

## EVALUATION OF TREATMENT WITH NATALIZUMAB THERAPY ON TRIPLE RISK PACIENTS REGARDING PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

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### BACKGROUND

Natalizumab approved for the treatment of RRMS (relapsing-remitting multiple sclerosis) since 2006 is associated with development of PML (progressive multifocal leukoencephalopathy), a serious opportunistic brain infection caused by JCV (John Cunningham Virus) that usually leads to death or severe disability.

### OBJECTIVE

Because no one can predict who will get PML, we try to evaluate Natalizumab benefit-risk ratio regarding PML, "on triple risk" patients:

- Long term Natalizumab treated (more than 2 years);
- Immunosuppressive pretreatment;
- JCV antibody positive status;

It is known that patients with all of the above risk factors have a significantly higher risk for PML (13/1000) than general probability 2,1/1000.

### METHODS

Retrospective observational study including patients with at least one of the three risk factors for PML.

Different variables were obtained from medical records of Neurology Department databases .

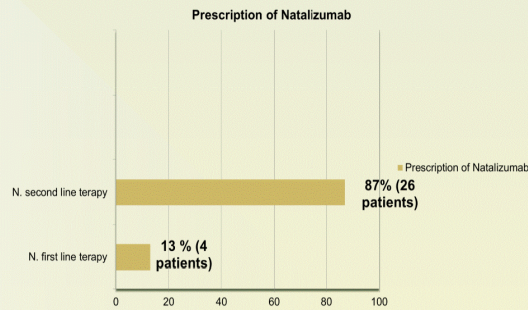
- Patients characteristics (age, gender);
- Clinical data
- Treatment related information (previous and concomitant treatments, Natalizumab exposure, outcome of treatment);

### RESULTS

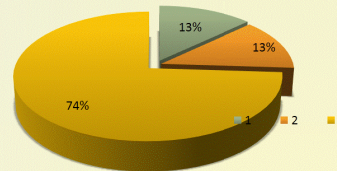
#### DATA ABOUT PATIENTS

- 30 patients Included: 21 9
- Mean age: 36,6 [22;55]
- Mean time from Natalizumab exposure: 37 months

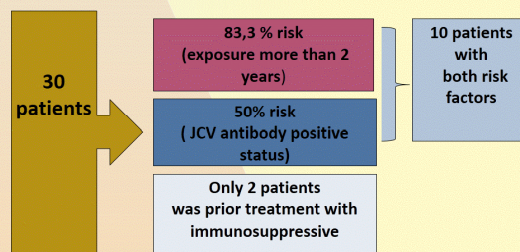
### REASONS TO USE NATALIZUMAB



### NATALIZUMAB TREATMENT DISTRIBUTION



### TRIPLE RISK FACTORS DISTRIBUTIONS



### CONCLUSIONS

- Estimating or accurately predicting an individual's risk of PML is still a major challenge. Natalizumab shows on 97% patients:
- Better results than expected despite the triple risk factors distributions;
- Good profile benefit/risk even after long time Natalizumab exposure;
- One case was suspected of PML – suggestive MRI lesions, positive JCV, exposure >5 years, despite negative JVC-DNA , correlated with JCV antibody index value 3,37 - PML was confirmed;

Natalizumab remain one of the most effective therapies alternative to immunomodulators non-responders and for PML risk management on all this patients is crucial to evaluate periodically if expected benefit with Natalizumab is enough to outweigh the risk.