549 BOOSTER VACCINATION OF A HER2 HELPER T-CELL VACCINE INCREASED HER2 IMMUNITY IN METASTATIC HER2 POSITIVE BREAST CANCER.

[1]Sasha Stanton*, [2]Jennifer Childs, [2]Doreen Higgins, [3]Angela Kask, [2]Yi Yang, [2]Mary Disis. *[1]Earle A. Chiles Research Institute, Portland, OR, United States; [2]University of Washington, Seattle, WA, United States; [3]Fred Hutchinson Cancer Research Center, Seattle, WA, United States*

Background NCT00194714 vaccinated women with HER2+ metastatic breast cancer after first line therapy with a 3 epitope HER2 T-cell helper peptide vaccine. Patients received six vaccines with concurrent trastuzumab with median progression free survival of 17.7 months at 3 years and median overall survival of 86% at 4 years. Ten years later, 10 of the 22 patients were still living. We therefore determined whether HER2 immunity persisted and whether adding two booster vaccinations could boost that HER2-specific immunity.

Methods Ten eligible patients were contacted about the vaccine booster and four participated. All four patients received the six vaccine series between 2004 and 2006 and the booster vaccine series between 2017 and 2018. Patients received two booster vaccinations of the HER2 T-cell helper tri-peptide vaccine 6 months apart. Peripheral blood was collected prior to booster, 48 hours after each booster, and six months after the second booster to evaluate HER2 immunity by IFN-g ELISPOT. Pre-existing immunity was defined as mean antigen specific spots per well significantly higher than mean no antigen wells.

Results At the time of enrollment, two of the patients had progressive disease and two had no evidence of disease. The boosters were well tolerated with 28 AEs, 39% (11/28) related to the booster vaccines. The majority of AEs were grade 1 including injection site reactions in all four patients and flu like syndromes. The grade 2 toxicities included hypotension and dizziness after the vaccine. Prior to the booster vaccinations, two of the patients had pre-existing immunity to the 3 epitopes included in the vaccine and all four patients had pre-existing immunity to HER2 intracelluar (ICD) and extracellular (ECD) peptide pools. After the boosters, all four patients had increased IFN-g T cell responses to the three pooled epitopes included in the vaccine with average precursor frequency prior to vaccination of 1:133,333 (range 0 to 61,539) increasing to 1:9381 after vaccination (range 1:53,333 to 1:4878, p=0.05). All four patients had augmented IFN-g immunity to the HER2 ICD peptide pool from baseline 1:2875 (range 1:400,000 to 1:1043) to 1:1851 (range 1:12,698 to 1:957, p=0.01). There was no significant augmentation in immunity to the HER2 ECD peptide pool from baseline (p=0.31).

Conclusions Patients receiving HER2 booster vaccines a decade after the initial vaccine series had augmented immune response to the immunizing epitopes and the HER2 ICD. Future studies will determine if boosters can improve long term disease control with vaccines.

Trial Registration Trial registration number NCT00194714

Ethics Approval This study had ethics approval from the Fred Hutchinson Institutional Review Board and all participants gave informed consent before taking part.

Consent No sensitive or identifiable information were used in this abstract.

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