

## A prospective, randomized control trial of concurrent paclitaxel and carboplatin along with radiotherapy versus concurrent cisplatin along with radiotherapy in carcinoma cervix patients at a tertiary care hospital of central India.

Praghnya Subhash Tejale, Prachi Ketanbhai Padia Jr., Ashok Diwan, Vijay Mahobia; Government Medical College, Nagpur, India; Government Medical College and Hospital, Nagpur, India

**Background:** In India, cervical cancer accounted for 9.0% of all cancers and 18.3% (127,526) of new cases in 2022 as per GLOBOCAN. It is leading cause of cancer-related deaths in women in low and middle-income countries. Concurrent chemoradiotherapy (CCRT) with Cisplatin is standard for LACC but is often limited by nephrotoxicity & ototoxicity. Hence, the combination of paclitaxel and carboplatin has been explored for its potentially favorable toxicity profile and effectiveness. Thus comparative analysis of two concurrent chemoradiotherapy regimens examining their efficacy, toxicity profiles and suitability for patients. is assessed. The results can have significant implications for clinical practice, particularly in resource-limited settings where treatment-related toxicity and patient compliance are critical concerns. **Methods:** Simple randomization with open label study conducted to compare the efficacy and toxicity of concurrent radiotherapy with paclitaxel and carboplatin versus concurrent radiotherapy with cisplatin in patients with locally advanced cervical cancer. Conducted in Department of Radiation Oncology, GMC Nagpur from July 2024 to December 2026. Sample size 100 (50 each group assuming 10% dropout) Inclusion criteria: Age 18–70 years, histologically confirmed diagnosis, FIGO stage IB1 to IVA, ECOG 0–3, written informed consent, baseline audiometry. Exclusion criteria: Prior chemo-radiotherapy for cervical cancer, severe comorbid conditions, pregnant or breastfeeding women, and known hypersensitivity to study drugs. Intervention: Arm A: Concurrent Cisplatin with EBRT to pelvis with dose of 45–50 Gy/ 23–25 fractions followed by brachytherapy. Chemotherapy: Cisplatin 40 mg/m<sup>2</sup> IV weekly for up to 6 cycles. Arm B: Concurrent RT with Paclitaxel and Carboplatin. RT: Same as Arm A. Chemotherapy: Paclitaxel 50 mg/m<sup>2</sup> and carboplatin AUC 2 IV weekly for up to 6 cycles. Primary Outcomes: Locoregional control (RECIST criteria at 3,6,12 and 24 months post-treatment). Secondary Outcomes: Overall Survival, Progression-Free Survival, Disease-free survival, Toxicity, Quality of Life (EORTC QLQ-C30) questionnaire. Data Collection and Analysis: Baseline assessments-Medical history, physical examination, laboratory tests, imaging studies. During treatment- Weekly clinical assessments, laboratory tests and toxicity evaluations. Follow-up: Clinical assessments, Imaging studies and QoL at 0, 3, 6, 12 and 24 months post-treatment. Ethical Considerations: Ethical approval is obtained from relevant institutional review boards on 04/12/2024. Patients are under accrual. Research Sponsor: None.