OP001 / #520

Topic: *AS06. Tumor Types / AS06b. Endometrial & Uterine Corpus Cancers*

SURGICAL MORBIDITY AFTER SENTINEL LYMPH NODE MAPPING VERSUS SENTINEL LYMPH NODE MAPPING WITH SYSTEMATIC LYMPHADENECTOMY IN ENDOMETRIAL CANCER: SECONDARY ENDPOINT RESULTS OF THE ALICE TRIAL (NCT03366051)

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Introduction: The ALICE trial is a multicenter, open-label, non-inferiority randomized trial comparing sentinel lymph node(SLN) mapping alone versus SLN mapping with systematic pelvic and para-aortic lymphadenectomy in high-intermediate and high-risk endometrial cancer. Here we report the prespecified secondary outcomes of surgical morbidity.

Methods: One hundred eighty patients were randomized 1:1 to SLN only (n=89) or SLN and lymphadenectomy (n=91). Groups were balanced for age, BMI, histologic type, myometrial invasion, and surgical approach. Early complications were graded by the Clavien–Dindo classification. Lymphedema was assessed by clinical examination and by lower-limb volume measurement at 12 months minus preoperative baseline.

Results: Surgery time (180 vs 360 min), estimated blood loss (50 vs 100 mL), hospital stay (1 vs 2 days), and ICU admission (5.6% vs 28.6%) were all significantly higher in the lymphadenectomy arm (all $p<0.001$). Postoperative complications within 30 days were significantly more frequent with lymphadenectomy (30.8% vs 9.0%;$p<0.001$), including grade ≥3 events (8.8% vs 1.1%;$p=0.001$). Lymphocele occurred exclusively in the lymphadenectomy arm (11.0% vs 0%;$p=0.002$). Clinically detected lymphedema was more prevalent after lymphadenectomy (20.9% vs 5.6%; $p=0.003$). Lymphedema by volumetric measurement at 12 months was not different between groups ($p=0.261$). On multivariate logistic regression, lymphadenectomy (OR 4.65, 95% CI 1.95–11.0) and open surgical approach (OR 3.53, 95%CI:1.15–10.8) were independent predictors of surgical complications.

Conclusion/Implications: SLN mapping alone is associated with significantly less surgical morbidity than SLN and systematic lymphadenectomy, including fewer postoperative

complications, shorter hospital stay, and lower rates of lymphocele and clinical lymphedema. Lymphadenectomy and open approach were the only independent predictors of complications.

OP002 / #74

Topic: *AS02. Clinical Disciplines / AS02e. Surgical Techniques & Perioperative Management*

NEOADJUVANT CHEMOTHERAPY AND INDIVIDUALIZED DE-ESCALATION SURGERY FOR FERTILITY PRESERVATION IN STAGE IB1-IIA2 CERVICAL CANCER: A MULTICENTER PROSPECTIVE STUDY（FIND STUDY）

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Introduction: This prospective study (NCT02624531) evaluated an individualized, neoadjuvant chemotherapy (NACT)-based fertility-sparing strategy for patients with FIGO 2018 stage IB1-IIA2 cervical cancer aiming to explore the possibility of expanding the population eligible for fertility-sparing treatment and de-escalating surgery.

Methods: Patients with baseline tumors <1 cm proceeded directly to simple trachelectomy (ST). Those with tumors ≥1 cm received 2–3 cycles of platinum-based NACT, followed by tailored surgery based on post-NACT MRI: cervical conization (CON) for complete response, ST for residual disease ≤2 cm, or radical trachelectomy (RT) for residual disease 2–4 cm.

Results: Between 2015 and 2023, 99 patients were enrolled. Of these, 84 received NACT, and 80 ultimately underwent fertility-sparing surgery (FSS). After a median follow-up of 67 months, 5-year progression-free survival (PFS) and overall survival (OS) were 88.9% and 93.9% for the entire cohort, and 91.3% and 96.3% for the 80 patients who received FSS. Lymphovascular space invasion (LVSI) was significantly associated with poorer outcomes. For patients with initial tumors ≤2 cm, 2–4 cm, and ≥4 cm, 5-year PFS rates were 95.2%, 86.2%, and 88.9%, respectively, with corresponding OS rates of 97.6%, 93.1%, and 100%. Regarding reproductive outcomes, 19 of 40 patients attempting conception (47.5%) achieved at least one pregnancy, resulting in 17 live births (3 after CON, 14 after ST). No successful pregnancies occurred after RT.

Conclusion/Implications: The prospective study demonstrates that that fertility-sparing strategy involving NACT and individual less radical FSS provides favorable long-term oncologic safety and meaningful reproductive potential in patients with FIGO 2018 IB1-IIA2 cervical cance.

