Does risk stratification decrease the risk of natalizumab-associated PML? Where is the evidence?

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Abstract: The use of natalizumab has likely been limited by its association with progressive multifocal leukoencephalopathy (PML), an infection caused by the human polyomavirus John Cunningham (JC). Three factors were recently identified that contribute to the overall risk of natalizumab-associated PML: (1) Positive serostatus for anti-JCV antibodies, (2) prior use of immunosuppressants, and (3) duration of natalizumab therapy. This risk stratification algorithm has not led to a reduction in the incidence of PML in natalizumab-treated patients with multiple sclerosis between April 2010 and February 2014. This observation may appear perplexing, as treatment duration and JCV serostatus are modifiable risk factors. Potential reasons for the lack of success of companion diagnostics that determine the overall risk of natalizumab-associated PML are discussed.

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