

4CPS-137

NATALIZUMAB: A REVIEW OF ITS USE IN THE MANAGEMENT OF MULTIPLE SCLEROSIS, EXPERIENCE IN A UNIVERSITY HOSPITAL

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Background

Natalizumab is the **first** licensed treatment, given by **infusion**, monthly, for highly active relapsing remitting multiple sclerosis (**SMRR**) or rapidly evolving **severe MS**. Is not a cure, its safety issues represent a relevant limitation and impose strict clinical surveillance mainly because of risk of **PML** (progressive multi-focal leukoencephalopathy) a potentially lethal brain disorder.

Purpose

Review of use: effectiveness, safety, reason for start or switch.

Methods

- ✓ Retrospective observational study, from January 2015 to December 2018.
- ✓ Patients with chronic treatment for years.
- ✓ Treatment history, demographic and clinical data was collected from the patients' medical records.
- ✓ **Effectiveness** was assessed by the change in **EDSS score**-expanded disability status scale (improvement/stability/worsening) and by **number of outbreaks**.
- ✓ **Safety** was assessed by incidence of adverse reactions and risk of PML-stratified in high/medium/low, based on 3 major risk factors algorithm.

Results

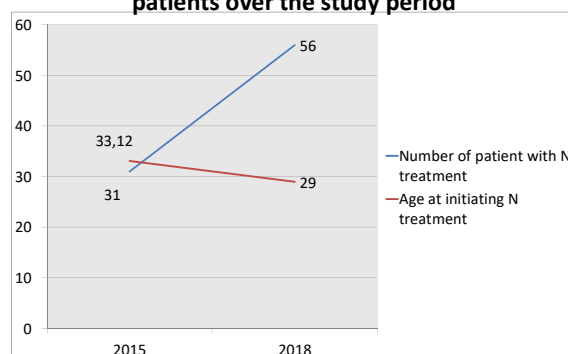
Review of Natalizumab use shows:

| | |
|-----------------------------------|---|
| Patients | N=56 (57% women) |
| Age at diagnosis | Median= 26,4 years |
| EDSS baseline | Median score = 2 (still ambulatory) 93% prior to natalizumab |
| Number of patients with outbreaks | Only 15% after 12 months of natalizumab |
| Treatment duration | Mean=3,3 years (1-10) |
| Treatment history | First option natalizumab=11 patients Switch from other immunomodulatory=45 |
| Treatment discontinuation | 5 patients (1 left for PML and 4 for inefficacy) |
| Risk of PML | n=40 patients no risk (<1:10000) and n=16 patients moderate risk. |

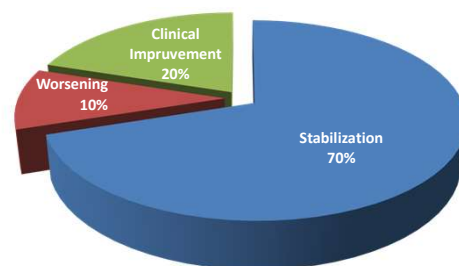
Conclusion

Natalizumab provides efficacy in **slowing disease progression** and **reducing relapses**, effective particularly in patient with less disability and without prior treatment. As long the risk of PML is managed effectively and patients are constantly informed about their benefit - risk level, remains a valuable therapeutic option.

Evolution of age and number of treated patients over the study period



Change in EDSS



- Improvement-a decrease of ≥ 1 point-(20%)
- Stability-a change of < 1 point(70%)
- Worsening- an increase of ≥ 1 point (10%)

