IC: paclitaxel, pegylated liposomal doxorubicin, or topotecan. Primary endpoint was PFS; key secondary endpoints: objective response rate (ORR), OS, and patient-reported outcomes (PRO) (hierarchical order).

Results 227 pts were randomized to the MIRV arm; 226 to the IC arm. Baseline characteristics were well balanced ; 14% of pts had one, 39% two, and 47% three PLOT. In pts with 1 or 2 PLOT (n=245), PFS hazard ratio (HR), 95% confidence interval was 0.61 (0.45, 0.81) ; and 3 PLOT (n=208), PFS HR was 0.71 (0.52, 0.98). In patients with 1 or 2 PLOT, OS HR was 0.66 (0.45, 0.98); and 3 PLOT OS HR was 0.65 (0.43, 0.96). Compared with IC, MIRV was associated with lower rates of grade 3+ treatment-emergent adverse events (TEAEs) (42% vs 54%), serious AEs (24% vs 33%), and discontinuations due to TEAEs (9% vs 16%). The key secondary PRO endpoint, EORTC QLQ-OV28 (abdominal/GI symptom scale), will be presented.

Conclusion MIRV demonstrated a longer OS and PFS vs IC, regardless of the number of PLOT. MIRV is the first treatment to demonstrate both an OS and a PFS benefit in a phase III trial in PROC. These efficacy data, along with the well-characterized safety profile, position MIRV as a new standard of care for pts with FRα positive PROC.

#1056 MIRVETUXIMAB SORAVTANSINE DEMONSTRATES EFFICACY OVER INVESTIGATOR'S CHOICE CHEMOTHERAPY REGARDLESS OF PRIOR PARPI EXPOSURE IN PHASE III MIRASOL TRIAL

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Introduction/Background Mirvetuximab soravtansine (MIRV), an antibody-drug conjugate targeting folate receptor alpha (FRα), demonstrated an improvement in progression-free survival (PFS) and overall survival (OS) in patients (pts) with platinum-resistant ovarian cancer (PROC) compared to investigator choice chemotherapy (IC) (Moore K et al. ASCO 2023; LBA5507). Here we present efficacy data by prior PARPi (with nominal p-values).

Methodology 453 PROC pts with high FRα expression with 1–3 priors were randomized 1:1 to MIRV or IC: paclitaxel, pegylated liposomal doxorubicin, or topotecan. Primary efficacy endpoint was PFS; key secondary endpoints: overall response rate (ORR), overall OS, and patient-reported outcomes (hierarchical order).

Results 227 pts were randomized to the MIRV arm; 226 to the IC arm. Baseline characteristics were well balanced; 14% of pts had one, 39% two, and 47% three prior lines of therapy; 55% received prior PARPi. In pts with prior PARPi (n=251) PFS HR was 0.58 (95% confidence interval 0.43, 0.78, p-value=0.0002) and ORR 45% vs 17%, p-value <0.0001, favoring MIRV. In the PARPi-naïve subset (n=191), PFS HR was 0.74 (0.54, 1.03, p-value=0.0685) and ORR 40% vs 14%, p<0.0001. In pts with prior PARPi, MIRV had lower rates of grade 3+ treatment-emergent adverse events (TEAEs) (45% vs. 58%), serious TEAEs (21% vs. 35%), and discontinuations due to TEAEs (9% vs. 22%) compared with IC. Additional patient characteristics, safety, and OS data will be presented.

Conclusion MIRV is the first treatment to demonstrate both an OS and a PFS benefit compared to IC in a phase III trial in PROC. In this subset analysis, the benefit extends to patients regardless of prior PARPi, with the greatest benefit in pts with prior PARPi exposure. These efficacy data, along with the well-characterized safety profile, position MIRV as a new standard of care for pts with FRα-positive PROC.

10. Quality of life after treatment

#461 PATIENT REPORTED OUTCOMES FROM CCTG CX.5 (SHAPE): RANDOMIZED TRIAL COMPARING RADICAL HYSTERECTOMY (RH) AND PELVIC NODE DISSECTION (PND) VS SIMPLE HYSTERECTOMY (SH) AND PND IN WOMEN WITH LOW-RISK EARLY-STAGE

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Introduction/Background CX.5 (SHAPE) is a Canadian Cancer Trials Group (CCTG) led Gynecologic Cancer Intergroup international randomized phase III randomized non-inferiority trial comparing RH to SH in women with low-risk early-stage cervical cancer. The primary endpoint was pelvic recurrence rate at 3 years. Quality of Life (QoL) and Sexual Health are important survivorship issues for women undergoing this surgery and Patient Reported Outcomes (PROs) were important secondary endpoints in this trial.

Methodology PROs included QoL measured by EORTC QLQ-C30 with QLQ-CX24 and sexual health assessment (SHA) by the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R). These were measured at baseline and at 3, 6, 12, 24, and 36 months after the surgery. Change scores from baseline were calculated and analyzed by linear mixed models.

