Natalizumab: effectiveness and safety in patients with relapsing-remitting Multiple Sclerosis in a tertiary hospital .

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Background

Natalizumab is indicated in relapsing-remitting Multiple Sclerosis (RRMS) with high activity despite treatment with Interferon B and Glatiramer Acetate and in rapidly evolving severe RRMS.

Purpose

To analyze efficacy, safety and appropriate Natalizumab use in patients with RRMS.

Material and Methods

Observational, retrospective study including patients with natalizumab at the time of data collection(August 2014). Data were obtained from medical records and electronic prescription programme.
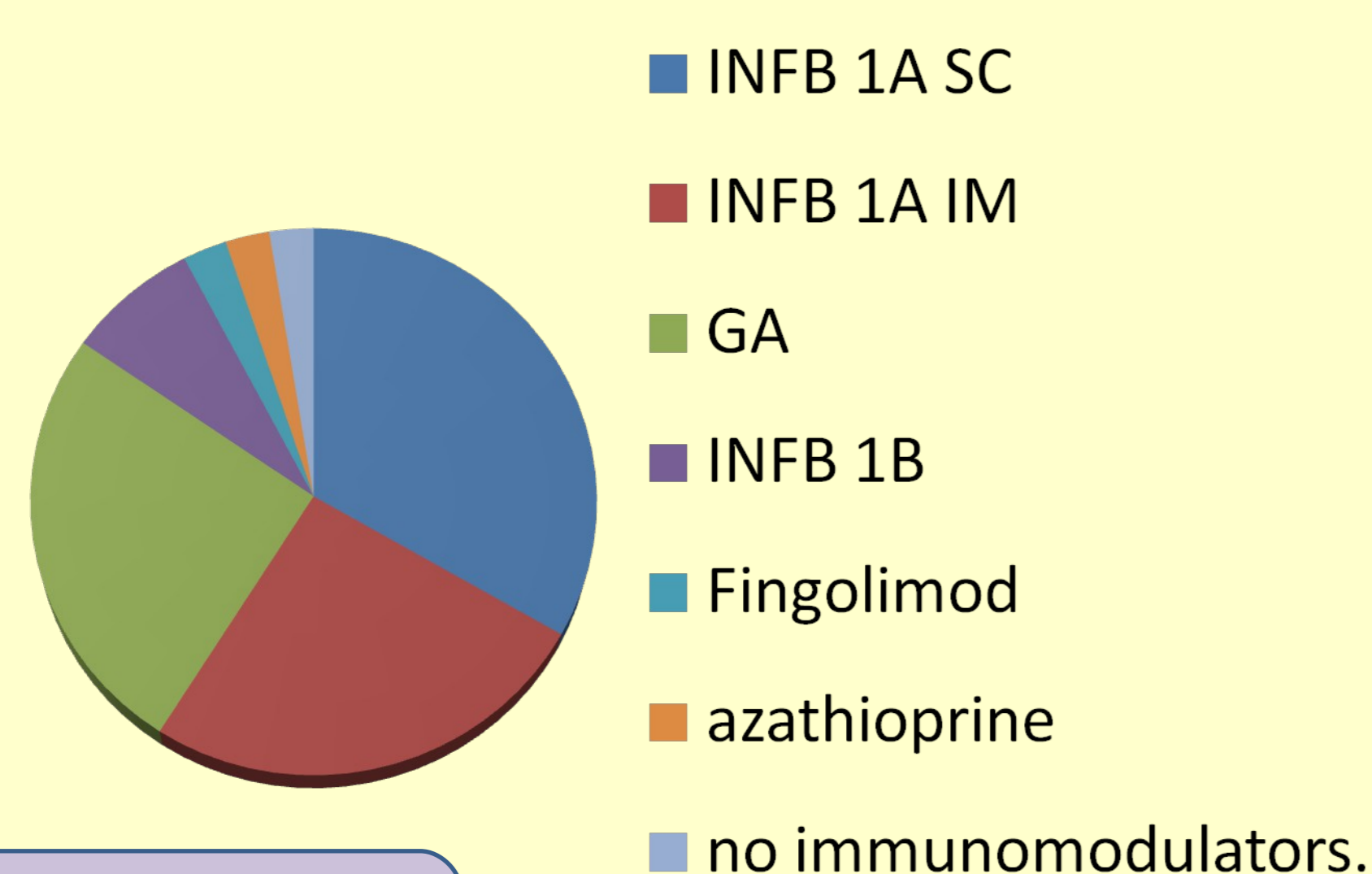
Variables included:

