



THE EFFECTIVENESS OF NATALIZUMAB AND FINGOLIMOD IN RELAPSING-REMITTING MULTIPLE SCLEROSIS. AN OBSERVATIONAL MULTICENTRE ITALIAN STUDY



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Background and aims

Both natalizumab (NTZ) and fingolimod (FTY) are highly effective in the treatment of relapsing-remitting multiple sclerosis (RRMS). However, no head-to-head clinical trials have been conducted so far and observational studies comparing the efficacy of the two drugs have produced conflicting results. The aim of this study was to investigate the efficacy of NTZ and FTY in a cohort of RRMS patients in an observational, retrospective study of prospectively collected data.

Methods

We included all consecutive RRMS patients who started NTZ or FTY in three Italian MS centres with a follow-up till 24 months, collecting clinical (relapses, EDSS score) and brain MRI data. We used propensity score (PS) matching analysis to compare the two treatment groups.

Results

From our database of 281 patients, after 1:1 PS matching, we compared 102 patients in both groups, with similar baseline features.

Tab. 1 Baseline demographic, clinical and radiological features of treatment groups after propensity score matching

Characteristics	Matched		p
	NTZ (102 pts)	FTY (102 pts)	
Age at therapy start (mean±SD)	36.3±8.59	38.2±9.06	ns ^a
Sex %F	50%	50%	ns ^b
MS centre (PR/MO/FE)	33/28/41 (32.4/27.5/40.2%)	35/29/38 (34.3/28.4/37.3%)	ns ^b
Baseline Gd+ lesions % pts	22.5%	22.5%	ns ^b
AIFA % criterion A	81.4%	90.2%	ns ^b
Number of relapses in the previous year (mean±SD)	1.3±0.93	1.2±0.91	ns ^a
EDSS baseline (mean±SD)	3.1±1.35	3.2±1.58	ns ^a
Disease duration (mo) (mean±SD)	91.5±90.07	115.9±81.33	0.04 ^a

AIFA prescription criteria:
Criterion A: pts not responders to first-line treatments
Criterion B: pts naïve with highly active disease

^a t-Student's test ^b χ² test

Fig. 1 Annualized relapse rate (ARR) (24-mo f-u)

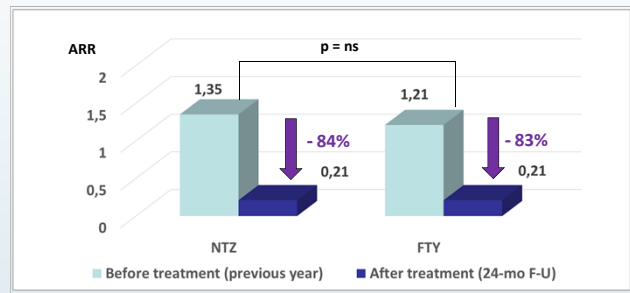


Fig. 2 Patients with MRI combined unique activity (≥ 1 Gd+ lesion and/or ≥ 1 T2 new/enlarged T2 lesion) (24-mo f-u)

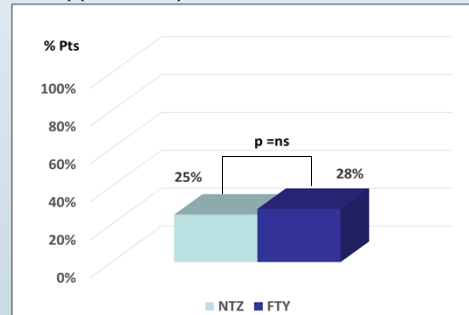


Fig.3 Patients with 6-month confirmed disability progression (24-mo f-u)

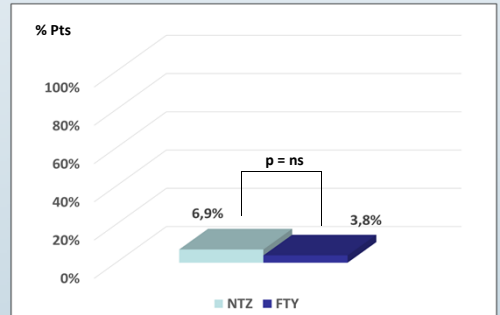


Fig. 4 Patients with no evidence of disease activity (NEDA-3) (24-mo f-u)

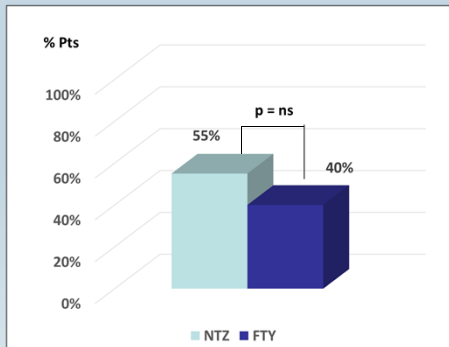


Fig.5 Relapse-free patients (24-mo f-u)

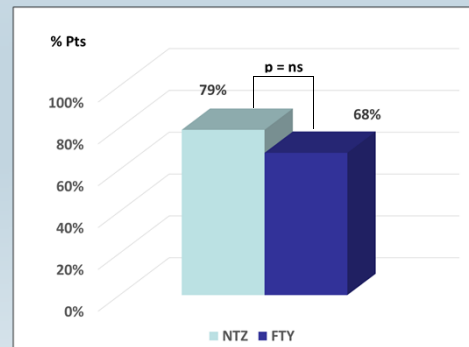
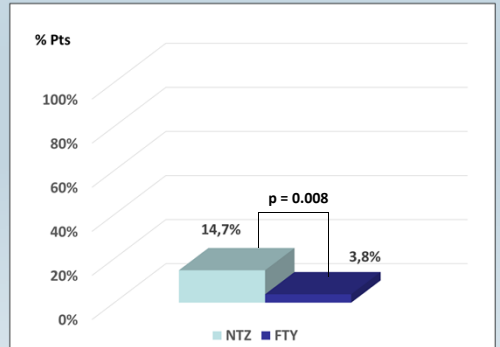


Fig. 6 Patients with confirmed disability regression (24-mo f-u)



Conclusions

Both NTZ and FTY were highly effective in our cohort. NTZ was superior in inducing regression of disability.

References

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