# Sex and baseline lymphocyte count as predictors of early Fingolimod-induced lymphopenia.

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## OBJECTIVES

Risk factors which could affect Fingolimod (FTY)-induced lymphopenia are still undiscovered. This study was conducted to assess predictive variables of lymphopenia in a cohort of 160 FTY treated relapsing Multiple Sclerosis (MS) patients at the first month of therapy.

## METHODS

We collected clinical and demographic data of all patients *(Table1)* at the start of FTY (**T0**): current age, sex, disease duration, previous treatment with other Disease Modifying Drugs (DMDs). Total lymphocyte count (LC) was assessed at T0 and after 1 month of therapy (**T1**) by flow cytometry.

A ***cut-off value of 892 lymphocytes/ul*** was identified ***to define lymphopenia***, obtained from lymphocytes medium value at T0 -2 standard deviations. To correlate LC and clinical and demographic variables non parametric tests were performed (Spearman test). Simple and multivariate logistic regression models, adjusted for age and sex, were used to identify predictive factors of lymphopenia.

***Table 1*** *Patients characteristics*

| | |
|---|---|
| **Sex (F/M)** | **106/54** |
| Age at FTY start,years | 38.3±9 |
| Disease duration,years | 12.5±7.3 |
| Previuos DMD before FTY | |
| • IFN/GA | 141 (97/44) |
| • NTZ | 16 |
| • Naive | 3 |
| Wash-out period before FTY, days | |
| • IFN | 76.5±207.7 |
| • GA | 89.7±168.4 |
| • NTZ | 171.9±100 |

## RESULTS

Sixty-seven percent of our cohort was female. The mean age was 38.3±9 years. One-hundred and fifty seven patients were previously treated with other DMDs; 3 patients were “naïve”. Previous treatment duration was 2.5±2.6 years and wash-out period before FTY was 90±190 days.

We observed a direct ***correlation between LC at T0 and the duration of wash-out period*** from last DMD (***r=0.18; p=0.02***), while LC value at T0 was not affected by the type of DMD previously used. ***Female sex*** (***beta=-0.13; p=0.04***) *(Figure 1)* and a ***lower LC at T0*** (***beta=0.43; p<0.001***) *(Figure 2)* were correlated with ***a lower LC at T1***.

The cut-off value of lymphopenia was reached in 83.8% of patients at T1. ***LC at T0*** resulted a ***predictive factor of*** developing ***lymphopenia*** with values ≤ 892 lymphocytes/ul at T1 (***p<0.0001; OR=0.99; IC 95%: 0.99-0.99***).

