Real life efficacy and tolerability of Teriflunomide: a multicentre study

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Objective: Aim of this study is to confirm post-marketing Teriflunomide (TFU) efficacy and safety profile, and to identify predictors of response to TFU.

Materials and Methods: We enrolled all patients receiving TFU in ten northern Italy MS centres, starting from Jan 2014, until Mar 2016. Patients were prospectively followed, collecting demographic and clinical data as well as laboratory assessment abnormalities

Results

- Patients characteristics are illustrated in tab 1
- TFU efficacy data, in terms of ARR, Relapse-free survival and disability variations from baseline to follow-up are illustrated in fig 1, 2 and 3.
- Predictors of relapse free-status are shown in tab 2
- TFU safety and tolerability data are illustrated in fig 4 and persistence on TFU is shown in figure 5

550 patients		Median	I e III quartile
Sex	M 34%, F 66%	28 % of the female patients were of childbearing potential	
Mean age (years)	46,7 ± 9,6		
Mean disease duration (years)	15 ± 10	14	8-21
EDSS	3 ± 1,8	3	2-4
Mean ARR in the prev. 2 y	0,4 + 0,3	0	0-1
Previous therapies (#)	1,5	1	1-2
Mean follow-up (months)	16,3 ± 12,2	14	8-19

Tab 1: *patients baseline characteristics*

ARR *= Annualized Relapse Rate*
DMD *= Disease Modifying Drugs*
NTZ *= Natalizumab*
FTY *= Fingolimod*
CFX *= Cyclophosphamide*
MTX *= Mitoxantrone*

Type of patients

- Naive or restarted therapy after quitting Ist line DMDs **19,2 %**
- Switch from Ist line DMDs for lack of tolerability **52 %**
- Switch from Ist line DMDs for lack of efficacy **17,8 %**
  - 23% from NTZ
  - 62% from FTY
  - 15% from CFX/MTX
- Switch from II line DMDs for safety or lack of tolerability **11 %**

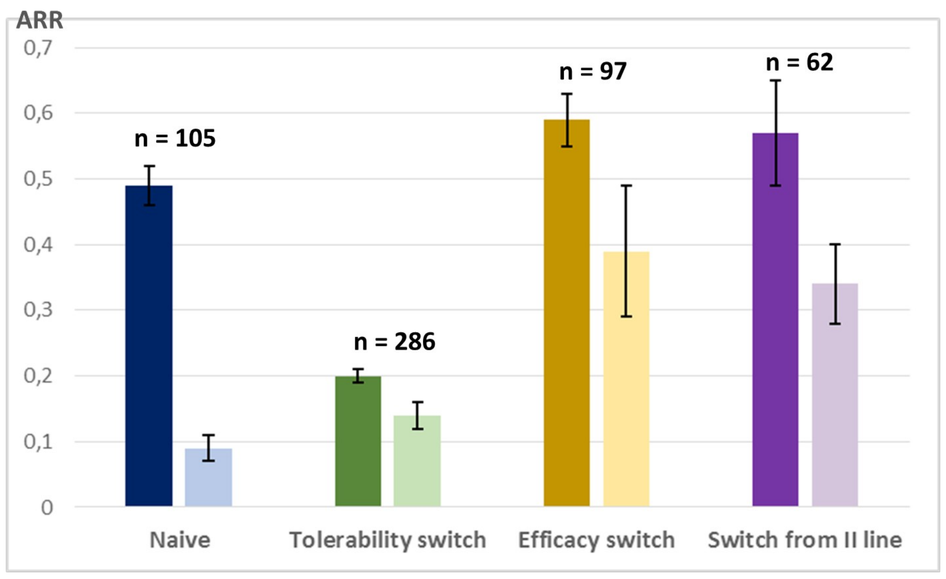

Fig 1: *Annualized relapse rate (ARR) according to patients type, 2 y before (darker color bars) and after (lighter color bars) TFU start. Error bars represent standard error*

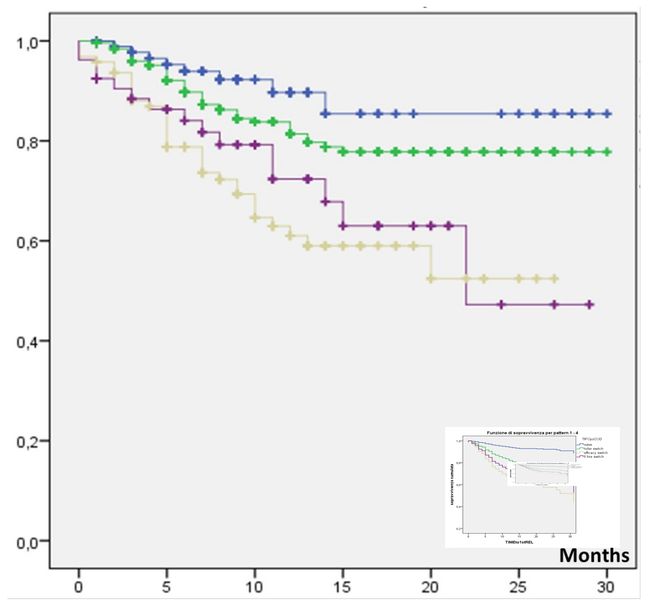

Fig 2: *Relapse-free survival Kaplan –Meier curve, according to patient type.*

	OR	95% IC	P
Age			ns
Gender (F)	1.8	0.9-3.5	0.07
MS duration			ns
Baseline ARR	0.8	0.3-1.01	0.08
Baseline EDSS			ns
Patient type			0.02
Naive	3.6	1.2-10.7	
Tolerability switch	2.2	1.3-5.3	

