SIGNIFICANT BURDEN OF DISEASE DURING MAINTENANCE TREATMENT OF ANCA-ASSOCIATED VASCULITIS (AAV) PATIENTS IN REAL WORLD PRACTICE IN EUROPE

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INTRODUCTION

ANCA-associated vasculitis (AAV) is now a relapsing remitting long term condition but which still is associated with a significantly raised long term mortality risk. Patients are at risk from long term organ damage which is due to both recurrent active vasculitis and treatment related adverse events, in particular, glucocorticoids.

Achieving and sustaining remission are critical steps in clinical therapy and the long term morbidity and mortality risks during the maintenance phase remain unmet medical needs.

This retrospective study of AAV patients managed in real world clinical practice in Europe aimed to examine the definition of the maintenance phase, the therapies used for maintenance and clinical outcomes including vasculitis control, adverse events and infections.

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 preiod

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%

Figure 1. Definition of maintenance phase of AAV therapy – Physicians defined the time of maintenance phase start with a variable time from the commencement of remission induction therapy. This time was longer in relapsed patients but was approximately 6 months.

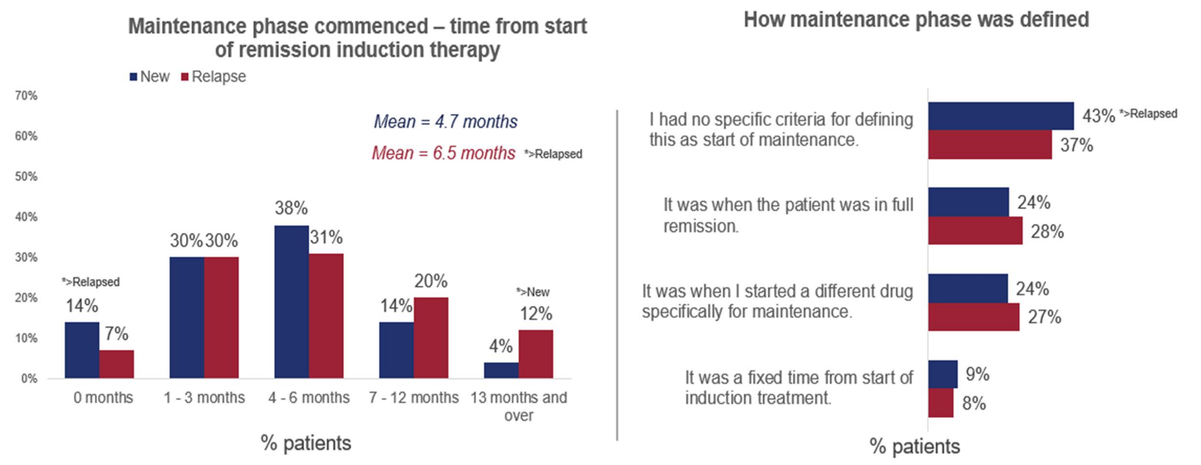


Figure 2 – Drugs and vasculitis control at start of maintenance phase A variety of maintenance treatments were employed. and even time when maintenance began, many patients were not in full remission. Most patients still were taking GCs.

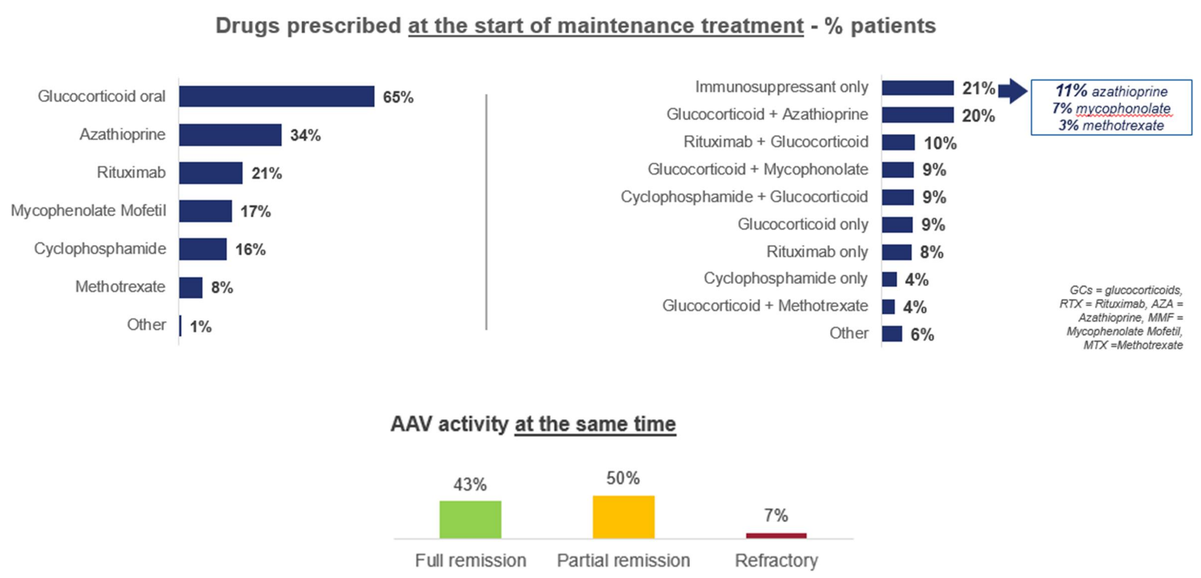
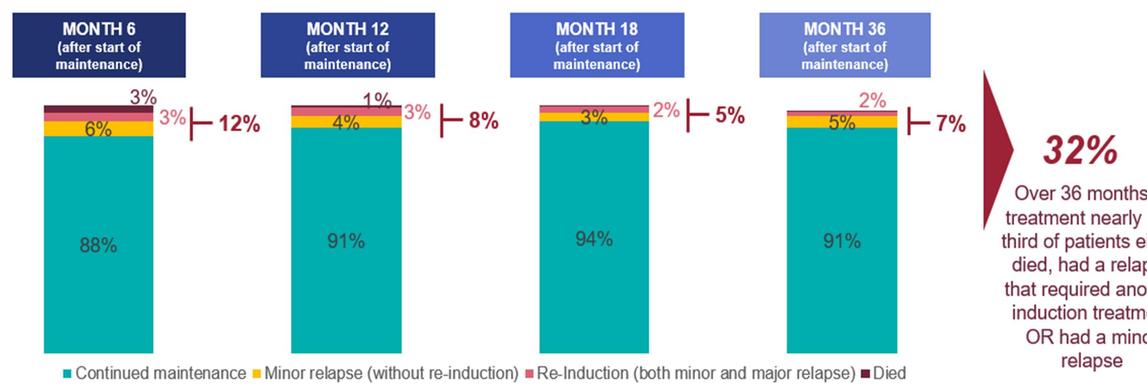


