

Investigational immunotherapeutic increased bladder cancer survival

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Background: Noguchi explained that immunotherapy has emerged recently as a viable and attractive strategy for the treatment of advanced cancer. "In this study, we assessed whether a novel immunotherapeutic approach that we have devised, called personalized peptide vaccination, could improve outcomes for patients who have advanced bladder cancer that has progressed after platinum-based chemotherapy," he continued. "This is a disease for which the prognosis is poor; median survival is just 13 to 15 months from the time of starting platinum-based chemotherapy."

How the Study Was Conducted: Noguchi and colleagues enrolled 80 patients with bladder cancer that had progressed after platinum-based chemotherapy in the phase II clinical trial. Thirty-nine patients were randomly assigned to personalized peptide vaccine and best-supportive care and 41 to best-supportive care. Best-supportive care included palliative radiotherapy, antibiotics, and pain relief. Noguchi explained that personalized peptide vaccination involved patients receiving two to four peptides once a week for eight weeks and then once every two weeks for four doses. The peptides were selected from a pool of 31 peptides, and the identity of the peptides selected for each patient was determined by which form of a marker called [human leukocyte antigen](#) (HLA) class IA was expressed by the patient and whether there were signs of an existing [immune response](#) to the peptides in the patient's blood.

Results: Nine patients assigned personalized peptide vaccine and best-

supportive care and no patients assigned best-supportive care had a partial response, as assessed by RECIST 1.1 criteria. Two of the patients who had a partial response were alive with no disease progression at the time of data cutoff, April 20, 2014.

The median overall survival for patients assigned personalized [peptide vaccine](#) and best-supportive care was almost twice as long as that for patients assigned best-supportive care: 7.9 months versus 4.1 months.

The median progression-free survival was not significantly different between the two groups. Noguchi explained that this might be because it takes time for personalized peptide vaccination to cause an effective antitumor immune response, in contrast to chemotherapy or small molecules, which can cause immediate tumor shrinkage.

Author Comment: Noguchi said, "We were excited to see that personalized peptide vaccination led to a significant improvement in overall survival. This suggests that this immunotherapeutic approach might become a treatment option for advanced bladder cancer after failure of platinum-based regimens. However, large-scale, randomized [clinical trials](#) are needed to confirm our results."

Study Limitations: According to Noguchi, major limitations of the study are that the researchers enrolled only a small number of patients and that the clinical trial did not have blinded study design. To address this concern, he said that they are planning a double-blinded, placebo-controlled, randomized phase II study in [patients](#) with advanced metastatic urothelial cancer (pelvis, ureter, and [bladder cancer](#)) after [platinum-based chemotherapy](#).

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has served as an advisory board consultant for Green Peptide Co. Ltd.

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