

The Use of Natalizumab and previous disease-modifying therapy (DMT) in cohort of Patients with Multiple Sclerosis

A. Katerina Ferencova, Brian Sweeney, Ethna Mitten, Eileen O' Mahony
B. Department of Neurology, Cork University Hospital, Cork, Ireland

ABSTRACT

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•TITLE: Use of Natalizumab and previous disease-modifying therapy (DMT) in cohort of Patients with Multiple Sclerosis (MS)

• BACKGROUND:

•Natalizumab is humanized monoclonal antibody targeting VLA-4 integrin. It is approved for relapsing remitting MS. Totally 4 patients developed Progressive Multifocal Leukoencephalopathy (PML), caused by JC virus (JCV) occurring in immuno-suppressed patients. TOUCH and TYGRIS observational studies collect data regarding the safety of natalizumab in USE and worldwide.

•OBJECTIVE:

•To study the safety and effectiveness, side effects, allergy reactions, relapse rates, previous DMT in the cohort of patients with Multiple Sclerosis (MS) treated with natalizumab.

•METHODS:

•Prospective observational ongoing study of 45 patients with MS treated with natalizumab. Data cover patient's age when diagnosed with MS, age of first symptom, neurological presentation of the first symptom, age, previous DMT their mean duration, need of walking aid and need intermittent self-catheterisation, number of relapses prior treatment. Patients were objectively assessed with EDSS (Expanded Disability Status Scale) in month 1, 3, 6, 9, 12 of the treatment. MRI scan of brain and cervical spine with gadolinium is performed within 12-15th month of the therapy with natalizumab. Routine bloods and questionnaire regarding allergic and infusion related reactions, side effects, infections or clinical progression before infusion given.

•RESULTS:

•5 patients (10%) developed allergic reactions after natalizumab infusion and were withdrawn from this therapy. 3 patients (4%) withdrawn from (1 patient became pregnant).

•20 patients (44%) need walking aid and 11 (24%) require intermittent self-catheterization.

•The mean number of relapses prior therapy with natalizumab is 7.67.

•Previous DMT treatment see table 2

•1 patient was treated with IVIG and plasma exchange and 1 patient reported that was using low dose Naltrexone (LDN) as alternative therapy. •EDSS see table 5.

•19 patients (42%) have been on natalizumab therapy more than 1 year (mean 14.21 months). From those 68.4% have been relapse free or stable for one year and 21.05% experienced 1 or maximum 2 relapses in first year. The mean EDSS in month 12 of these 19 patients is 4.9.

•5 patients (10%) developed allergic reactions after natalizumab infusion and were withdrawn from this therapy. 2 patients (4%) withdrawn from treatment and 1 patient became pregnant and subsequently withdrawn and reported to natalizumab pregnancy



RESULTS

FIRST NEUROLOGICAL SYMPTOM

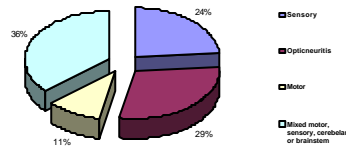


Table 1

DMT PRIOR NATALIZUMAB TREATMENT

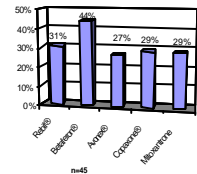


Table 2

MEAN DURATION OF PREVIOUS DMT

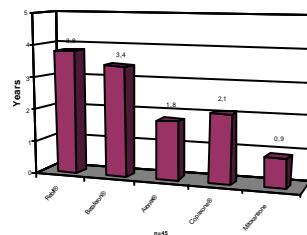


Table 3

HISTORY OF OPTIC NEURITIS (ON)

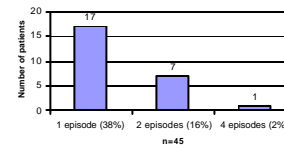


Table 4

Evaluation of clinical progress on natalizumab therapy using EDSS

Month	1	3	6	9	12*
mean EDSS	4.2	4.3	4.3	4.3	4.9

*Note: EDSS in 12 months was assessed only in 19 patients (42%).

Table 5

CONCLUSIONS

- Natalizumab is effective drug but the data on safety, interactions and long term effects are still awaited.
- 10% of our patients developed allergic reactions in our cohort.
- There is a need for careful monitoring of the patients during the therapy with natalizumab.



These guidelines are authored by The Irish Nurse Advisory Group for MS patients and follow an Advisory Board organized and sponsored by Biogen Idec (Ireland) Limited. They reflect best practice standards for the administration of TYSABRI (natalizumab) as of May 2008.

[Irish National Infusion Guidelines for TYSABRI® \[natalizumab\]](#)

Stage 1

Pre-infusion: (Within three months of commencing treatment)

- MRI
- Neurological assessment as per standard of care
- Patient education
- Information pack
- Discuss risks / benefits/side effects
- Management of patient expectations (e.g. time taken for each infusion including pre and post review)
- Baseline bloods (FBC, LFTs) these should be done no more than 2 weeks prior to 1st infusion.

Stage 2

1st Infusion

- Ensure requirements in Step 1 are complete.
- Standard nurse care plan to include medical history, allergies e.t.c
- Ensure patient has Patient AlertCard
- Ensure Patient has consented (verbal consent is sufficient) & prescription is available
- Complete pre infusion check-list questionnaire with patient [Attached]
- Temperature, pulse, respirations and blood pressure to be monitored pre and post infusion.
- Send standardized letter to GP [Attached]
- Schedule next appointment with patient.
- Pregnancy test not routinely recommended unless suspected or mandated by hospital management
- Check that emergency equipment and medication at hand to deal with hypersensitivity reaction should it occur.

Stage 3

2nd and subsequent infusions

- Standard nurse care plan updated
- Complete pre infusion check list questionnaire with patient
- Temperature, pulse, respirations and blood pressure to be monitored pre and post infusion
- Ensure patient is carrying their Patient Alert Card
- Ensure increased observation for hypersensitivity and infusion -related reactions during the first three infusions or first three infusions following a prolonged break in treatment