respectively). One bacterial family was also prominent—Lachnospiraceae ($p=0.024$).

Conclusions In this innovative study, we demonstrated a significant difference in vaginal microbiome of ovarian cancer patients compared to healthy controls. Interestingly, these bacterial species that were prominent in ovarian cancer patients where previously linked to other malignancies such as lung and colon cancer. As described in previous studies, lactic acid producing bacteria were associated with a healthy microbiome. A possible mechanism that can be suggested here is lactic acid consumption by these bacteria. Expanding research in this field may lead to early diagnosis, disease prevention, and targeted therapy in patients with EOC.

Objectives Progression-free survival (PFS) is a rational surrogate primary endpoint in ovarian cancer (OC) trials. However, PFS is subject to biases, with validity dependent upon proper methodologic assessment. Therefore, blinded independent centralized radiologic review (BICR) is often recommended. We evaluated BICR and investigator-assessed evaluation of progressive disease (PD) in the PRIMA/ENGOT-ov26/GOG-3012 trial examining niraparib monotherapy in intent-to-treat (ITT) and homologous recombination deficient (HRd) populations.

Methods In the randomized, double-blind, placebo-controlled phase 3 PRIMA/ENGOT-ov26/GOG-3012 trial, patients with newly diagnosed stage III/IV OC were assigned to receive either niraparib or placebo. The primary endpoint was PFS (per RECIST v.1.1) by BICR. Discordance between BICR and investigator assessments of PD ([#BICR reviews with unconfirmed PD assessment]/[total # investigator-triggered reviews]) was monitored throughout the study. A training intervention was developed for BICR reviewers based on PD determination in OC.

Abstract EP224/#531

**OPTIMIZATION OF ASSESSMENT OF DISEASE PROGRESSION BETWEEN BLINDED CENTRAL INDEPENDENT REVIEW AND INVESTIGATOR ASSESSMENT IN THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL**

1Thomas Herzog*, 2Shaun A Wahab, 3Mansoor Mirza, 4Bhavana Pothuri, 5I Ignace Vergote, 6Whitney S Graybill, 7Izabela A Malinowska, 8Whitney York, 9Jean A Hurteau, 10Divya Gupta, 11Antonio Gonzalez-Martin, 12Bradley Monk. University of Cincinnati Cancer Center, Medical Oncology, Cincinnati, USA; 2University of Cincinnati Medical Center, Department of Radiology, Cincinnati, USA; 3Nordic Society of Gynaecological Oncology Clinical Trial Unit (NSGO-CTU) and Rigshospitalet-Copenhagen University Hospital, Department of Oncology, København, Denmark; 4Gynecologic Oncology Group (GOG), NYU Langone Health, Department of Obstetrics/gynecology, New York City, USA; 5Leuven Cancer Institute, University Hospitals Leuven, Department of Obstetrics and Gynaecology and Gynecologic Oncology, Leuven, Belgium; 6GOG, Medical University of South Carolina, Obstetrics & Gynecology, Charleston, USA; 7GlaxoSmithKline, Clinical Science, Waltham, USA; 8GlaxoSmithKline, Oncology Statistics, Upper Providence, USA; 9GlaxoSmithKline, Women’s Oncology Program, Waltham, USA; 10GlaxoSmithKline, Clinical Development, Waltham, USA; 11Grupo Español de Investigación en Cáncer de Ovario (GEICO), Program in Solid Tumors, Center for Applied Medical Research (CIMA), Pamplona, and Clínica Universidad de Navarra, Medical Oncology, Madrid, Spain; 12HonorHealth Research Institute, University of Arizona College of Medicine/Creighton University School of Medicine, Division of Gynecologic Oncology, Phoenix, USA

10.1136/ijgc-2022-igcs.315

Objectives Progression-free survival (PFS) is a rational surrogate primary endpoint in ovarian cancer (OC) trials. However, PFS is subject to biases, with validity dependent upon proper methodologic assessment. Therefore, blinded independent centralized radiologic review (BICR) is often recommended. We evaluated BICR and investigator-assessed evaluation of progressive disease (PD) in the PRIMA/ENGOT-ov26/GOG-3012 trial examining niraparib monotherapy in intent-to-treat (ITT) and homologous recombination deficient (HRd) populations.

