

IMMUNOTHERAPY

Significant overall survival advantage for RCC patients treated with autologous tumor lysate vaccine

Advances in nephron-sparing surgery, laparoscopic approaches, and novel targeted therapies have dramatically improved the outcomes for patients with renal-cell carcinoma. Despite these advances, adjuvant treatment options following surgery are needed, and one approach that was shown to be successful in a previous multicenter phase III trial was an autologous tumor-based vaccine. In this trial, the vaccine produced significant tumor regression after radical nephrectomy compared with surgery alone.

Investigators of another study have now shown that the 10-year overall survival rates are particularly impressive with this adjuvant vaccine approach. “The findings of our analysis, demonstrating a significant overall survival advantage by treatment with autologous tumor vaccine especially in patients with stages pT3 and UICC stage 3, are in line with the results of a previous phase III study using the same vaccine in the adjuvant setting”, explains Matthias May, lead investigator of the study.

“...the vaccine produced significant tumor regression after radical nephrectomy compared with surgery alone”

This multicenter trial included 1,267 patients from 84 German hospitals. Patients received either radical or partial nephrectomy and were randomly assigned to treatment with the autologous tumor vaccine (Reniale®) or to no vaccine (control arm). The overall outcomes for all cancer stages combined were not significantly different between the two groups. The 5-year and 10-year overall survival rates were 80.6% and 68.9% for the vaccine group and 79.2 and 62.1% for the control group. When outcomes were assessed according to tumor stage, no survival differences were observed for patients with pT2 tumors. However, the 5-year overall survival rates were considerably higher in the vaccine group

compared with controls for patients with stage pT3 tumors (71.3% versus 65.4%, $P=0.022$). The respective 10-year overall survival rates were 53.6% and 36.2%.

Multivariate regression analysis revealed that the absence of tumor-cell vaccination resulted in a significantly worse overall survival for patients with pT3 tumors. The researchers comment that “controlled trials, using the recent TNM classification and incorporating known risk factors for prognosis, are required to identify further patient groups that may benefit from treatment with autologous tumor cell vaccination”. Further research regarding the application of tumor vaccines in the adjuvant setting is underway.

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Original article May, M. *et al.* Ten-year survival analysis for renal carcinoma patients treated with an autologous tumour lysate vaccine in an adjuvant setting. *Cancer Immunol Immunother.* 59, 687–695 (2010)