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Natalizumab-associated melanoma: A report of 139 cases from the southern network on adverse reactions (SONAR)

Virginia Noxon and **Charles Bennett**
University of South Carolina, USA

Natalizumab is an effective immunosuppressive therapy for multiple sclerosis that received its initial FDA approval in 2004. Its most notable toxicity is progressive multifocal leukoencephalopathy (PML); an opportunistic infection that is the focus of an FDA mandated Registry (the Tysabri Outreach Commitment to Health (TOUCH) Outcomes Registry). The Southern Network on Adverse Reactions identified a fatal case of Natalizumab associated urethral melanoma and undertook an extensive evaluation of all cases of Natalizumab-associated melanoma included in the FDA's Adverse Event Reporting System (FAERS) (between 2005 and 2014). Characteristics of these patients and report quality were analyzed. Report quality was based on a 15 point scale of various components. The mean patient age at the time of diagnosis of melanoma was 46 (s.d. 11). Seventeen patients were diagnosed with cutaneous melanoma developing in non-sun-exposed areas. We found that cases reported through the TOUCH registry were of lower quality (mean score 7.7) compared to others that reported outside of the USA (mean score 8.5, $p<0.008$). Our findings suggest that in the United States, the TOUCH Registry should be expanded to require clinicians to report details of Natalizumab-associated melanoma, an opportunistic illness that frequently develops in immune-compromised persons. Also, the FDA-approved product label for Natalizumab should be revised to include information on occurrences of melanoma among Natalizumab-treated MS patients, particularly those who have cutaneous nevi prior to Natalizumab initiation. Natalizumab-treated MS patients and their physicians should be vigilant for changes in nevi's appearances and development of new cutaneous lesions (particularly in non-sun-exposed cutaneous areas).

Biography

Virginia Noxon is a PhD candidate at the University of South Carolina in Clinical Pharmacy and Outcomes Sciences. She joined SONAR last year and contributed to several of their publications over the past year.

vnoxon@gmail.com

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