SAFETY PROFILE OF GLATIRAMER ACETATE 40 mg

G. Calzado Gómez[1], F. Gutierrez Nicolás[1], N. Yurrebaso Eguilior[1], G.J. Nazco Casariego[1], G.A. González de Fuente[1], S. García Gil[1], J. Ramos Rodriguez[1].
[1]Complejo Hospitalario Universitario de Canarias, Pharmacy, La Laguna, Spain.

Background

Glatiramer Acetate (GA), is a first-line therapy approved for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS). GA 20 mg/ml (GA20)administered once daily by subcutaneous injection is using since 2009. In 2014, modified treatment regimens-alternative dosages and low-frequency administration schedules, it is GA 40 mg/ml (GA40) three-times weekly.

Objetive

To analyse injection related adverse events (IRAEs) reported of GA20 and GA40 in our clinical practise.

Material and methods

A retrospective, observational study of patients diagnosed of RRMS, in treatment with GA at least for 6 months (January 2016-June2016).

We studied all patients who started to used GA 40 three-times weekly, including converting from GA 20 once daily to GA 40. Including naive and further lines of treatment. We excluded patients who wanted to get pregnant.

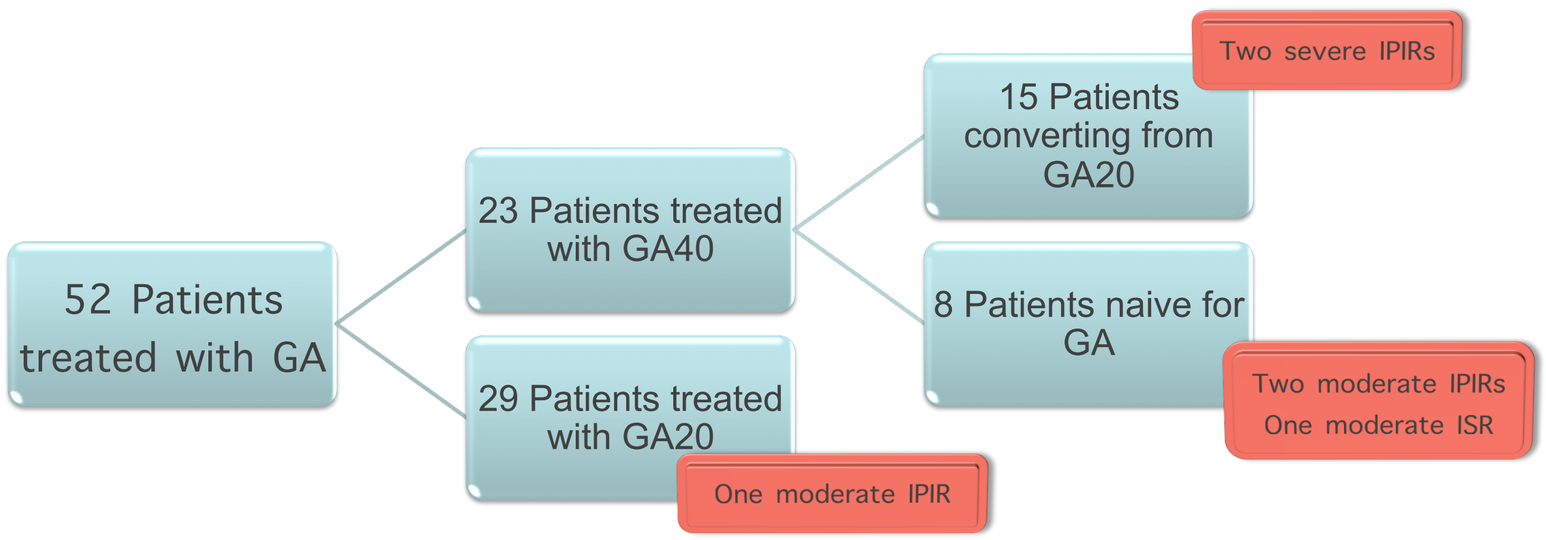
The IRAEs analysed according to System Organ Class (SOC) were general disorders and administration site condition, including local injection-site reaction (ISRs), symptoms or events related to immediate post-injection reactions (IPIRs).

Results

A total of 52 patients were included.

On the one hand 23 patients (14 women, 9 men; mean age 43) in treatment with GA40, 15 of them (7 women, 8 men) converting from GA 20, 8 patients naive for GA. Five moderate/severe IRAEs related to ISRs and IPIRs were reported (21,7%). Note 2 of them were patients who were converting from GA20.

On the other hand 29 (19 women, 10 men; mean age 46) in treatment with GA20 for at least 6 months. One moderate IRAE associated to IPIR (3,4%), was reported in this group.



Conclusions

To our knowledge post-hoc analyses showed that patients receiving GA40 demonstrated a 60% reduction in the annualized event rate of moderate/severe IRAEs compared with GA20.

Concerning to our study, the total number of ISRs and IPIRs reported, GA40 has a significant increase rate compared with GA20 ($p<0.04$). These outcomes suggest that moderate or severe reactions related to general disorders and administration site condition were less frequent in GA20-treated patients. Due to size of group is not enough, these results should be interpreted with caution; its necessary future analysis in clinical practise.

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No conflict of interest