Second-line Use of Fingolimod in RRMS is as effective as Natalizumab

Stefan Braune, Michael Lang & Arnfin Bergmann on behalf of the NTD Study Group

INTRODUCTION

- In Europe, both natalizumab (Tysabri®) and fingolimod (Gilenya ®) have obtained approval for the second-line treatment of relapsing-remitting multiple sclerosis (RRMS).
- There are no head-to-head clinical studies comparing the efficacy of fingolimod with natalizumab
- Nixon et al.[1] demonstrated by using a modelling approach that fingolimod has similar efficacy to natalizumab for decreasing relapse rate and disability progression in patients with RRMS, when differences in patient characteristics and endpoint definitions were taken into account.
- However, in the absence of direct comparative studies, conclusions from statistical modelling should be interpreted with caution.

OBJECTIVES

- Strong efficacy of second-line DMDs is of major importance to prevent further disease progression in highly active MS.
- No data comparing the efficacy of natalizumab with fingolimod in real-life settings or observational studies have been published yet.
- In the present naturalistic study we provide the first large-scale clinical real-life data on both natalizumab and fingolimod.

METHODS

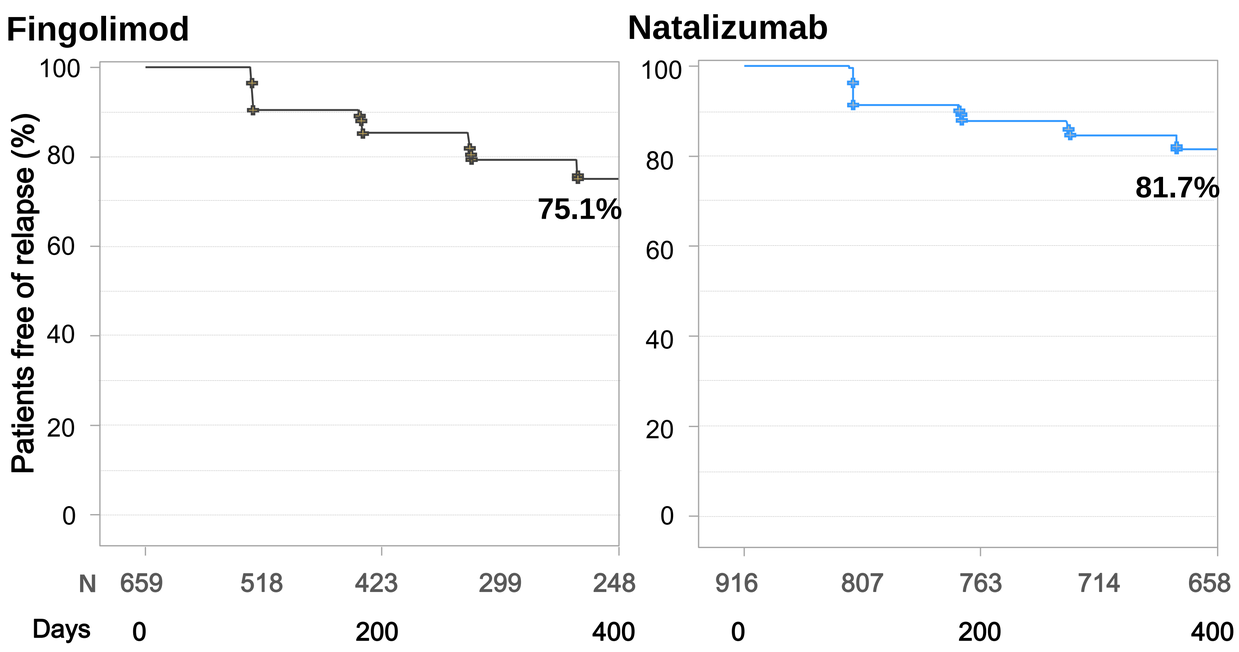
- This study is a multi-center prospective observational study conducted by the German NeuroTransData (NTD) study group.
- NTD operates a real-time database to document clinical data of outpatient MS patients prospectively approved by the Ethical Committee of the Bayerische Ärztekammer Germany.
- All natalizumab and fingolimod patients (documented between 01/01/08 and 8/31/12) were included if the observation has been initiated at least 6 months prior to second-line therapy (no selection bias).
- Clinical examinations were conducted every three months in accordance with German treatment guidelines.
- Relapse- and progression free survival was assessed using the Kaplan Meier method. Progression was defined as an increase of 1 point on the EDSS if Baseline EDSS was less than 5.5 and 0.5 point if Baseline EDSS was greater or equal to 5.5. Patients who did not have a relapse or progression at the end of the observational period or who were lost to follow-up without a relapse or progression were censored.
- Change in EDSS was defined as any change, regardless of the baseline EDSS

Table 1. Baseline demographics of natalizumab and fingolimod patients

Parameter	Natalizumab	Fingolimod
Number of patients	455	461
Females - percent	71.5	71.1
Mean age - years	37.15 ± 9.9	40.25 ± 9.4
Mean EDSS	3.2 ± 1.9	2.6 ± 1.5
Mean annualized relapse rate	1.29 ± 5.9	1.02 ± 4.3
Mean time since diagnosis - years	9.15 ± 6.9	9.89 ± 6.9