Methods In the randomized, double-blind, placebo-controlled phase 3 PRIMA/ENGOT-ov26/GOG-3012 trial, patients with newly diagnosed stage III/IV OC were assigned to receive either niraparib or placebo. The primary endpoint was PFS (per RECIST v.1.1) by BICR. Discordance between BICR and investigator assessments of PD ([#BICR reviews with unconfirmed PD assessment]/[total # investigator-triggered reviews]) was monitored throughout the study. A training intervention was developed for BICR reviewers based on PD determination in OC.

Abstract EP224/#531 Table 1

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>BICR</th>
<th>Hrd population</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT population</td>
<td>Niraparib (n=487)</td>
<td>Placebo (n=246)</td>
</tr>
<tr>
<td>BICR</td>
<td>13.8 (11.5, 14.9)</td>
<td>8.7 (7.5, 9.3)</td>
</tr>
<tr>
<td>Investigator*</td>
<td>13.8 (11.3, 14.2)</td>
<td>8.2 (7.0, 9.6)</td>
</tr>
</tbody>
</table>

*Investigator includes both clinical and radiologic assessments

Abstracts
Results In an initial patient subset (n=80), a 39% discordance rate was identified between BICR and investigator-assessed PD by the sponsor, most commonly due to peritoneal carcinomatosis or fluid collections arising from new non-target lesions. After reviewer intervention, final discordance rate between BICR and investigator improved to 12% and 13% for ITT (N=733) and HRd (n=373) populations, respectively (figure 1). Across the entire study population, median PFS and hazard ratios for the ITT and HRd populations were comparable between BICR and investigator (table 1).

Conclusions PRIMA/ENGOT-ov26/GOG-3012 highlights the need to optimize BICR and investigator concordance using early, specialized OC-specific training to maximize trial validity.

Funding: GlaxoSmithKline (GSK) study. Editorial support provided by Fishawack Health, funded by GSK.

EP225/#402 FACTORS CONTRIBUTING TO SURGEON’S DECISION FOR DIVERTING ILEOSTOMY AT THE TIME OF CYTOREDUCTIVE SURGERY IN PATIENTS WITH ADVANCED OVARIAN CANCER

Objectives Anastomotic leak (AL) occurs in 1.2–9% following cytoreductive surgery with large bowel resection (LBR) for advanced ovarian cancer (AOC). Diverting ileostomy (DI) can mitigate the consequences of AL, however, is associated with compromised quality-of-life. Objectives: 1. Assess factors contributing to surgeon’s decision to perform DI in AOC cytoreduction with LBR. 2. To study complications rates and survival outcomes.

Methods Retrospective cohort study, AOC patients, undergoing cytoreductive surgery with LBR and re-anastomosis between 01-Jan-2010–01-July-2020. Multivariable analysis was performed on factors contributing to DI on univariate analysis.

Results 140 patients met inclusion criteria; 57 patients (41%) had DI. Median follow-up was 32.1 months (0.3–59.74), median age 52 (26–86) Longer operative time (600 vs. 390 minutes), multiple bowel resections (>1 vs 1), pre-operative paracentesis, intra-operative ascites, positive air-leak-test were found to contribute to surgeons’ decision for DI on univariate analysis. Multivariable analysis confirmed longer operative time (OR=1.71, p<0.0001), paracentesis (OR=3.47, p=0.05) and more than 1 bowel resection (OR=4.40, p=0.01) to be significant for this decision. AL rate was 3.65% (n=5). Patients with DI had higher rates of dehydration (41.5% vs 8.4%), acute kidney injury (17% vs 1.2%) and post-operative fever (26.4% vs 12%). Progression-free-survival (PFS) was similar (23.9 vs 21.3, no vs yes DI, p=0.61).

Conclusions Paracentesis, >1 bowel resection and longer operative time contributed to surgeon’s decision to perform DI. Patients with DI had similar PFS to the non-DI group but experienced more post-operative complications. Developing prospective model to predict risk of AL may enable safe reduction in DI rates while maintaining acceptable AL rates.