OP003 / #836

Topic: *AS06. Tumor Types / AS06a. Cervical Cancer*

OMITTING PELVIC LYMPHADENECTOMY IN SENTINEL NODE-POSITIVE CERVICAL CANCER: RESULTS OF THE PHENIX-II TRIAL

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Introduction: The PHENIX-I trial demonstrated that pelvic lymphadenectomy can be safely omitted in patients with negative sentinel lymph nodes on frozen section. However, it remains unclear whether completion lymphadenectomy benefits those with positive sentinel lymph nodes and whether intraoperative frozen section is necessary for treatment triage.

Methods: This multicenter non-inferiority randomized trial (PHENIX-II) enrolled patients with FIGO 2009 stage IA1–IIA1 cervical cancer and intraoperative frozen-section-confirmed sentinel lymph node metastases. Patients were randomly assigned 1:1 to sentinel lymph node biopsy alone (n=35) or completion lymphadenectomy (n=35). Radical hysterectomy and adjuvant radiotherapy were performed for all patients. The primary endpoint was 3-year disease-free survival.

Results: After a median follow-up of 68.6 months, the 3-year disease-free survival was 88.4% in the biopsy alone group versus 74.3% in the lymphadenectomy group (hazard ratio 0.60; 95% confidence interval 0.21–1.68; P=0.32); 3-year cancer-specific survival was 97.1% versus 74.3% (hazard ratio 0.20; 95% confidence interval 0.04–0.91; P=0.02). Recurrences occurred in 6 and 9 patients, with nodal recurrence in 2 and 3 patients, respectively. Lymphadenectomy-related complication rates appeared higher in the lymphadenectomy group: lymphedema (8.6% vs 31.4%), lymphocyst (8.6% vs 28.6%), paresthesia (2.9% vs 14.3%), and venous thrombosis (0% vs 8.6%).

Conclusion/Implications: Completion lymphadenectomy does not benefit sentinel lymph node-positive patients in terms of survival while increasing surgical complications. Given the consistent lack of lymphadenectomy benefit regardless of nodal status (PHENIX-I and II), routine intraoperative frozen section may be unnecessary, and lymphadenectomy can be safely omitted as long as sentinel lymph node mapping is successful.

OP004 / #610

Topic: *AS06. Tumor Types / AS06b. Endometrial & Uterine Corpus Cancers*

SIX-YEAR SURVIVAL OUTCOMES WITH DOSTARLIMAB MONOTHERAPY IN PATIENTS WITH MISMATCH REPAIR DEFICIENT/MICROSATELLITE INSTABILITY-HIGH ENDOMETRIAL CANCER IN THE GARNET TRIAL

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Introduction: GARNET (NCT02715284) is the largest trial of an anti–PD-1 monotherapy, dostarlimab, in patients with dMMR/MSI-H advanced/recurrent endometrial cancer (A/R EC) after platinum-based chemotherapy and supported global approvals. Previously published results provided robust evidence of clinical benefit and demonstrated durable antitumor activity with an acceptable safety profile. Here, we report updated efficacy and safety at 6y follow-up accompanied by conditional survival analyses.

Methods: GARNET is a multicenter, open-label, single-arm study of dostarlimab monotherapy. Patients received dostarlimab for up to 2y or beyond 2y with investigator and sponsor agreement. Primary endpoints are ORR and DOR by BICR. As final OS is pending, interim efficacy and post hoc conditional OS analyses were conducted for cohort A1 (dMMR/MSI-H A/R EC; median follow-up 69 mo).

Results: Dostarlimab monotherapy demonstrated sustained benefit at this analysis. ORR was 45.5% with a disease control rate of 60.1% (Table). Since the previous data cut (01Nov2021), a deepening of response was observed as 9 patients (21.4%) with previous PR achieved CR (previously 23 CR and 42 PR of 65 responders). At 6y, neither median DOR nor OS were reached. No new safety signals were observed. Conditional OS analyses estimated ≥86.0% of patients alive at 2y and 3y were estimated to remain alive at 6y.

Conclusion/Implications: At 6y of follow-up in GARNET, the high rate of durable remission was confirmed with median DOR and OS not reached. The substantial long-term benefit observed supports dostarlimab monotherapy as a meaningful option in patients with dMMR/MSI-H A/R EC with disease progression following prior platinum therapy.

	Cohort A1 N=143[a]
ORR, n (%; 95% CI)	65 (45.5, 37.1–54.0)
Disease control rate, n (%; 95% CI)	86 (60.1, 51.6–68.2)
Complete response, n (%)	32 (22.4)
Partial response, n (%)	33 (23.1)
Stable disease, n (%)	21 (14.7)
Median DOR (range), mo	NR (1.2–85.6+)
6y DOR rate % (95% CI)	73.1 (56.1–84.4)
Median OS (95% CI), mo[b]	NR (23.8 to NR)
6y OS rate % (95% CI)[b]	50.1 (41.3–58.2)
Conditional OS probability, % (95% CI)[b]	
1y landmark (n=101)	
Additional 5y	68.9 (58.4–77.2)
2y landmark (n=80)	
Additional 4y	86.0 (75.2–92.4)
3y landmark (n=75)	
Additional 3y	88.3 (77.5–94.1)
[a]Efficacy population; patients with measurable disease at baseline [b]Safety population (N=153); pts who received ≥1 dostarlimab dose +, ongoing; NR, not reached	

