 28%, P = 0.82). Older patients discontinued treatment due to toxicity 9% of the time, compared to 18% in the patients <70 (P = 0.25). Survival was 465 versus 244 days (P = 0.46) in the <70 and ≥70 groups, respectively. Of older patients, 63% achieved clinical benefit with a response rate of 16%.

Conclusion: While historically older patients have not been routinely considered for enrollment in phase 1 trials, our data demonstrate similar toxicity profiles to those of younger patients and 63% clinical benefit rate. Thus, with careful selection, patients ≥70 years should be considered for enrollment in phase I trials when faced with recurrent or refractory gynecologic cancer.

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49 - Scientific Plenary

Endometrial cancer survivors' access to recommended self-care resources to target obesity in a high poverty urban community

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Objective: To examine endometrial cancer survivors' access to obesity-related self-care resources recommended by the Society of Gynecologic Oncology (SGO).

Method: Participants included women seen between 2010 and 2015 at an urban academic medical center for treatment of endometrial cancer and who lived in the surrounding 16 ZIP code areas on Chicago's South Side. Demographic and comorbidity data were abstracted from medical records. A socioeconomic status (SES) score (SES-1 = low, SES-5 = high) was generated for each patient using Census block group-level data. Self-care resources focused on exercise, healthy weight, and diet were obtained from a community resource database of the study area. Geospatial techniques assessed "walkable access" (~½-mile radius around a patient's home) to obesity-related recommended resources. Using multivariable logistic regression, we investigated associations between access to obesity-related self-care resources and patient sociodemographic characteristics and comorbid conditions.

Results: Of 195 endometrial cancer survivors included in the analysis, 81% identified as African-American and 34% lived in an SES-1 census block. Two thirds (68%) had stage I or II endometrial cancer; half (48%) were low grade. Sixty-two percent of survivors were obese (BMI ≥30 kg/m^2). Rates of obesity were inversely associated with SES (P = 0.05). Sixty-seven percent of survivors had access to at least 1 of all 3 recommended resources types; access was lower in low-SES regions. Lower SES score was a significant indicator of decreased odds of walkable access to at least 2 places for each of the three recommended obesity-related resource types for endometrial cancer survivors (aOR = 0.75, 95% CI 0.59–0.97). (See Fig. 1.)

Conclusion: Obesity rates were higher and access to recommended obesity-related self-care resources was lower for endometrial cancer survivors living in high-poverty areas. Gynecologic providers of survivorship care must understand patient resource walkable access to help women with a history of endometrial cancer fulfill SGO-recommended self-care guidelines targeting obesity.

