Patterns of drug treatment for maintenance phase of ANCA-associated vasculitis (AAV) in real world practice in Europe – prolonged glucocorticoid use is common and various treatment regimes are used

SAT0248

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INTRODUCTION

ANCA-associated vasculitis (AAV) is now a relapsing remitting long term condition and patients are at high risk of cumulative organ damage and have an elevated long term mortality risk.

Maintenance therapy is required in AAV for several years to prevent relapse but patients are still at risk from vasculitis activity and adverse events particularly from repeated high dose glucocorticoids (GCs) and/or prolonged GC use.

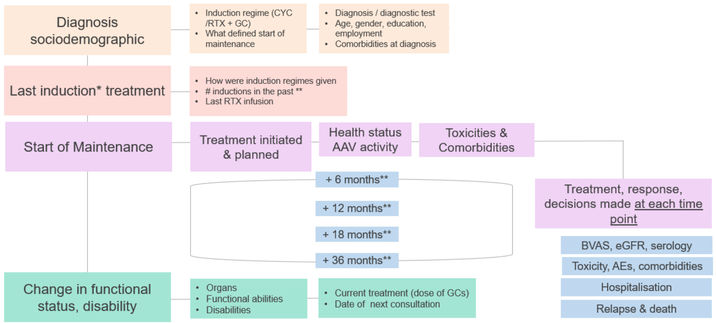
This retrospective study of AAV patients managed in real world clinical practice in Europe aimed to examine clinical outcomes and in particular the drug treatment used for maintenance of remission in AAV patients.

METHODS

STUDY DESIGN. Retrospective clinical audit of healthcare records from AAV patients managed by 493 physicians (293 nephrologists, 178 rheumatologists and 22 internal medicine physicians) who routinely manage AAV patients (France, Germany, Italy, Spain and UK).

INCLUSION & EXCLUSION CRITERIA. Physicians selected adult patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who had received a full course of remission induction therapy for organ or life threatening AAV. They had to have received this induction course between 2013 to 2016. Patients could be included with a first induction treatment or at the time of a relapse. In addition patients who relapsed or died in the maintenance phase could be included. Physicians had to have access to the patients entire treatment record for the period.

DATA COLLECTION AND ANALYSIS. Physicians completed up to 3 programmed patient record forms (PRF) - this online data collection tool was designed to gather clinical outcome data over the maintenance therapy phase from the point this was defined by the physician. Data were collected relating to induction treatment of AAV then outcomes at 6, 12, 18 ad 36 months following maintenance start. Descriptive statistics were used to analyze the data



RESULTS

Results 1 – Patient demographics and remission induction therapy - 1478 AAV patients were studied – 49% GPA and 51% MPA. Mean age was 54.2 years with 56% male. BVAS was reported in only 21% of PRF but 44% had severe progressive disease, 56% moderate systemic disease and 0% mild localized disease.

49% of patients received remission induction therapy for incident disease and 51% at relapse.

Induction treatment

Oral cyclophosphamide – 15%, IV - cyclophosphamide 55%, Rituximab – 30%, Glucocorticoids (GCs) – 71%

GC regime – 84% received IV GC followed by oral GC, 16% received oral GC only

Plasma exchange – 28%

RESULTS

Figure 1. Drugs and vasculitis control at the start of maintenance phase of AAV therapy – Physicians defined the time of maintenance phase start at approximately 6 months (new patients 4.7 months and relapsed patients 6.5 months).

The majority of patients are taking GCs at the start of the maintenance phase. The use of other drugs varied more between countries - Rituximab in particular.

At this point – only approximately 50% of AAV patients are in a full remission.

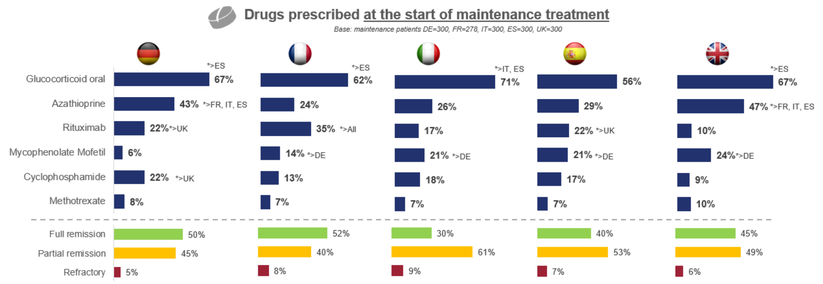


Figure 2 – GC dose and Rituximab regimes at start of maintenance – Many European patients were still receiving GCs and the daily prednisolone dose was > 7.5mg for 81 % of patients.