Tab 2: *Relapse-free survival Cox multivariate regression analysis*

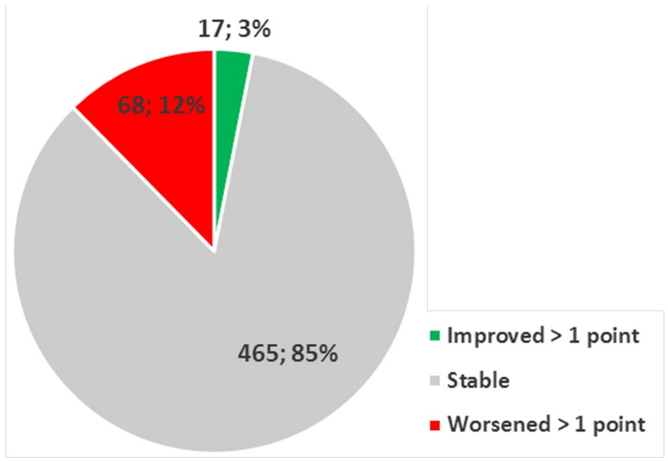

Fig 3: *EDSS variation from baseline to last follow-up*

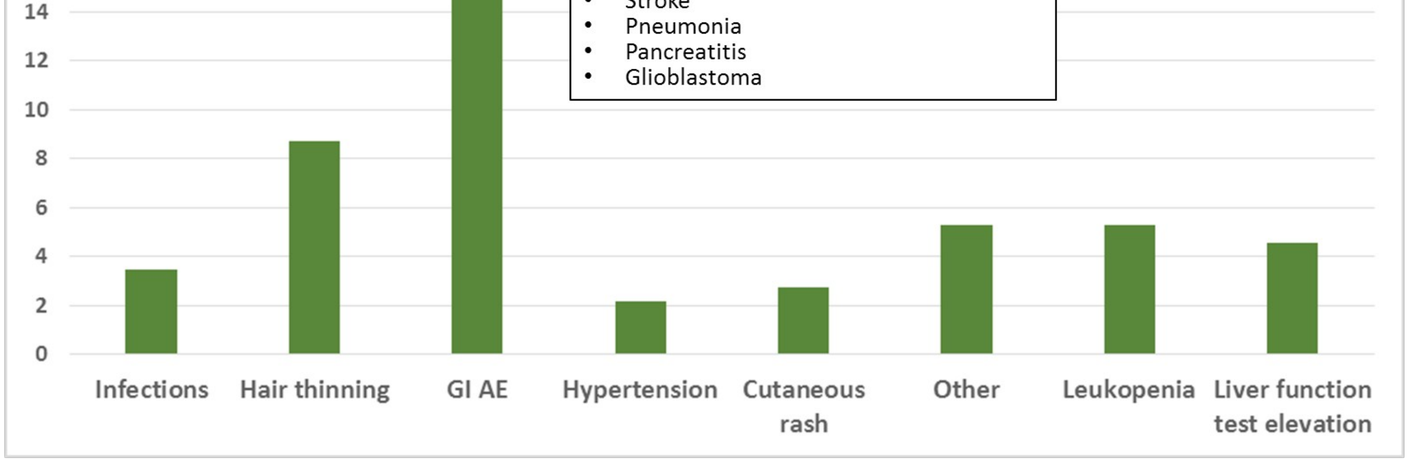

Fig 4: *TFU tolerability profile*

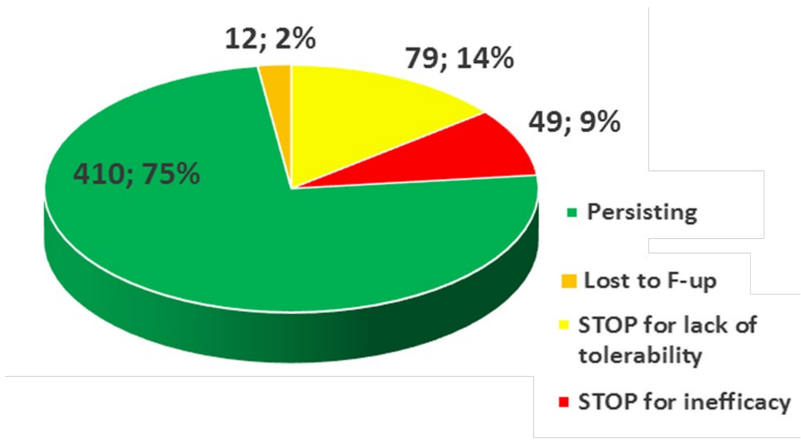

Fig 5: *Persistence on TFU and causes of TFU interruption (n = number of patients)*

Conclusions: Even with the limitations of an open label study, our data confirm the efficacy and tolerability profile of TFU, especially as a first-line agent or alternative to injectable therapies for a better tolerability.