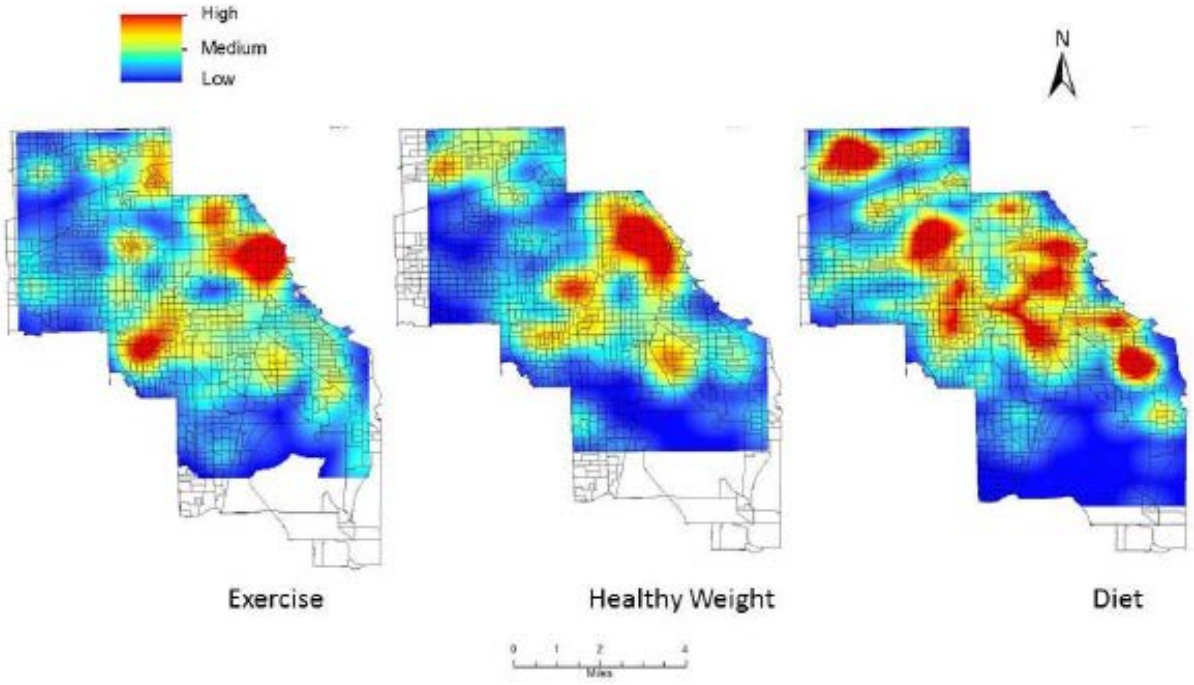

Fig. 1. Density of SGO-recommended self-care resource types to target obesity within the 16 ZIP code study area. The density of each obesity-related self-care resource recommended by SGO is shown in Figure 1. Exercise resources per square kilometer, healthy weight resources per square kilometer, and healthy diet resources per square kilometer are demonstrated in Figures 1. Square kilometer was chosen to measure the density and access because it equates to ~½-mile, the United States federal government definition of "walkable" distance in urban areas.

Scientific Plenary IX: Cutting to the Chase: Surgical Questions
Wednesday, March 15, 2017
Moderators: Leigh A. Cantrell, MD*, University of Virginia, Charlottesville, VA, USA*
Antonio Braga, PhD*, Dr. Antonio Braga, Rio de Janeiro, Rio De Janeiro, Brazil*

50 - Scientific Plenary
Oncological and obstetric outcome of abdominal radical trachelectomy: An updated series of 263 cervical cancer patients from a 12-year experience
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Objective: To update the oncological and obstetric outcome of our study on abdominal radical trachelectomy (ART) for young patients with cervical cancer.

Method: We conducted a retrospective review of a prospectively maintained database of patients undergoing ART for cervical cancer at our institution from April 2004 to June 2016.

Results: Three hundred and fourteen patients were planned for ART. Among 263 patients who succesfully underwent ART, 40 had stage IA1 disease, 23 had stage IA2, and 200 had stage IB1 (104 had tumor ≥2 cm). Histology included 39 (14.8%) with adenocarcinoma, 217 (82.5%) with squamous carcinoma, and 7 (2.7%) with adenosquamous carcinoma. With a median follow-up of 40 months (range 0–146), 9 patients recurred and 3 of them died. For patients with tumors ≥2 cm, 6 recurred and 3 died. The 5-year RFS and 5-year OS were 94.2% and 97.2%, respectively. Tumor size ≥2 cm and adenosquamous carcinoma were found to have a significant impact on RFS on univariate analysis. On multivariate analysis, however, only adenosquamous carcinoma retained independent predictive value. Among 103 patients (40%) who attempted to get pregnant, 17 (16.5%) succeeded (3 were pregnant twice). Among those 20 pregnancies, 1 had elective termination in the first trimester, 5 had first-trimester miscarriages, 1 had second-trimester miscarriage, 11 had third-trimester deliveries, and 2 were ongoing pregnant. About 60% of the patients did not try to conceive after ART: 89 (57.8%) had children prior to the surgery, 36 (23.4%) were single, 12 (7.8%) were worried about cancer and dare not to conceive, and 11% for other reasons. Overall, 57 (55.3%) who were trying to conceive had infertility problems. Infertility before surgery (13/57, 22.8%) and tubal (10/57, 17.5%) and

cervical factors (15.8%) were the most frequent known causes of infertility. Assisted reproductive technology was utilized more and more often, and 6 (30%) out of 20 patients succeeded.

