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HORMONE IMMUNOTHERAPY IN ENDOCRINE DEPENDENT METASTATIC BREAST CANCER PATIENTS

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Insoluble and inactive protein aggregates knownHormone therapy is advised for ER+ metastatic breast cancer patients due to its efficacy concomitant with low toxicity; however, in most patients the occurrence of resistance is a not well yet understood hurdle to overcome. In these patients, during clinical benefit (CB) from conventional anti-estrogens, the addition of cycles of sequential immunotherapy could prolong the benefit and delay the arising of acquired hormone resistance. In order to validate this hypothesis, in 1992 we started an open exploratory clinical trial. Forty-two of these patients in CB during first line anti-estrogen salvage therapy also received beta-interferon (INF-beta) 3,000,000 IU i.m./day 3 days/week for 1-4 weeks and successively recombinant *interleukin*-2 (IL-2) 3,000,000 IU s.c./day 3 days/week for 5-8 weeks until progression. The immunotherapy cycle lasted 10 weeks and the patient continued anti-estrogen alone during 9-10 weeks, the 11th week being the first week of the successive cycle. At each control visit, routine laboratory examinations and serum measurement of a CEA, TPA, CA15.3 tumor marker (TM) panel were carried out, and an immunological assessment was made (total lymphocytes, CD4+, CD8+, NK cells, T-reg, IL-6, IL-10, IL-12, TNFa, TGFbeta1 and IFN-gamma). The addition of INF-beta-IL-2 sequence significantly prolonged clinical benefit and overall survival from conventional antiestrogens. During CB as opposed to progression, a significant immune stimulation was observed. During CB also a significant CEA, TPA, CA15.3 decrease occurred 24–72 h after interleukin-2 administration. At the progression a significant increase for CEA and for all three markers (standardized values) was found 24–72 h after interleukin-2 administration. In patients who survived less than five years, the Treg cell increase occurred at a significantly shorter time interval than in those who survived longer than five years (20 vs. 45.5 months, respectively; P=0.001). To further confirm these promising results, a multicenter prospective phase II trial is going to be launched by the Cancer Center Institute of Tuscany in Italy.

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