A phase II study of recombinant adeno-viral human p53 gene combined with radiotherapy in treatment of patients with locally advanced cervical carcinoma.

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Abstract:

Background: The study objective was to evaluate the efficacy and safety of recombinant adeno-viral human p53 gene (rAd-p53) conbined with radiotherapy (RT) in treatment of advanced cervical carcinoma. **Methods:** Patients aged ≥18 years, with stage IIB--IVA cervical carcinoma, expecting to live more than 3 months, without any anti-tumor treatment in 2 weeks, with an Eastern Cooperative Oncology Group (ECOG) performance status score of 0-2 were randomly assigned in two groups: experimental group (EG) receiving weekly intratumoral injection of $1\text{-}4\times10^{12}$ rAd-p53 viral particles (VP) for 6 weeks conbined with 1.8-2Gy/f of external beam therapy in Point B (total dose of 45-50Gy) and 7Gy/f of high dose rate (HDR) brachytherapy in Point A (total dose of 70 Gy) in 6 week; control group (CG) receiving the same dose of RT. The response rate, long-term effecacy and adverse effects were evaluated. **Results:** Thirty-nine eligible patients, 21 in EG and 18 in CG, were enrolled between 2008 and 2009. In EG, 11 patients (52.4%) achieved a complete response (CR), 10 (47.6%) had a partial response (PR), and the overall response rate (RR) was 100%, In CG, there was 8 (44.4%) CR, 5 (27.8%) PR, 3 (16.7%) stable diseases (SD) and 2 (11.1%) progressive diseases (PD), and the RR was 72.2%. The RR difference is statistically significant (Fisher's Exact Test: p=0.0149). In EG, 15 (71.4%) patients has self-limited fever and 8 (38.1%) had a grade 1 or 2 myelosuppression. In CG, 9 patients (50%) had a grade 1 or 2 myelosuppression. The result of long-term effecacy is not available at this time. **Conclusions:** Intratumoral rAd-p53 injection combined with radiotherapy significantly increases overall response rate. The main adverse effect of rAd-p53 is fever.