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OP005 / #1090

Topic: *AS06. Tumor Types / AS06c. Ovarian Cancer*

A PHASE II EVALUATION OF SACITUZUMAB GOVITECAN IN PLATINUM-RESISTANT OVARIAN CANCER (NCT06028932)

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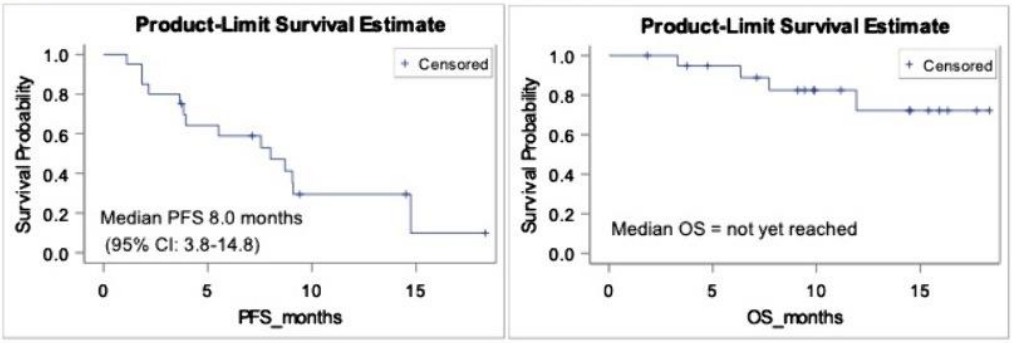
Introduction: Patients with platinum-resistant ovarian cancer (PROC) have few therapeutic options. More than 60% of high-grade serous ovarian cancers overexpress Trop2, a key regulator of growth pathways and marker of aggressive disease. Sacituzumab govitecan (SG) is an antibody-drug conjugate consisting of a Trop-2–specific antibody conjugated with SN-38, an active metabolite of irinotecan.

Methods: NCT06028932 is a single-institution open-label phase II study. Patients received SG at 10 mg/kg intravenously days 1,8 of a 21-day cycle until prohibitive toxicity or progression. The primary endpoint was objective response rate (ORR) by RECIST 1.1. Secondary endpoints included progression-free (PFS) and overall (OS) survival, as well as safety. Trop-2 H-score was examined in relationship to endpoints.

Results: Twenty patients enrolled. Median age was 67 years (range: 45-84). Most participants (85%, n=17) were White. The median number of prior lines prior to enrollment was 3 (range: 1-8). Most patients had a poorly differentiated tumor (90%, n=18) with stage III/IV disease at initial diagnosis (85%, n=17). Across a median follow-up of 9.9 months, there were 15 progressions and 4 deaths. ORR was 35% (7/20); there were no complete responses, and stable disease was achieved in 40% (8/20). Median PFS was 8.0 months (95% CI:3.8-14.8); median OS was not yet reached (**Figure 1**). No new safety signals were observed. The most common grade 3-4 treatment-emergent adverse events were neutropenia (n=15), hypokalemia (n=3), and anemia

(n=2).

Figure 1. Progression-free (left) and overall (right) survival



Conclusion/Implications: SG exhibits encouraging efficacy for PROC with manageable toxicities. Future studies are warranted, including confirmation of predictive biomarkers.

OP006 / #891

Topic: *AS01. Basic & Translational Science / AS01b. Translational Findings*

BIOMARKER CONCURRENCE IN HIGH-GRADE SEROUS OVARIAN CANCER: IMPLICATIONS FOR THERAPEUTIC DECISION-MAKING

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Introduction: High-grade serous ovarian cancer (HGSOC) treatment is increasingly dependent on tumor biomarkers, yet limited data exist on the frequency and concurrence of actionable markers.

Methods: HGSOC samples with whole-exome and whole-transcriptome next generation sequencing, immunohistochemistry (IHC), and homologous recombination deficiency (HRD) data were selected from Caris databases. Biomarker-positive ($^+$) tumors were defined as FOLR1^{hi} (folate receptor alpha IHC: ≥2+ intensity in ≥75% tumor cells), HER2$^{2+/3+}$ (HER2 IHC: 2+ or 3+ in ≥10% tumor cells), or HRD$^+$ (*BRCA1/2*mut or genomic scar score ≥ 46); sub-threshold scores were biomarker-negative ($^-$). mRNA expression of novel targets included: *CCNE1*, *TACSTD2* (TROP2), *CLDN6*, *CDH6*, *ERBB3* (HER3), *VTCN1* (B7H4), and *F3* (Tissue Factor).

