# Over time determinants of first therapy choice in newly diagnosed MS patients: a multicentre Italian study

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## Background:

Awareness of early treatment relevance and availability of new therapeutic options are rapidly changing MS therapeutic scenario. Guidelines for treatment management are not established yet and drivers of choice among drugs have never thoroughly investigated.

## Aim

To provide a snapshot of first treatment timing and choice prior to the introduction of new therapies (namely teriflunomide, dimethylfumarate and alemtuzumab), in a large Italian MS population.

## Patients & Methods

Newly diagnosed patients between Jan 2010 and Dec 2014 were included in the study. Baseline demographic, clinical and MRI data were correlated with first disease modifying treatment choice and timing. Heterogeneity among centres in the first therapeutic approach was evaluated. Chi square test was used to assess heterogeneity among centres and logistic regression to evaluate the association of baseline factors with treatment choice. All significant characteristics in univariate analysis were considered into the multivariate model. A p-value < 0.05 was considered statistically significant. SPSS (v.20) was used for computation.

## Results

Data on 993 MS patients (female=66.4%) from 14 Italian MS centres were collected (**Table 1**).
High heterogeneity in first treatment choice was detected among centres (p<0.001). The median time to treatment start from diagnosis was 38 days (range=0-1209) and it was highly heterogeneous among centres (p<0.001).

Older patients with comorbidity at baseline, with a lower lesion load and a lower disability were more probably treated with GA instead of IFN (**Table 2**).

Younger with an higher baseline EDSS, presence of active lesions on baseline MRI and higher relapse rate were associated with the choice of FTY or NTZ vs injective therapies. (**Table 3**)

**Table 1 – Clinical and demographic characteristics at baseline**

| Characteristics | N = 993 |
|---|---|
| Age at diagnosis, mean (SD) | 34.5 (11.1) |
| Female, n(%) | 659 (66.4) |
| EDSS at diagnosis, median (Range) | 2 (0 – 7) |
| Relapses in the previous year, median (Range) | 1 (0 – 4) |
| Active lesions at baseline, n/N(%) | 424/890 (47.6) |
| Baseline spinal cord lesions, n/N(%) | 511/761 (67.1) |
| Comorbidities, n/N(%) | 196/790 (24.8) |
| First therapy, n(%) | |
| IFNb1a-im | 201 (20.5) |
| IFNb1a-sc | 334 (34) |
| IFNb1b | 174 (17.7) |
| Glatiramer acetate (GA) | 156 (15.9) |
| Fingolimod (FTY) | 27 (2.7) |
| Natalizumab (NTZ) | 65 (6.6) |
| Others | 25 (2.6) |

**Table 2 – Characteristics driving to GA vs IFN treatment**

| Characteristics | Multivariate logistic [OR (95% CI)] |
|---|---|
| Age at diagnosis (1-year increase) | 1.04 (1.02 – 1.06); p < 0.001 |
| Comorbidity at baseline | 2.02 (1.27 – 3.24); p = 0.003 |
| T2 lesions < 9 | 1.60 (0.96 – 2.66); p = 0.072 |
| EDSS < 2.5 | 1.62 (0.92 – 2.85); p = 0.094 |

OR: Odds-ratio; CI: confidence interval

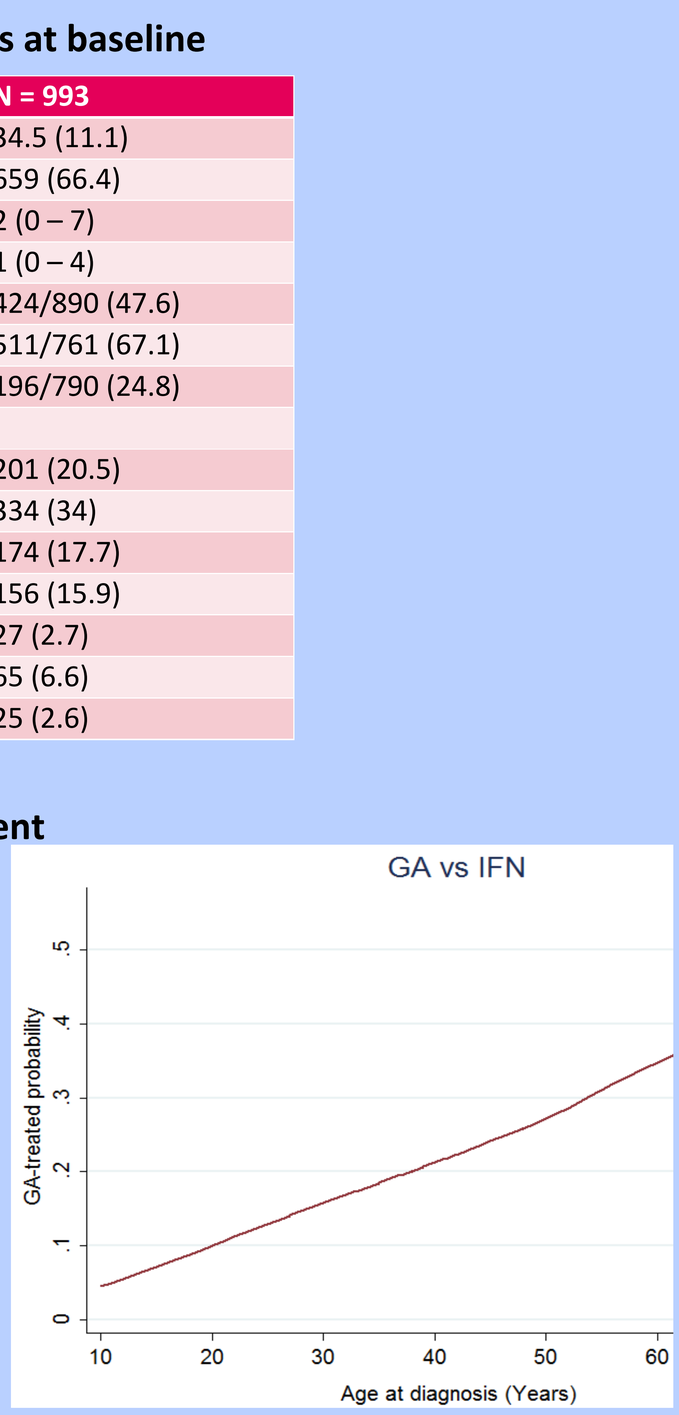


**Table 3 – Characteristics driving to FTY/NTZ vs Injectable (GA/IFN) treatment**

| Characteristics | Multivariate logistic [OR (95% CI)] |
|---|---|
| Age at diagnosis (1-year increase) | 0.97 (0.94 – 1.00); p = 0.026 |
| Baseline EDSS (1-point increase) | 2.17 (1.64 – 2.88); p < 0.001 |
| Active brain lesions at baseline MRI | 2.06 (1.08 – 3.97); p = 0.03 |
| Baseline spinal cord lesions | 2.24 (1.04 – 4.80); p = 0.039 |
| Relapses one year before (1-unit increase) | 1.61 (1.02 – 2.52); p = 0.039 |

OR: Odds-ratio; CI: confidence interval

## Conclusions

These data are part of a larger study aimed at understanding how MS therapeutic scenario is going to change after the introduction of new oral drugs.
For the time being, our data highlight the early treatment and the widespread use of IFN over GA as first therapy, with older age, comorbidities, lower disability and lower lesion activity driving to GA treatment respect to IFNs.
Higher relapse rate and disability, MRI activity and younger age are, instead, drivers of second line therapy.

## References

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