Results Among 700 patients randomized, 508 (73% of expected) and 432 (86% of expected) completed respectively baseline QOL and SHA. Compliance post-baseline was 56% to 69% for QOL and 63% to 79% for SHA with 58% of patients reporting QoL and 63% responding to the SHA at 36 months. Mean baseline scores were high for all EORTC QLQ-C30 functional scales. EORTC symptoms with the highest (worst) mean baseline scores were fatigue (24.5 on SH and 24.1 on RH) and sleep (29.9 on SH and 32.0 on RH). Mean baseline FSFI and FSDS-R total scores were respectively 27.1 and 10.9 on SH and 27.6 and 10.1 on RH; all were in the non-clinical range.. Significant differences in favor of treatment with SH was found for the following domains: EORTC QLQ-C30 pain scale; EORTC QLQ-CX24 symptom experiences, body image, sexual-vaginal functioning, and sexual worry, sexual activities, and sexual enjoyment scales; FSFI desire, arousal, lubrication, pain scales and total score; and FSDS-R total score.

Conclusion Better quality of life and sexual health were observed with SH compared to RH.

#630 LOWER-LIMB LYMPHEDEMA AFTER SENTINEL LYMPH NODE BIOPSY IN CERVICAL CANCER PATIENTS: FINAL RESULTS OF THE SENTIX PROSPECTIVE INTERNATIONAL STUDY (CEEGOG CX-01/ENGOT-CX2)

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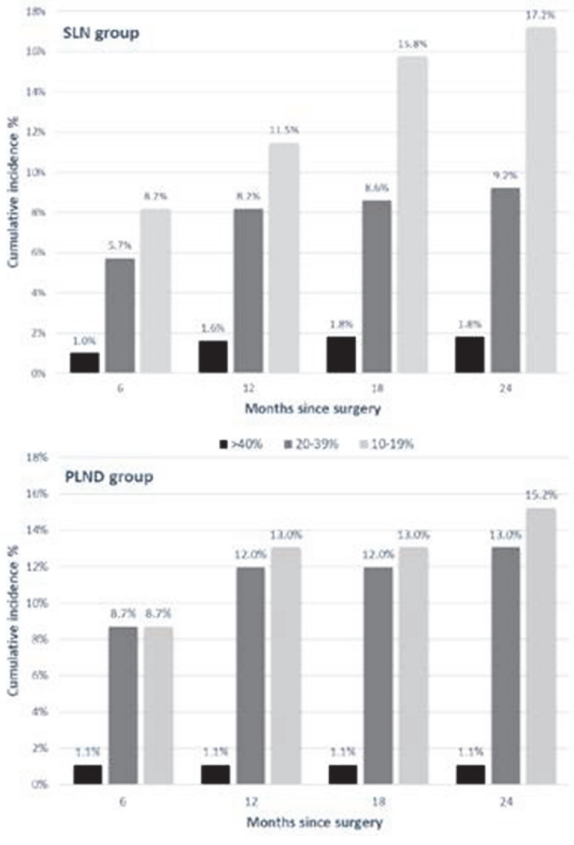
Introduction/Background Background The sentinel lymph node (SLN) concept was developed with the purpose of alleviating postoperative morbidity, particularly lower limb lymphedema (LLL). We report the final analysis of the occurrence of LLL after SLN biopsy or systematic pelvic lymph node dissection (PLND) in the prospective SENTIX study.

Methodology SENTIX was conducted at 47 sites in 18 countries. Patients with stages 1A1/LVSI+ to 1B2 (FIGO 2018), usual histological types, and no suspicious lymph nodes on imaging were prospectively enrolled between 05/2016 and 10/2020. All patients underwent SLN biopsy and hysterectomy/trachelectomy. Patients with unilaterally detected/undetected SLNs and those in whom the SLN was intraoperatively positive, underwent systematic PLND. LLL was assessed at 6-month intervals for the period of 2 years. The assessment was based on a persistent limb volume increase [LVI] calculated using serial limb circumference measurements.

Results Among 578 evaluable patients, 486 underwent SLN biopsy only and 92 underwent PLND. The cumulative incidence of LLL at 24 months in the SLN and PLND groups was 28.0% and 29.0% (p=0.900). Persistent LVI >40% occurred at a similar frequency in both groups, with cumulative rates of 1.8% and 1.1% in the SLN and PLND groups, respectively (p=1.0) (figure 1). Although we observed a tendency towards more frequent mild LLL in the SLN group, the difference was not statistically significant (p=0.256). The median interval to LLL onset was 9 months in both groups. Transient oedema that resolved without intervention within 6 months was reported in an additional 15.2% and 13.0% of patients in the SLN and PLND groups, respectively.



Abstract #630 Figure 1 Postoperative cumulative incidence of LLL in the SLN and PLND cohorts. LLL: limb lymphedema defined as a limb volume increase black (LVI); black (LVI >40%); dark grey: moderate LLL (LVI 20–39%); light grey: mild LLL (LVI 10–19%)