Results: Among 4,074 tumors, FOLR1^{hi}, HER2$^{2+/3+}$, and HRD$^+$ occurred in 42.4%, 14.1%, and 27.5% (Fig 1A). Age and race were associated with HRD$^+$ and HER2$^{2+/3+}$ ($p<0.01$), but not FOLR1^{hi}. IHC H-scores (staining intensity * % cells) and mRNA were positively correlated for FOLR1 (Rho=0.73) and HER2 (Rho=0.55; all $p<0.0001$). While 35.2% of tumors were FOLR1^{low}, HER2$^{\leq 1+}$, and HRD$^-$, 26-39% of biomarker$^-$ tumors had top-tertile mRNA expression of one or more novel targets. mRNA expression of *VTCN1* was enriched in biomarker$^+$ vs biomarker$^-$ subsets (all $p<0.01$; Fig 1B). *NECTIN4*, *ERBB3*, *CCNE1*, and *BRCA1/2* mRNA were enriched in HER2$^{2+/3+}$ tumors ($p<0.0001$). *CLDN6*, *TACSTD2*, *F3*, *CDH6*, *CCNE1*, *BRCA1*, and *ERBB2* mRNA were enriched in HRD$^-$ vs HRD$^+$ tumors ($p<0.0001$).

Conclusion/Implications: This is the most comprehensive dataset to date evaluating biomarker concurrence relevant to emerging therapies. These findings may help inform treatment personalization, trial design and therapy

sequencing.

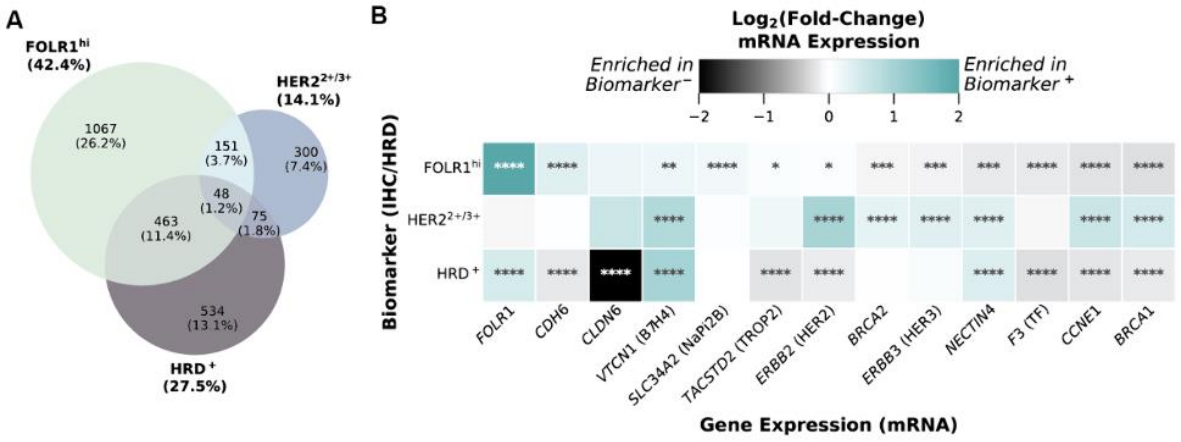

Figure 1. Concurrence and gene expression between biomarkers. A) Biomarker prevalence Venn, expressed as n (% all-comers). B) Expression heatmap of target gene mRNA (x-axis) represented as fold-change between biomarker⁺/biomarker⁻ tumors (y-axis). Pairwise Mann-Whitney U tests with FDR-BH-adjusted p-values are shown (*p<0.05, **p<0.01, ***p<0.001, ****p<0.0001).

OP007 / #1103

Topic: *AS02. Clinical Disciplines / AS02e. Surgical Techniques & Perioperative Management*

SURVIVAL OUTCOMES BY SURGICAL TIMING AND RESIDUAL DISEASE STATUS ACROSS BRCA-MUTATED, HRD, AND BRCA−/HRD− ADVANCED HIGH-GRADE SEROUS OVARIAN CANCER

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Introduction: Achieving no gross residual (NGR) at cytoreductive surgery is the strongest prognostic factor in advanced epithelial ovarian cancer (AEOC), but whether this holds uniformly across BRCA-mutated (BRCAm), HRD (non-BRCAm), and BRCAm−/HRD− subgroups is unclear. We compared survival by surgical outcome after primary (PCS) versus interval cytoreduction (ICS) within each molecular groups.

Methods: Patients with AEOC and known BRCA/HR status who underwent cytoreductive surgery between 2018-2024 were included. Any residual disease at time of cytoreductive surgery was defined as non-NGR. Survival was estimated by Kaplan-Meier and compared by log-rank tests.