Conclusion: Recurrent cases accumulated as the follow-up became longer. However, with a recurrence rate of 3.4% and 5-year OS of 97.2%, ART still seems to be a reasonable option for selected patients whose tumors are no larger than 4 cm. Adenosquamous carcinoma may have intrinsic risk for recurrence when compared with other pathological subtypes. The unsatisfactory obstetric outcome was largely attributed to the proportion of patients who did not attempt to conceive. Assisted reproduction technology was utilized to improve obstetric outcomes.

Table 1. Patients Characteristics and the Oncologic, Obstetric Results.

Characteristic	
Median Age , years	(18-44, median 32.1)
Histology	263
Squamous cell carcinoma	217 (82.5%)
Adenocarcinoma	39 (14.8%)
Adenosquamous	7 (2.7%)
FIGO Stage	263
IA1(with LVSI/positive margin)	40 (15.2%)
IA2	23 (8.7%)
IB1	200 (76%)
Tumor size<2cm	96(48%)
2cm ≤Tumor size≤4cm	104(52%)
Parity	263
None	174(66.2%)
One or more	89(33.8%)
Oncological Result	
Recurrent rate	9/263(3.4%)
5-year OS	260/263(98.8%)
Recurrent rate（Pts with T≥2cm)	6/104(5.7%)
5-year OS（Pts with T≥2cm）	101/104(97.1%)
Recurrent cases	9
Tumor size≥2cm	6(66.7%)
Tumor size<2cm	3(33.3%)
Squamous cell carcinoma	5 (55.6%)

Adenocarcinoma	2(22.2%)
Adenosquamous	2(22.2%)
Obstetric Outcome	
Attempt to conceive	103(40%)
succeed to conceive	17pts 20 preg
Not attempt	154 (60%)
already had kid(s)	89 (57.8%)
single	36(23.3%)
afraid of cancer	12(7.8%)
just finish treatment	11(7.1%)
other reasons	6(17%)

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51 - Scientific Plenary

GOC2: A multicenter prospective trial comparing open, laparoscopic and robotic surgical outcomes in women with endometrial cancer. Part B: Patient-reported outcomes

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Objective: GOC2 is a multicenter prospective cohort study comparing minimally invasive surgery (MIS, laparoscopy [LPS] and robotic) to open surgery in the primary treatment of women with endometrial cancer (EC). The objective was to evaluate perioperative, patient-reported, and cost-effectiveness outcomes between these groups. This abstract presents the PROs data including quality of life (QOL), pain, and sexual health.

Method: Between 2012 and 2014 women from 8 centers were enrolled. Overall QOL and pain were measured using the Functional Assessment of Cancer Therapy–Endometrial (FACT–EN) and Brief Pain Inventory (BPI) at baseline and 1 week, 3 weeks, and 3/6 months after surgery. Sexual health was measured using the Female Sexual Functioning Index (FSFI) and the Sexual Adjustment and Body Image Scale–Gynecology (SABIS–G) at baseline and 3/6 months after surgery. Primary analysis was between MIS and open surgery using t test or Wilcoxon test as appropriate.

