Plenary 6

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33 OLAPARIB MONOTHERAPY VERSUS (VS) CHEMOTHERAPY FOR GERMLINE BRCA-MUTATED (GBRCAM) PLATINUM-SENSITIVE RELAPSED OVARIAN CANCER (PSR OC) PATIENTS (PTS): PHASE III SOLO3 TRIAL

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Background Data from a randomized Phase II trial (NCT00628251) of olaparib (capsules, 200 or 400 mg bid, n=32 per arm) vs pegylated liposomal doxorubicin (PLD, n=33) in gBRCAm OC pts with recurrence ≤12 months after prior platinum therapy indicated efficacy for olaparib (Kaye et al. JCO 2012). However, the efficacy of PLD was higher than previously reported in this setting. We led a confirmatory Phase III, open-label study of olaparib vs non-platinum chemotherapy in gBRCAm PSR OC pts (NCT02282020).

Methods Pts were randomized (2:1) to olaparib tablets (300 mg bid) or chemotherapy treatment of physician's choice (TPC) (paclitaxel [P; 80 mg/m2 on day 1 (D1), D8, D15, D22 every 4 weeks (q4w)], topotecan [T; 4 mg/m2 D1, D8, D15 q4w], gemcitabine [G; 1000 mg/m2 D1, D8, D15 q4w] or PLD [50 mg/m2 D1 q4w]) until progression, stratified by: TPC, prior lines of chemotherapy (2–3 vs ≥4) and platinum-free interval (6–12 vs >12 months). Primary endpoint: ORR (blinded independent central review [BICR]). Secondary endpoints included PFS and safety.

Results 266 gBRCAm PSR OC pts were randomized (olaparib, n=178; TPC, n=88 [PLD, n=47; P, n=20; G, n=13; T, n=8]); 12 in the TPC arm withdrew before receiving study treatment. 223 pts (84%) had baseline BICR measurable disease (olaparib, n=151; TPC, n=72). ORR was 72% with olaparib vs 51% with TPC (OR 2.53, 95% CI 1.40–4.58; P=0.002). HR for PFS by BICR was 0.62 (95% CI 0.43–0.91; P=0.013; median 13.4 vs 9.2 months [olaparib vs TPC]) and by investigator assessment was 0.49 (95% CI 0.35–0.70; P<0.001; median 13.2 vs 8.5 months, respectively). Most common adverse events (AEs) with olaparib were nausea (65% vs 34% [TPC]) and anemia (50% vs 25%) and with TPC were palmar-plantar erythrodysesthesia (PPE; 36% vs 1% [olaparib]) and nausea. Most common grade ≥3 AEs in either arm were anemia (21% [olaparib] vs 0 [TPC]), PPE (0 vs 12%) and neutropenia (6% vs 11%). For olaparib vs TPC, serious AEs were reported by 24% vs 18% and AEs led to treatment discontinuation in 7% vs 20%.

Conclusions Pts with gBRCAm PSR OC receiving olaparib monotherapy had a significant, clinically relevant improvement in ORR and PFS vs TPC, with no new safety signals.

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34 LESS RADICAL FERTILITY SPARING THAN RADICAL TRACHELECTOMY IN EARLY CERVICAL CANCER – 20 YEARS EXPERIENCE

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Objectives Purpose of study was to determine long term experience of less radical surgery, sentinel lymph node identification (SLNI) with Tc^{99}+blue day with laparoscopic surgery.

Methods From 1999 to 2018, 91 women with tumor less than 20 mm in largest diameter, infiltration less than half of cervical stroma underwent SLNI, frozen section (FS) of SLN, extirpation of afferent parametrial lymphatic channel, pelvic lymphadenectomy or only SLN. FS SLN positive patients underwent radical hysterectomy. Seven days after final histopathological processing of dissected nodes, large cone or simple trachelectomy was performed.

Results 15 women (16.5%) lost fertility. 9 women had positive lymph nodes (9.9%), 2 close invasive margin (2.2%), so radical hysterectomy was performed. Four cases had SIL in margin or patient decision, had laparoscopic hysterectomy. One patient N1 had recurrence and died of disease. All other are in complete remission. Fertility was save in 76 cases. Three central recurrences (isthmic part of uterus) were observed (3.9%), one died (1.3%), 2 are in CR 15 and 7 years. We have no distant recurrence. 62 of 76 women whose reproductive ability had been maintained tried to conceive (82%). Of these 62 women, 49 became pregnant (79%) in total 76 pregnancies. 43 mothers gave birth to 48 children, two children were by surrogate mothers.

Conclusions Less radical fertility sparing surgery in early cervical cancer can be feasible method that yields high, successful pregnancy rate.

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