

Preoperative recombinant adeno-viral human p53 gene (rAd-p53) therapy in treatment of locally advanced papillary thyroid cancer (PTC) and follicular thyroid cancer (FTC).

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Abstract:

**Background:** Locally advanced PTC and FTC increase the complexity of surgery or become unresectable, and have a poor prognosis. This study is to evaluate the benefits of pre-operative rAd-p53 therapy combined with post-operative radioactive iodine ( $I^{131}$ ) in treatment of locally advanced PTC and FTC. **Methods:** Patients with historically-diagnosed stage IIB-IVA PTC and FTC or failed primary tumorectomy, were randomly assigned in two groups: experimental group (EG) control group (CG). EG received intratumoral injection of  $1-3 \times 10^{12}$  rAd-p53 viral particles (VP) per 3 days for 5 times, surgery, and post-operative standard  $I^{131}$  therapy. CG received surgery and post-operative standard  $I^{131}$  therapy. Surgery success rates, long-term efficacy and adverse effects were evaluated. The tumor samples were analyzed for tissue histology, p53 protein expression, and apoptosis. **Results:** EG including 31 cases, 19 female and 12 male, had radically operative rate of 100%, one-year survival rate of 100%, and no local recurrence and distant metastases. The tissue histological analysis showed increased fibrous tissues, apoptotic cells, and decreased tumor cells in the tumor sample from EG. CG including 29 cases, 18 female and 11 male, had radically operative rate of 79.3%, one-year survival rate of 86.2%, and distant metastatic rate of 10.3%. Six cases of CG could not remove all the tumor tissues due to involving nearby key structures: carotid artery, recurrent laryngeal nerve, larynx, and trachea. The main side effects of rAd-p53 were self-limited fever, occurring in 24 of EG patients. All the study patients are still followed-up, until 3 years after treatment according to the protocol. **Conclusions:** rAd-p53 might increase radical surgical rate and improve the long-term efficacy of locally advanced PTC and FTC.