

1. ABSTRACT

Title

An Observational, Cross-Sectional Survey to Assess PML Risk Awareness and Understanding From Patients' Perspective and Effectiveness of the Tysabri (Natalizumab) Patient Alert Card in the UK

Keywords

Tysabri, Multiple sclerosis (MS), Patient survey, Progressive multifocal leukoencephalopathy (PML), Patient Alert Card (PAC)

Rationale and Background

CCI [REDACTED] and noted that the effectiveness of the PAC as a risk minimization tool had not been measured CCI [REDACTED].

This study was designed to assess the effectiveness of the PAC in educating patients and their partners or caregivers on the risks of PML.

Study Objectives

- To estimate the proportion of patients who were aware of the risk of PML.
- To estimate the proportion of patients who received the PAC and who understood the key safety messages communicated on the PAC.

Study Design

This was an observational, cross-sectional study in patients enrolled in the UK MS Register with relapsing-remitting multiple sclerosis (RRMS) who were receiving Tysabri. A survey was conducted to assess basic PML knowledge and the effectiveness of the PAC in conveying this knowledge to patients.

Setting

Inclusion Criteria:

- RRMS patients currently receiving or had stopped receiving Tysabri 6 months before the survey.
- Patients ≥ 18 years who could read and understand English.

Subjects and Study Size, Including Dropouts

A total of 460 patients were enrolled in the study.

Variables and Data Sources

The survey included questions related to treatment history with Tysabri, basic knowledge of PML, patient adherence to the PAC (patient-related metrics), and healthcare

professional (HCP) contributions in communicating the risk of PML (HCP-related metrics).

Patients' baseline characteristics were extracted from the UK MS Register and linked to survey results.

Key Results

Basic knowledge of PML (N = 460)

- 52.3% of responders were able to answer most basic PML knowledge questions correctly.
- 51.1% knew PML can occur up to 6 months after stopping Tysabri.
- 97.2% of responders knew PML could occur in patients treated with Tysabri, and 72.0% were aware that management of PML requires immediate discontinuation of Tysabri.
- 40.4% had a partner or caregiver who was aware of the signs and symptoms of PML.

Receipt of the PAC (N = 450)

- 70.0% of patients received a PAC for Tysabri.
- Among PAC receivers, 76.5% still had it, and of these patients, 95.4% had read it.

Patient-related metrics (N = 450)

- On average, patients answered more questions on PML correctly when they had read the PAC, still had it with them, and had a partner or caregiver aware of it (all $p < 0.001$).

HCP-related metrics (N = 450)

- On average, patients answered more questions on PML correctly when they received the PAC and had its purpose explained to them (both $p < 0.001$).

Discussion

Knowledge of PML in this study was high; almost all patients knew PML is a risk associated with Tysabri use that can lead to severe disability or death and when to seek immediate medical attention. Furthermore, almost all patients reported receiving the PAC (70.0%), and those who had received, read, and still carried the PAC had better basic knowledge of PML than those who did not.

This study demonstrates that the current Tysabri PAC effectively educates patients and their partners or caregivers on the risks of PML. Therefore, we conclude that no change to the PAC is necessary.

Marketing Authorization Holder

Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

Names and Affiliations of Principal Investigators

Rod Middleton
Swansea University, Wales, United Kingdom