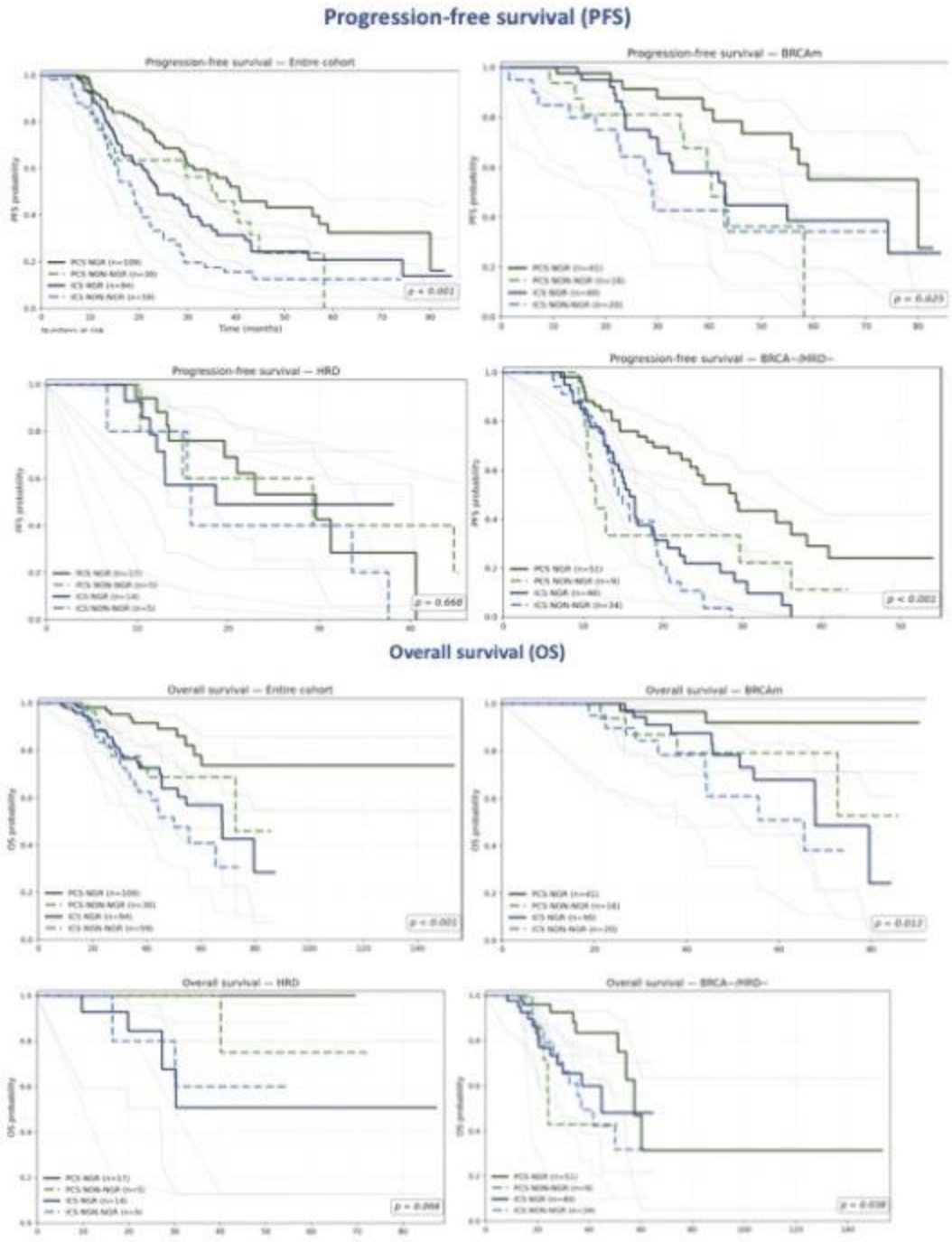
Results: Among 292 patients (117 BRCAm, 41 HRD, 134 BRCA−/HRD−), median age was, 62.0 (54.0–69.0), 66.1% had stage III, 47.6% had PCS, 76% had high disease scores, 69.5% had NGR (Table 1). In BRCAm, PCS NGR yielded the best survival (PFS 80.0 months/OS NR); PCS non-NGR and ICS NGR had similar PFS (40.4 vs 43.0 months, p=0.60) and OS (NR vs 67.9 months, p=0.65). Similar pattern held in HRD: PCS NGR PFS 29.7/ OS NR; PCS non-NGR and ICS NGR had similar PFS (29.3 vs 18.7 months, p=0.92) and OS (both NR, p=0.21). In BRCA−/HRD−, PCS NGR showed survival benefit (PFS 29.2/OS 57.5 months); PCS non-NGR vs ICS NGR PFS 11.6 vs 15.8 months (p=0.66), OS 24.3 vs 44.8 months

