■ Article

Optimizing the Efficiency and Quality of Sipuleucel-T Delivery in an Academic Institution

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Background: Sipuleucel-T, an autologous cellular immunotherapy, is approved for the treatment of certain patients with metastatic castration-resistant prostate cancer (mCRPC). Sipuleucel-T is the first personalized treatment for prostate cancer to be manufactured using the immune system of each individual patient. Patient preparation and compliance are critical because patients undergo serial leukapheresis and reinfusion procedures within a relatively short time period, which may result in transient reactions.

Objectives: The study aims to identify patients best suited for sipuleucel-T treatment, provide an overview of treatment, and encourage infusion sites to consider a primary contact model for the efficient coordination of care.

Methods: Treatment experiences were evaluated from 124 patients with mCRPC who received sipuleucel-T from January 2010 to August 2013 according to current best practices. Feedback was collected from reflective interdisciplinary discussion within the sipuleucel-T delivery team (nurses, advanced practice providers, urologists, and medical oncologists).

Findings: Early patient identification and education on treatment rationale, delivery, and expectations help ensure a successful sipuleucel-T treatment experience. A multidisciplinary coordinated-care process can facilitate proficient sipuleucel-T delivery, and the selection of a primary contact for care coordination offers benefits, such as clear and efficient education.

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Sipuleucel-T is an autologous cellular immunotherapy approved by the U.S. Food and Drug Administration (FDA) in April 2010 for the treatment of asymptomatic or minimally symptomatic metastatic castration-resistant (previously termed "hormone-refractory") prostate cancer (mCRPC) (Dendreon Corporation, 2010). Sipuleucel-T is unique in its field as the first personalized treatment for prostate cancer manufactured using the immune system of each individual patient (Drake, 2010).

Research on sipuleucel-T has demonstrated statistically significant improvement in overall survival in men with asymptomatic to minimally symptomatic mCRPC being treated with sipuleucel-T. In the phase III Immunotherapy for Prostate Adenocarcinoma Treatment (IMPACT) trial, sipuleucel-T improved median survival by 4.1 months (25.8 months with sipuleucel-T versus 21.7 months with placebo), improved three-year survival by 38%, and reduced the relative risk of death by 22% compared with placebo ($p = 0.03$) (Kantoff et al., 2010) (see Figure 1).

An integrated analysis of two earlier phase III trials also indicated that sipuleucel-T was associated with a significant survival benefit (Higano et al., 2009; Small et al., 2006). However, neither study demonstrated a difference between sipuleucel-T and