Rituximab regimes varied but 500mg every 6 months is most frequently used.

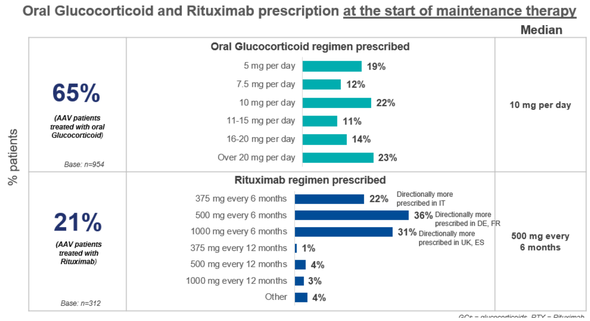
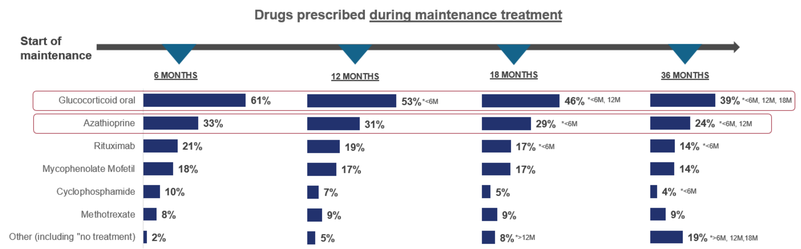


Figure 3 – Maintenance drug therapies over time – Many patients are still receiving GCs at 36 months and a growing minority of patients stop maintenance therapy



RESULTS

Figure 4 – Prolonged GC use is common – Although patients stop GCs over time, a significant proportion of patients are receiving 7.5mg or more

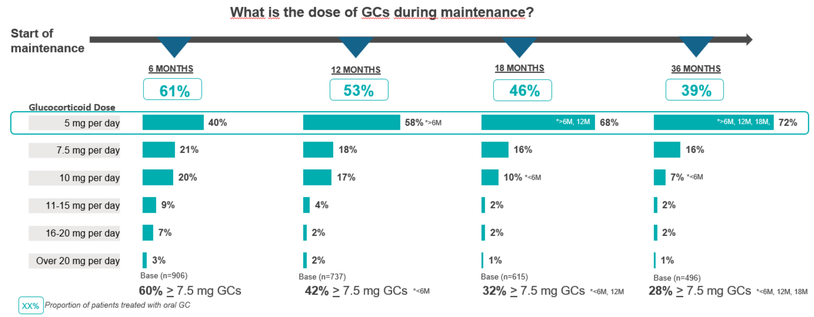
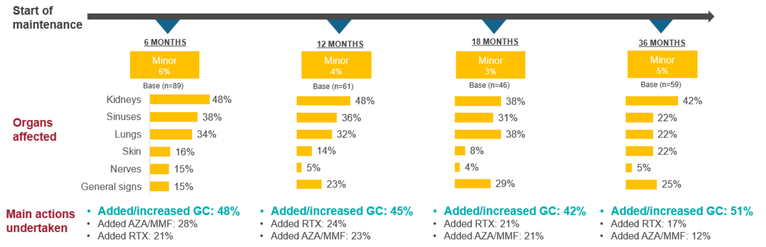


Figure 5 – Patients who experience a minor relapse during the maintenance phase often receive additional GCs – Major relapse requiring full induction remission therapy occurred in 10% of patients and patients left the study.

Minor relapse occurred in a further 18% of patients and management often included commencing or increasing the GC dose.



CONCLUSIONS

Maintenance therapy regimes used in Europe are variable in terms of GC dose and use of rituximab in a variety of schedules and doses.

Many patients remain on GCs for a prolonged period placing them at higher risk of GC related adverse events and organ damage.

Even a minor vasculitis relapse increases the use of GCs in the maintenance phase.

The high clinical burden of prolonged GC use in AAV should be more clearly recognized and new therapeutic approaches explored.

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