Table 1. Patient and surgical characteristics

Characteristic	Overall (N=292)	BRCAm (n=117)	HRD (n=41)	BRCA−/HRD− (n=134)
Age at diagnosis, median (IQR), years				
Overall	**62.0 (54.0–69.0)**	**58.0 (52.0–65.0)**	**55.0 (49.0–65.0)**	**66.0 (59.2–72.0)**
PCS	58.0 (52.0–65.5)	55.0 (51.0–61.0)	52.5 (48.0–60.2)	63.5 (56.8–68.2)
ICS	65.0 (57.0–73.0)	62.0 (55.0–68.2)	61.0 (54.0–72.5)	67.0 (62.0–74.0)
Surgery Type, n (%)				
Overall	**292 (100%)**	**117 (100%)**	**41 (100%)**	**134 (100%)**
PCS	139 (47.6%)	57 (48.7%)	22 (53.7%)	60 (44.8%)
ICS	153 (52.4%)	60 (51.3%)	19 (46.3%)	74 (55.2%)
FIGO stage III, n (%)				
Overall	**193 (66.1%)**	**76 (65.0%)**	**26 (63.4%)**	**91 (67.9%)**
PCS	102 (73.4%)	42 (73.7%)	15 (68.2%)	45 (75.0%)
ICS	91 (59.5%)	34 (56.7%)	11 (57.9%)	46 (62.2%)
FIGO stage IV, n (%)				
Overall	**99 (33.9%)**	**41 (35.0%)**	**15 (36.6%)**	**43 (32.1%)**
PCS	37 (26.6%)	15 (26.3%)	7 (31.8%)	15 (25.0%)
ICS	62 (40.5%)	26 (43.3%)	8 (42.1%)	28 (37.8%)
High pre-treatment disease score (DS=3) indicating upper abdominal disease, n (%)				
Overall	**222 (76.0%)**	**88 (75.2%)**	**33 (80.5%)**	**101 (75.4%)**
PCS	96 (69.1%)	39 (68.4%)	18 (81.8%)	39 (65.0%)
ICS	126 (82.4%)	49 (81.7%)	15 (78.9%)	62 (83.8%)
Aletti SCS, median (IQR)				
Overall	**6 (3–9)**	**6 (3–9)**	**7 (3–10)**	**5 (3–9)**
PCS	9 (5–12)	9 (6–12)	10 (6–12)	8 (4–11)
ICS	4 (3–6)	4 (3–6)	3 (2–6)	4 (3–6)
Aletti SCS group 3 (high complexity), n (%)				
Overall	**107 (37.2%)**	**45 (38.5%)**	**17 (41.5%)**	**45 (34.6%)**
PCS	85 (61.2%)	38 (66.7%)	14 (63.6%)	33 (55.0%)
ICS	22 (14.8%)	7 (11.7%)	3 (15.8%)	12 (17.1%)
Surgical outcome: NGR (no gross residual), n (%)				
Overall	**203 (69.5%)**	**81 (69.2%)**	**31 (75.6%)**	**91 (67.9%)**
PCS	109 (78.4%)	41 (71.9%)	17 (77.3%)	51 (85.0%)
ICS	94 (61.4%)	40 (66.7%)	14 (73.7%)	40 (54.1%)
Surgical outcome: non-NGR (any residual), n (%)				
Overall	**89 (30.5%)**	**36 (30.7%)**	**10 (24.4%)**	**43 (32.1%)**
PCS	30 (10.3%)	16 (13.7%)	5 (12.2%)	9 (6.7%)
ICS	59 (20.2%)	20 (17.9%)	5 (12.2%)	34 (25.4%)

Abbreviations: BRCAm, BRCA-mutated; HRD, homologous-recombination deficient (non-BRCA); BRCA−/HRD−, neither BRCA-mutated nor HRD (HRP + HRI); PCS, primary cytoreductive surgery; ICS, interval cytoreductive surgery; FIGO, International Federation of Gynecology and Obstetrics; DS, disease score; SCS, Surgical Complexity Score (Aletti); NGR, no gross residual disease; PARP, poly(ADP-ribose) polymerase.

(p=0.56).



Conclusion/Implications: In BRCAm/HRD AEOC, NGR at PCS yielded the best survival outcomes, and PCS with residual disease showed survival comparable to NGR at ICS — supporting an aggressive primary-surgery approach. In BRCA−/HRD− disease, only NGR at PCS yielded significant survival benefit.

OP008 / #391

Topic: *AS06. Tumor Types / AS06c. Ovarian Cancer*

SINGLE-AGENT NEOADJUVANT NIRAPARIB THERAPY FOR HRD-POSITIVE ADVANCED OVARIAN CANCER: MATURE OUTCOMES FROM THE PHASE 2 NANT TRIAL

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Introduction: Neoadjuvant chemotherapy followed by interval debulking surgery (IDS) is standard for advanced ovarian cancer unlikely to achieve complete cytoreduction, but non-cytotoxic neoadjuvant options remain limited. NANT evaluated upfront neoadjuvant niraparib monotherapy in homologous recombination deficiency (HRD)-positive advanced ovarian cancer.

Methods: NANT was a multicenter, prospective, single-arm phase 2 trial in treatment-naïve patients with unresectable FIGO stage III–IV HRD-positive high-grade serous or endometrioid ovarian cancer selected by prespecified resectability criteria. Patients received oral niraparib for two 28-day cycles. Co-primary endpoints were investigator-assessed objective response rate (ORR) and R0 resection rate at IDS.