Results: A total of 389 women were included in the analysis: 86 open and 303 MIS (137 LPS, 166 robotic). There was no difference in baseline scores of the FACT–EN or BPI between MIS versus open surgery or between LPS or robotic groups ($P > 0.5$). Women who had open surgery had significantly lower FACT–EN scores (worse QOL) and higher BPI (higher pain) scores compared to the MIS group at weeks 1 and 3 postsurgery ($P < 0.001$). At 3 and 6 months the BPI scores had reached baseline and were not different between groups ($P > 0.5$). The FACT–EN scores were lower in the open surgery group at 3 and 6 months ($P < 0.04$). Women undergoing open surgery had lower FSFI (worse sexual functioning) and SABIS-G (worse sexual distress) compared to the MIS group at baseline ($P < .02$). The FSFI scores increased in both surgical groups; however, it remained significantly lower in the open compared to the MIS group at 3 and 6 months ($P < 0.04$). The SABIS-G scores remained stable at 3 and 6 months for the MIS group; however, they were significantly greater than those for the open surgery group at 3 months ($P = 0.028$) and similar at 6 months ($P = 0.17$).

Conclusion: This study confirms the benefit of MIS (robotic or LPS) surgery for women with EC with improved QOL and pain in the first 3 weeks postoperatively. Even though QOL and pain are equivalent at baseline, sexual health status at baseline is worse for women who undergo open surgery compared to MIS and improves minimally within first 6 months.

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52 - Scientific Plenary

Contemporary recurrence and survival outcomes for stage IB squamous cell carcinoma of the vulva: Time to raise the bar

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Objective: There are little data regarding recurrence and survival outcomes for patients with stage IB squamous cell carcinoma (SCC) of the vulva. Our objective was to generate a contemporary database to better define the risk factors for recurrence and survival among patients with stage IB disease.

Method: A Vulvar Cancer Research Network was formed by 5 U.S. cancer centers to meet this and other study objectives. Clinicopathologic data from vulvar cancer patients diagnosed between 1995 and 2015 were entered into an institutional review board-approved REDCap database. Patients with stage IB SCC were abstracted, and risk factors for recurrence and survival were examined using the Fisher exact test and linear regression.

Results: Of 922 SCC cases, 285 (31%) were stage IB and 244 had recurrence data. The median patientt age was 57 and median tumor size was 2.5 cm. Nineteen percent were immune-compromised. Radical vulvectomy and nodal assessment were performed in 70%; 12% received adjuvant radiation (RT). After a median follow-up of 1.4 years, there were 59 recurrences (24%); 27 deaths occurred in this cohort, 89% due to disease. Excluding patients who received adjuvant RT (n = 4) and with unknown recurrence location (n = 7), 85% who relapsed had an isolated local recurrence. Relapses were managed variably, and currently only 26% of patients are disease free (Table 1). Recurrence risk did not vary according to treatment, but was significantly associated with primary tumor depth of invasion ≥6 mm (P = 0.034), and increased linearly with age (OR = 1.03, P = 0.002) and tumor size (OR = 1.19, P = 0.03). For each 1-year gain in age and 1-mm increment in tumor size, recurrence risk increased 3% and 19%, respectively. Of patients with lymph-vascular or perineural invasion, 43% recurred compared to 15% without these tumor factors (P = 0.056). Those with recurrence were more likely to have unreported margin status (63% vs 27%, P < 0.001). Three-year recurrence-free and disease-specific survival were 75.8 and 91.8%, respectively.

Conclusion: Nearly a quarter of patients with stage IB vulvar SCC will recur. While 85% are local relapses, salvage rates are poor. Determining which combinations of clinical and tumor-related factors have an impact on recurrence will aid in refining adjuvant therapy recommendations. Achieving this goal and improving cure rates is incumbent on standardizing pathology reporting for vulvar cancer.

Table 1. Salvage rates according to location of recurrence and treatment modality.