Demographics(age and sex), time from diagnosis, time with natalizumab, indication, previous treatments, pre/post disability (EDSS), outbreaks before/after change, JC virus antibodies, adverse reactions (ADRs), discontinuations and causes in 2013.
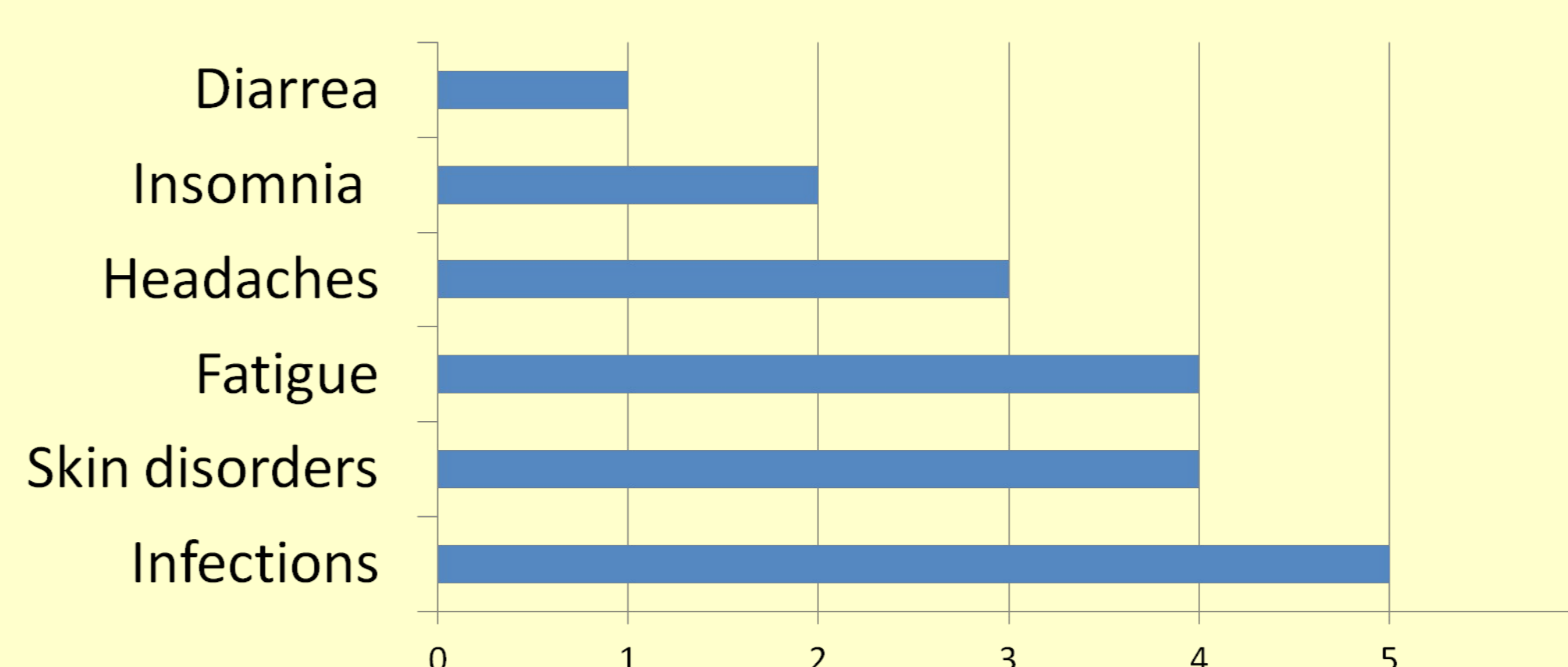
Results

24 patients: 58.3% women., mean age 37.8 years, median time from diagnosis 9.3 years and with Natalizumab 36.6 months.

MS with high activity for lack of efficacy with INF/GA(54.1%) and rapidly evolving severe MS(45.9%) .

Before mean EDSS = 4.35 (4 absent data). After mean EDSS = 4.64 (10 absent data).

Mean outbreaks before changing = 2.13. Only 6 patients had outbreaks during treatment and 3 of them during 2013.

Previous treatments received

- INFB 1A SC
- INFB 1A IM
- GA
- INFB 1B
- Fingolimod
- azathioprine
- no immunomodulators.

ADRs

33.3% patients had JC+ antibodies.

Conclusions

- Our baseline characteristics and selected variables are not always comparable with the reference clinical trial (CT). Our small sample size and the daily clinical practice characteristics of our patients make difficult an exhaustive comparation. However, as in the CT, our population presented a maintained EDSS, with a decrease in outbreaks and the ADRs were consistent with the most frequent observed in the CT.
- With these results, and according to published studies[1,2], Natalizumab demonstrates to be an effective alternative for immunomodulators non-responders.

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