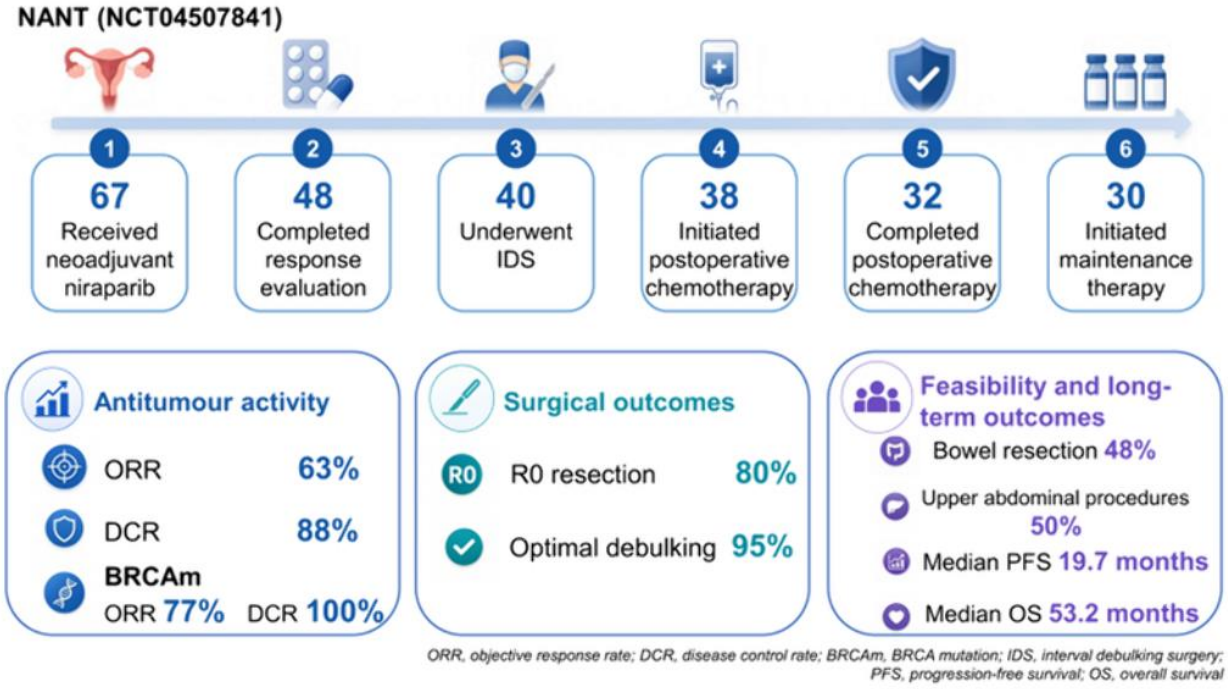
Results: Between Jan 8, 2021 and Jul 18, 2023, 67 patients received neoadjuvant niraparib monotherapy, 48 completed response evaluation, and 40 underwent IDS. ORR was 63% and disease control rate was 88%, with higher activity in the *BRCA1/2-mutated* subgroup. R0 resection and optimal debulking were achieved in 80% and 95% of operated patients, respectively. Bowel resection and upper abdominal procedures were performed in 48% and 50%, with no 30-day or 90-day postoperative deaths. Thirty-eight patients initiated postoperative chemotherapy and 30 subsequently initiated maintenance therapy. At data cutoff on Dec 29, 2025, median progression-free survival and overall survival were 19.7 and 53.2 months overall, 23.0 and not reached in the *BRCA1/2-mutated* subgroup, and 14.2 and 47.7 months in the *BRCA-wildtype*/HRD-positive subgroup. Grade ≥3 treatment-related adverse events occurred in 61%,

with no treatment-related deaths.

Outcome	All	*BRCAm*	*BRCAwt*/HRD
Antitumor activity	n=48	n=22	n=26
Objective response rate	63% (30/48)	77% (17/22)	50% (13/26)
Disease control rate	88% (42/48)	100% (22/22)	77% (20/26)
Surgical outcomes	n=40	n=21	n=19
R0 resection rate	80% (32/40)	86% (18/21)	74% (14/19)
Optimal debulking rate	95% (38/40)	95% (20/21)	95% (18/19)
Bowel resection	48% (19/40)	52% (11/21)	42% (8/19)
Upper abdominal procedures	50% (20/40)	48% (10/21)	53% (10/19)
30-/90-day mortality	0/0	0/0	0/0
Survival outcomes	n=48	n=22	n=26
Median PFS, 95% CI	19.7 (15.9–35.8)	23.0 (19.0–NR)	14.2 (12.3–NR)
Median OS, 95% CI	53.2 (39.8–NR)	NR	47.7 (38.2–NR)

Conclusion/Implications: Chemotherapy-free neoadjuvant niraparib showed meaningful activity, enabled high complete cytoreduction rates, and preserved downstream treatment

deliverability.