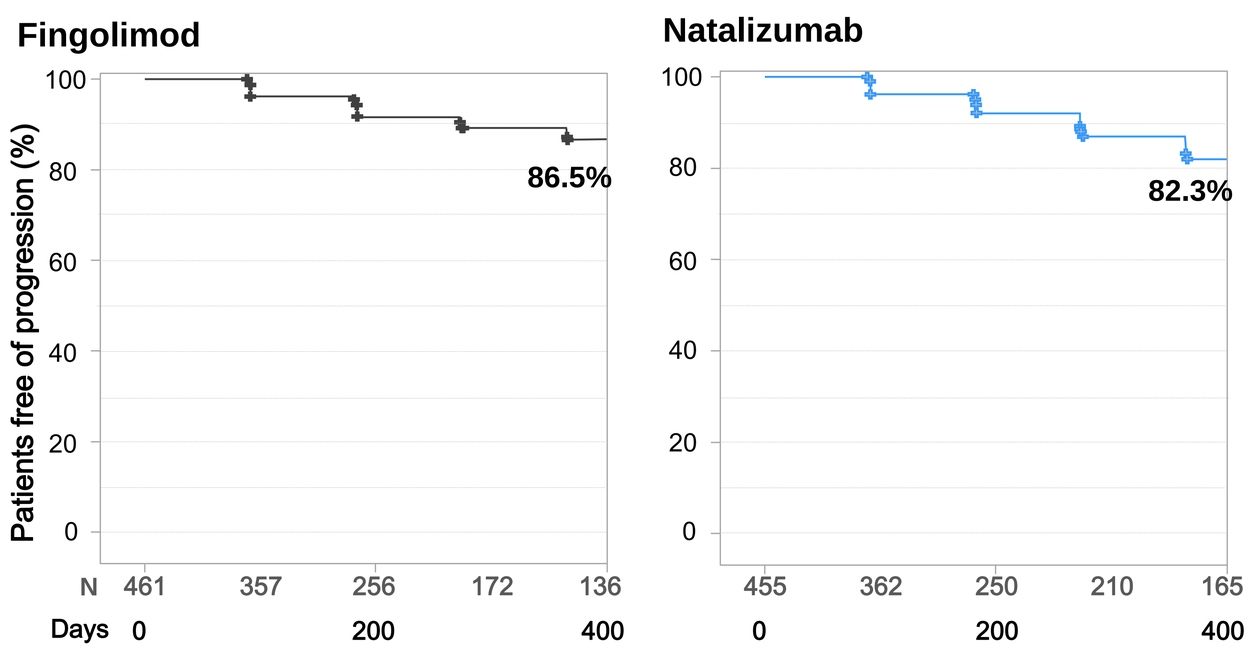
RESULTS

Figure 1. Proportion of patients free of relapses since treatment initiation



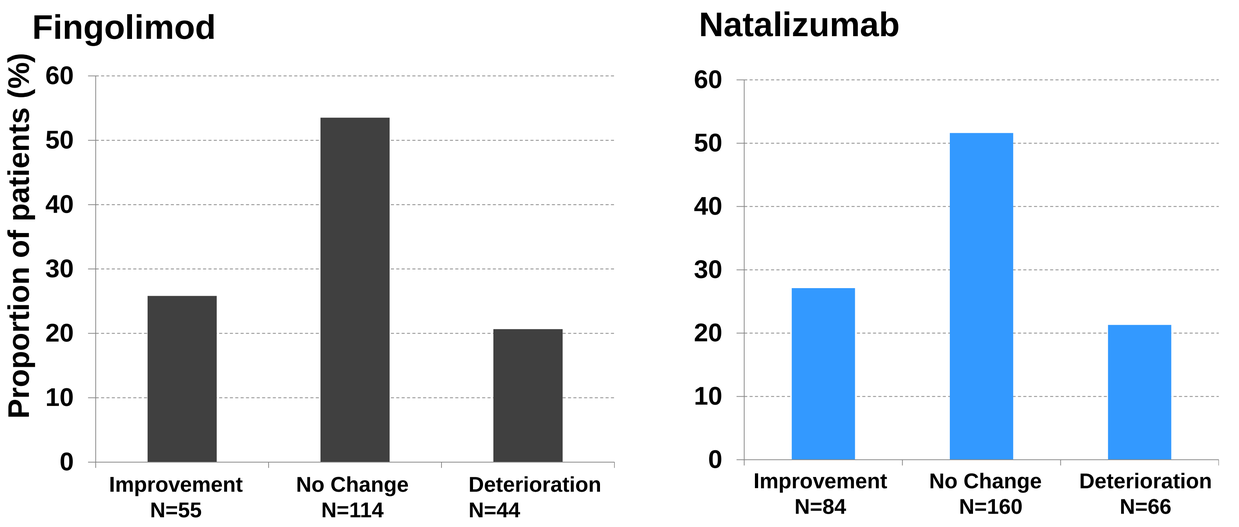
- After one year more than 75% of both natalizumab and fingolimod patients were free of relapses.

Figure 2. Proportion of patients free of EDSS progression since treatment initiation



- After one year more than 80% of both natalizumab and fingolimod patients were free of EDSS progression.

Figure 3. Mean EDSS change after 12 months of treatment



- Improvement of disability was frequently observed in both natalizumab and fingolimod patients to a similar extent.

CONCLUSIONS

- These real-life data demonstrate equal efficacy of natalizumab and fingolimod to prevent relapses and disability progression in a large German MS cohort of 916 patients with insufficient control of disease activity by first-line therapy.
- These data are in line with previously published data on efficacy from phase III trials[2, 3] for both substances.
- Further, the present observational study confirms findings from indirect comparisons in a real-life setting and may provide guidance for treatment decisions in highly active MS.

DISCLOSURES

All authors were either speakers, advisory board members, consultants, or received honoraria involving many German pharmaceutical companies in accordance with the guidelines of the German FSA Code of Conduct for Interaction with Healthcare Professionals and the Medical Association´s professional code of conduct.

REFERENCES

1. Nixon et al. 2012. Poster was presented at the European Neurological Society, 9–12 June 2012
2. Kappos L et al. N Engl J Med 2010;362:387–401.
3. Polman CH et al. N Engl J Med 2006;354:899–910.

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