BARCELONA 2024 ESMO congress

728P
Chemotherapy plus tislelizumab in young patients with cervical cancer preserve fertility: A phase II study

D. Wang, X. Xu, Z. Yang, Y. Dong, Y. Zhu

Gynecological Oncology Ward, Liaoning Cancer Hospital & Institute, Shenyang, China

Background

Cervical function damage from fertility-sparing surgery reduces pregnancy success rate. Recently, immunotherapy has made significant advances in treating cervical cancer (CC). Herein, we conducted this study to evaluate the efficacy and safety of chemo + tislelizumab (TIS, a PD-L1 inhibitor) in young pts with CC who required fertility preservation.

Methods

In this trial, FIGO2018 stage IB1-IB3 or IIIC1r (localized cervical lesions) CC and having fertility needs were enrolled. Pts received 4 cycles chemo (175 mg/m^2 paclitaxel + 70 mg/m^2 cisplatin/AUC 5-6 carboplatin, Q3W) + TIS (200 mg, Q3W), followed by surgery-diagnostic cervical conization and sentinel lymph node (SLN) biopsy (IIIC1r stage with pelvic lymph node [PLN] systematic dissection)-upon achieving radiographic complete response (CR). After surgery, pts with pathological complete response (pCR) in all samples will undergo 2-cycle chemo + TIS, followed by TIS maintenance therapy (MT) for 1 year. If the first conization did not achieve pCR for localized cervical lesion only, a second conization was performed after 2-cycle chemo + TIS, followed by 1 year of TIS MT upon achieving pCR. Primary endpoint was pCR (SLN/PLNs + cervical conization) after surgery.

Results

Between Mar. 2022 and Apr. 2024, 8 pts (mean age 31 years) were enrolled, with 2 having stage IIIC1r disease. All 8 pts received chemo + TIS; of these, 6 pts completed 4 cycles, CR rate was 83.3%(5/6), and patients with CR received surgery. The pCR was 100% (5/5) in pts who underwent surgery, with 1 reaching a pCR after the second conization. Amenorrhea occurred in 3 of 5 pts, with 2 recovering normal menstruation post-chemo, and 1 had not returned after 3 weeks post-last chemo+TIS. During 4 cycles of chemo+TIS therapy (n=7), common TEAEs included rash (62.5%), neutropenia (62.5%), and leukopenia (62.5%), alanine aminotransferase increased (50.0%). At data cutoff (median follow-up, 9 months, range 2-25), 1 pt developed progression during MT, and 1 pt got pregnant 3 months post-MT.

Conclusions

Chemo + TIS could mediate tumor regression and eliminate micro-metastases with a tolerable safety profile, potentially preserving fertility in many pts previously considered ineligible.

Clinical trial identification

ChiCTR2300067495.

Legal entity responsible for the study

The authors.

Funding

Has not received any funding.

Disclosure

All authors have declared no conflicts of interest.