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A randomized controlled trial of postoperative tumor lysate-pulsed dendritic cells and cytokine-induced killer cells immunotherapy in patients with localized and locally advanced renal cell carcinoma - Abstract

**A randomized controlled trial of postoperative tumor lysate-pulsed dendritic cells and cytokine-induced killer cells immunotherapy in patients with localized and locally advanced renal cell carcinoma - Abstract**

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**BACKGROUND:** It remains a challenge to inhibit the local recurrence or distant metastasis of localized or locally advanced renal cell carcinoma (RCC) after surgical resection.

We investigated the feasibility, safety and efficacy of immunotherapy using autologous tumor lysate (TL)-pulsed dendritic cells (DCs) and cytokine-induced killer (CIK) cells in patients with localized or locally advanced RCC.

**METHODS:** From January 2001 to July 2009, we collected 137 patients that met the selection criteria and randomly divided them into three groups. After surgery, immunotherapy with TL-pulsed DCs-CIK cells (DC-CIK group) and interferon (IFN)- $\alpha$  (IFN- $\alpha$  group) was performed in 46 patients, respectively. The other 45 patients received no postoperative adjuvant therapy (the control group).

The changes in the numbers of T lymphocyte subsets, including CD4<sup>+</sup>CD25<sup>high</sup> regulatory T cells (Treg), were determined before the operation and after immunotherapy. The overall survival was compared among the three groups.

**RESULTS:** An increase of the CD4<sup>+</sup>/CD8<sup>+</sup> ratio and a decrease of CD4<sup>+</sup>CD25<sup>high</sup> cells were observed after TL-pulsed DC-CIK cells or IFN- $\alpha$  immunotherapy. All patients tolerated the TL-pulsed DC-CIK cells immunotherapy very well, and side effects in the DC-CIK group were less than in the IFN- $\alpha$  group. The metastasis and recurrence rates were significantly decreased after TL-pulsed DC-CIK cells or IFN- $\alpha$  immunotherapy compared with the control group ( $P < 0.01$ ). The Log-rank test showed that the overall survival rates were significantly higher in the DC-CIK group and IFN- $\alpha$  group than that in the control group ( $P < 0.01$ ), but there was no difference between the DC-CIK group and IFN- $\alpha$  group ( $P > 0.05$ ).

**CONCLUSION:** Postoperative immunotherapy with TL-pulsed DC-CIK cells may prevent recurrence/metastasis and increase the overall survival rate after surgery in localized or locally advanced RCC.

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