***Figure 1*** *Correlation between sex and LC at T0 and T1*

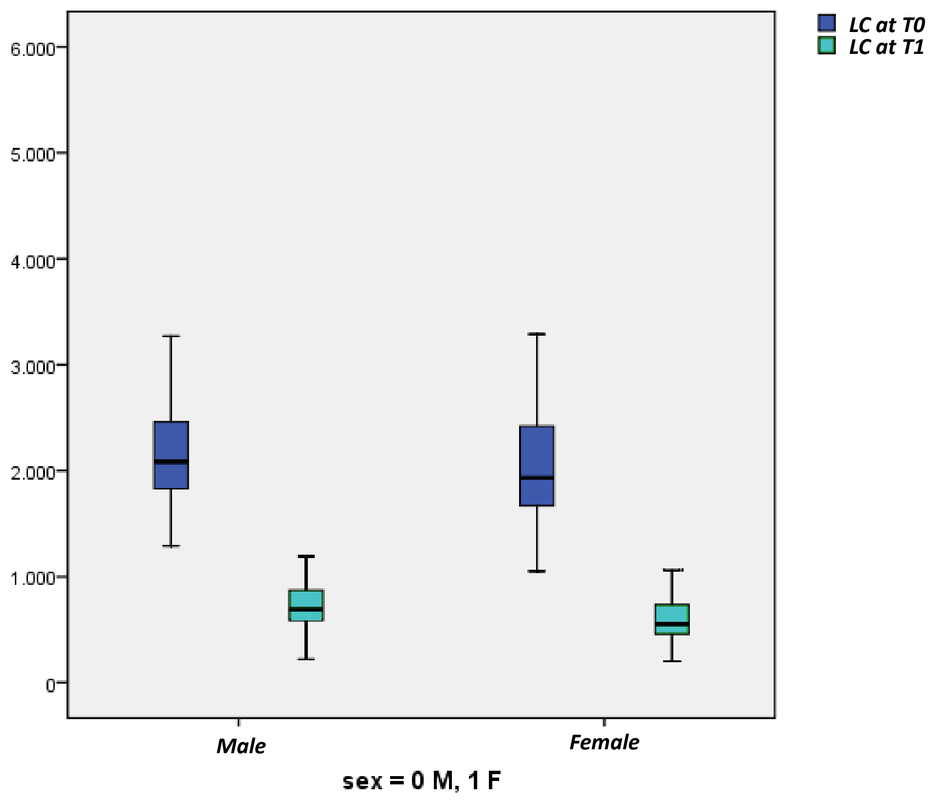
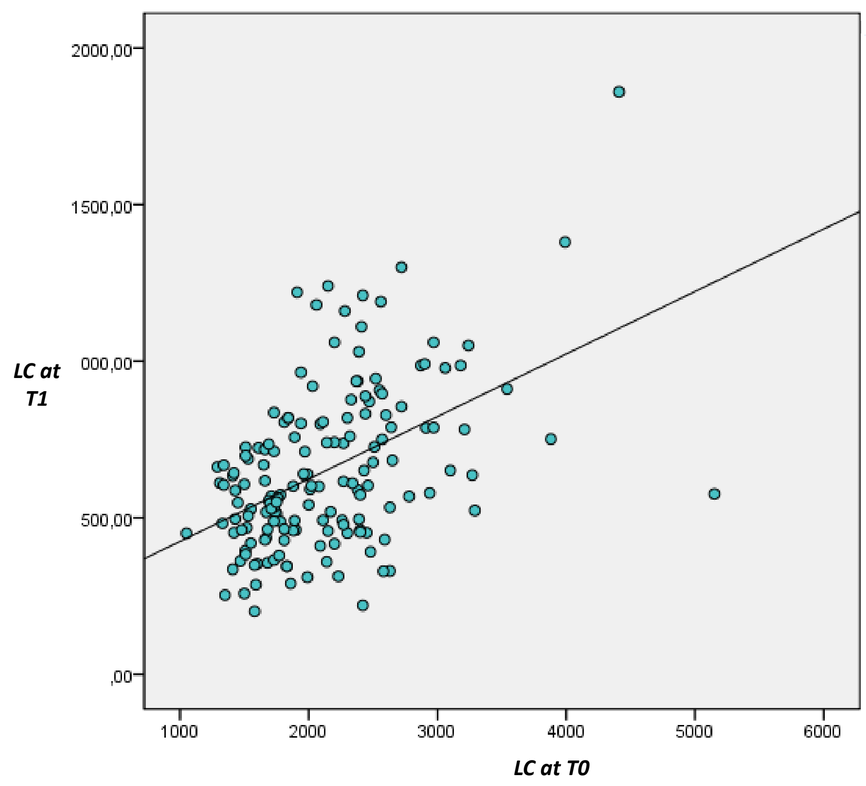



***Figure 2*** *Correlation between LC at T0 and LC at T1*




## CONCLUSION

Our study demonstrated the ***predictive value of sex and LC at FTY beginning for the development of lymphopenia at the first month of therapy***. This finding may be useful in clinical practice to define monitoring strategies for selected patients during FTY therapy.

## References

Warnke C et al. Neurology 2014;83:2153–2157
Henault D et al. Neurology 2013; 81:1768-1772