	Local (n = 39)	Groin Node (n = 4)	Distant (n = 3)
Surgery	12/23		
Surgery + RT	0/2	0/1	
Surgery + cRT	2/4	1/2	
RT	0/1		
cRT	0/3	0/1	0/2
Chemotherapy			0/1
Supportive care	0/5		
Unknown	0/1		

Table entries: # Disease free/# treated
RT = radiation; cRT = chemo-radiation
Known status at last follow-up, n = 57
Unknown location of recurrence, n = 7 (1 alive with disease, 3 dead of disease, 2 dead of other cause)

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53 - Scientific Plenary

A phase II, single-dose, open-label study to investigate the safety and efficacy of OTL38 injection for intraoperative imaging of folate receptor-alpha positive ovarian cancer

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Objective: OTL38 is a folate ligand conjugated with an indole-cyanine green dye. The objectives of this trial were to assess the efficacy and safety of OTL38 in detecting folate receptor-alpha (FRα+) ovarian cancer during surgery.

Method: Patients with suspected ovarian cancer planned for primary, interval, or secondary cytoreductive surgery were eligible to receive a single dose of OTL38 (0.025 mg/kg) 2 hours preoperatively. Intraoperative near-infrared (NIR) imaging was used to visualize target lesions for resection. Lesions were designated by the investigator as visible by normal light and/or by NIR imaging. Malignant cells were confirmed by histology and FRα immunohistochemistry (IHC) by a blinded pathologist. A modified intent to treat (mITT) population of lesions from all patients who received OTL38-NIR imaging, underwent surgery, and had at least 1 FRα+ target lesion was used to determine sensitivity and PPV. Two generalized linear models (GLM) were employed to evaluate sensitivity and PPV.

Results: A total of 48 patients were enrolled. A total of 225 lesions from 29 patients in the mITT population were evaluated. Only those lesions that were concordantly both positive or negative by pathology and FRα IHC were included in the primary analysis. The outcome for all lesions in the mITT population is presented in Table 1. The results of a GLM analysis accounting for the possible correlation of lesions within patients (includes a random effect for patients) yielded an estimate for sensitivity of 97.97%, with a 95% lower 1-sided CI = 87.75. The estimate for PPV was 94.93% with a 95% lower 1-sided CI = 86.13. GLM analysis assuming no correlation of lesions within patients (excludes a random effect for patients) resulted in an estimated sensitivity of 85.93%, with a 95% lower 1-sided CI = 81.19. The estimate for PPV was 88.14% with a 95% lower 1-sided CI = 83.59. A total of 48.3% (14/29, 95% CI 0.29–0.67) of patients had at least 1 additional pathology-confirmed lesion detected by OTL38 that was not identified by normal light or palpation. Eight patients (18.2%) had grade 1-2 study drug-related adverse events including infusion reaction, nausea, vomiting, abdominal pain, sneezing, increased lacrimation.

Conclusions: OTL38-NIR was a safe and efficacious intraoperative imaging tool in this preliminary phase 2 study and merits further evaluation in an upcoming phase 3 trial.

Table 1.

	OTL38 mITT Population (N=29)		
	Number of Lesions	**Estimate (lower one-sided 95% CI) [a] (with patient as random effect)**	**Estimate (lower one-sided 95% CI) [b] (without patient as a random effect)**
TP	171		
FP	23		
FN	28		
TN	3		
Sensitivity [3]		97.97 (87.75)	85.93 (81.19)
PPV [4]		94.93 (86.13)	88.14 (83.59)

Note: Includes lesions with positive result for both ovarian cancer and FRα+ or negative for both tests.
TP: Lesions that fluoresced and tested positive for FRα and ovarian cancer.
FP: Lesions that fluoresced but did not test positive for both FRα and ovarian cancer.
FN: Lesions that did not fluoresce but tested positive for both FRα and ovarian cancer.
TN: Lesions that did not fluoresce and did not test positive for both FRα and ovarian cancer.
[a] Estimated using Proc Glimmix in SAS® for binomial distribution with patient as a random effect
[b]Estimated using Proc Glimmix in SAS® for binomial distribution
[c] Sensitivity of OTL38 for the detection of FRα+ ovarian cancer lesions
[d] Positive Predictive Value (PPV) of OTL38 for the detection of FRα+ ovarian cancer lesions