OP009 / #902

Topic: *AS06. Tumor Types / AS06c. Ovarian Cancer*

Q-TWIST ANALYSIS OF PEMBROLIZUMAB PLUS WEEKLY PACLITAXEL ± BEVACIZUMAB IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER: ENGOT-OV65/KEYNOTE-B96

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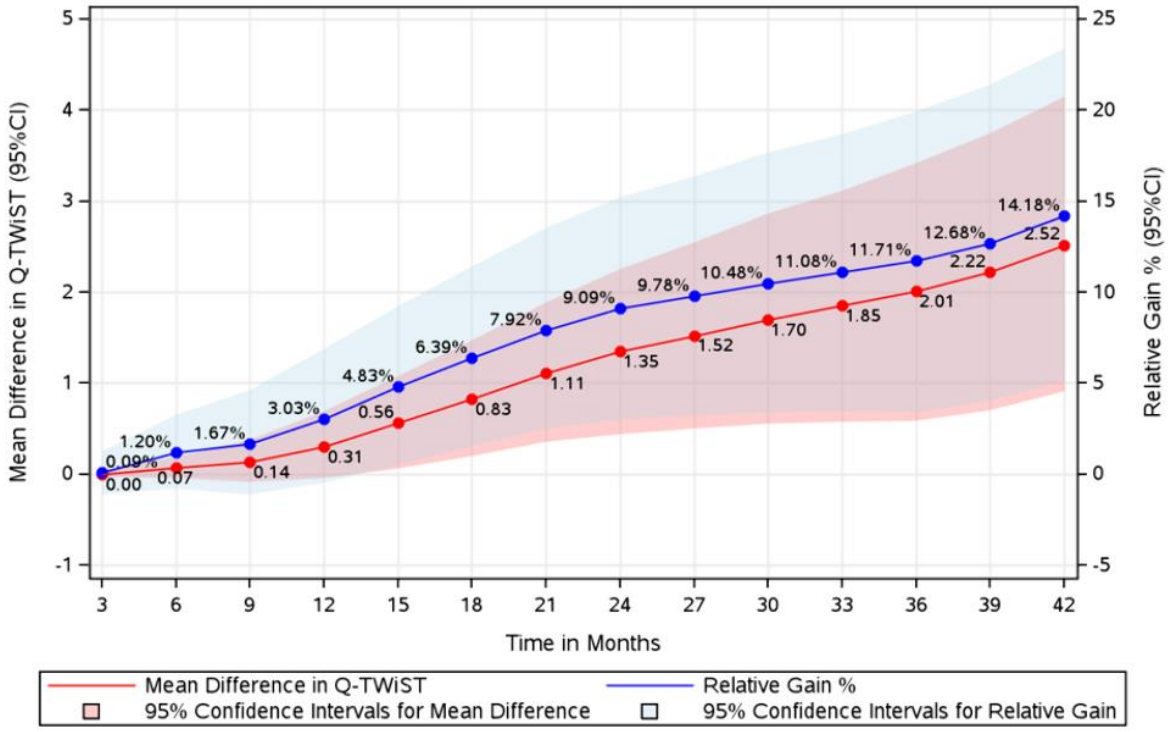
Introduction: In platinum-resistant recurrent ovarian cancer (PROC), where treatment-related toxicity is a major concern, understanding the impact of therapy on quality-adjusted survival is critical. In ENGOT-ov65/KEYNOTE-B96 (NCT05116189), the addition of pembrolizumab to weekly paclitaxel ± bevacizumab demonstrated significantly improved progression-free and overall survival. In this analysis, we evaluate quality-adjusted time without symptoms or toxicity (Q-TWiST) between treatment arms.

Methods: Overall survival among randomized patients in the pre-specified PD-L1 CPS ≥1 population was partitioned into three health states: TOX (time with grade 3–5 adverse events before progression), TWiST (time without symptoms or toxicity), and REL (time after progression). Q-TWiST was calculated as the weighted sum of time spent in each state, with utilities derived from EQ-5D-5L scores. Restricted mean differences in Q-TWiST and relative gain were estimated.

Results: Among patients with PD-L1 CPS ≥1, those randomized to pembrolizumab + paclitaxel ± bevacizumab (n=234) had a 1.85-month improvement in Q-TWiST (95% CI: 0.58–3.12) compared with placebo + paclitaxel ± bevacizumab (n=232) at 33 months of follow-up, representing a relative gain of 11.08%. At the current maximum follow-up of 42 months, the Q-TWiST gain was 2.52 months (95% CI: 0.91–4.15), representing a relative gain of

14.18%.

Figure: Restricted mean difference in Q-TWiST and relative gain (pembrolizumab + paclitaxel ± bevacizumab vs placebo + paclitaxel ± bevacizumab) over time in patients with PD-L1 CPS ≥1 from ENGOT-ov65/KEYNOTE-B96 final analysis.



Conclusion/Implications: This Q-TWiST analysis demonstrates a clinically important improvement (>10% relative gain) in quality-adjusted time without symptoms or toxicity with pembrolizumab combined with weekly paclitaxel ± bevacizumab in patients with PROC and PD-L1 CPS ≥1, supporting a favorable benefit–risk profile of this regimen.