T-Cell Enumeration Using Dried Blood Spots as a Surrogate for CD4+ T-Cell Counts to Monitor HIV+ Patients

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Technology description

Summary

Available for licensing and commercial development is a novel method for enumerating T-cells in HIV+ patients using dried blood spots, avoiding the need for fresh blood samples. The method relies on the distinctive nature of the TCR-beta gene, which undergoes a rearrangement during T-cell development that is required to produce a functional T-cell receptor protein. Since only mature T-cells contain a rearranged TCR-beta gene, the method quantifies the number of T-cells in a patient sample by quantifying the number of cells that contain a rearranged TCR-beta gene. In addition to dried blood spots, the assay can be also used with a wide variety of sample types from which T-cell counts were previously impossible to obtain, such as swabs and tissue slides. In addition, this method can be used for monitoring of a variety of T-cell leukemias/lymphomas, and easily adapted to monitor B-cell levels found in B-cell leukemias/lymphomas.

The assay was found to accurately predict TCR-beta levels ($r=0.985$, $p<0.0001$), and to correlate well with known CD4 counts ($r=0.670$, $p<0.0001$). Therefore, this novel method can be used to monitor HIV infection in order to determine antiretroviral therapy (ART) initiation and monitoring. A large international effort has been made to provide ART to the more then 33 million HIV+ people worldwide, but significant hurdles remain to large-scale implementation due to the lack of medical and laboratory infrastructure found in the developing world, where the majority of HIV+ individuals are found. In particular, a CD4 count, which requires fresh whole blood, a reliable cold-transport chain, and an expensive FACS based reader, is required to monitor patients and determine ART initiation. This requirement has become one of the largest impediments to expanding ART around the world. Therefore, this novel method provides a superior functional assay for HIV disease staging that does not require cold storage or fresh sample processing. Dried blood spots are an ideal sample collection method for large scale monitoring in the developing world due to the relatively simple manner in which samples can be obtained and the high stability of the sample in the absence of refrigeration. This method provides an easier and less expensive method for HIV monitoring for the developing world, and could be also used as an at home monitoring system for HIV-infected patients in developed countries.

Institution

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