Figure 3 – Clinical outcomes over 36 months of remission – Major and minor relapses remain a clinical problem with current maintenance therapy



At 3 years of continued maintenance therapy:

- 81% are still on maintenance, i.e. not relapsed to the extent they required re-induction or deceased
- 4% Died (≥ 2/3rds due to AAV relapse)
- 10% dropped out of study due to relapse requiring re-induction
- **18% minor relapses requiring either / or: an adjustment to / switch of maintenance regime**

Figure 4 – Active AAV symptoms and signs are still observed in the maintenance phase. Physicians report many patients are in only partial remission (reduced AAV activity with arrest of major organ damage).

Although eGFR was stable overall – some patients progressed to requiring RRT

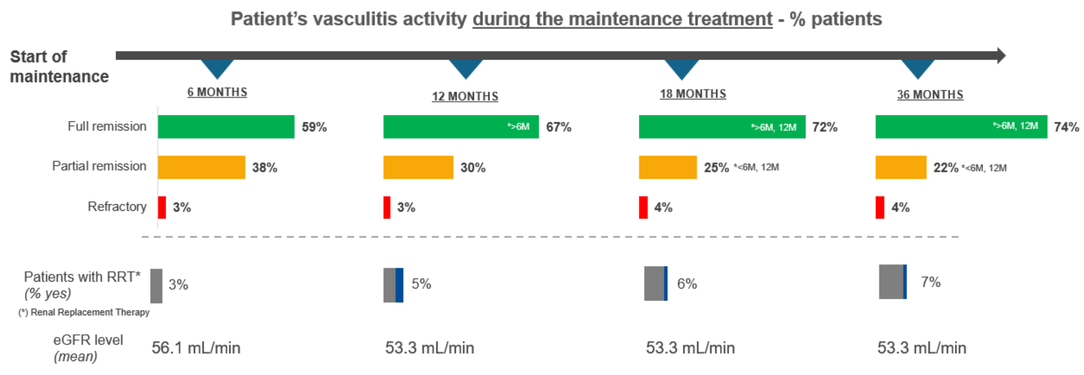
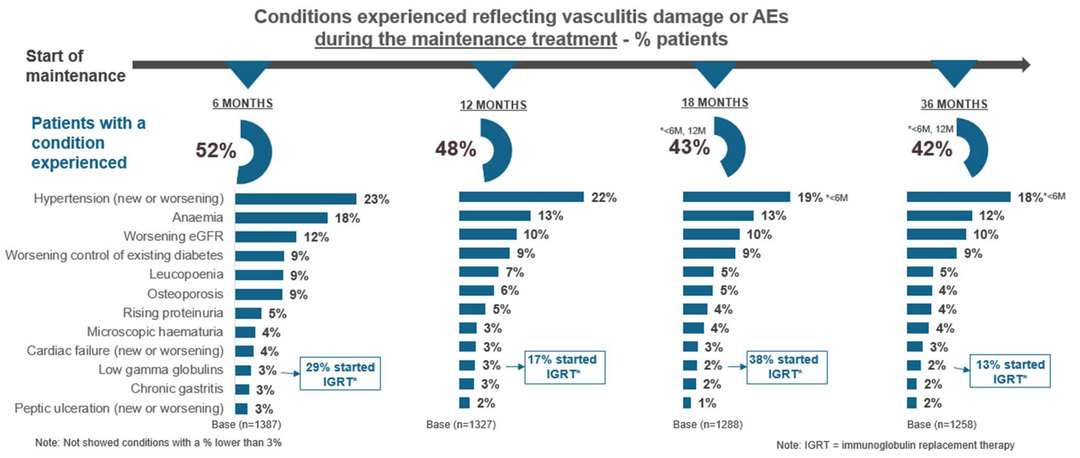


Figure 5 – Many patients experienced conditions reflecting vasculitis damage/AEs or infections and loss of functional status occurred - Organ damage was common over the maintenance phase and infections remain a problem. After 36 months, 13% had reduced working hours, 13% restricted social life, 6% had to leave employment, 5% were registered as disabled and 2% had to leave full time education



CONCLUSIONS

This study has examined real world outcomes in the maintenance treatment phase of AAV in Europe and demonstrated significant burden of disease and unmet medical need.

Clinicians variably define the beginning of the maintenance phase of treatment but it typically begins after approximately 6 months of remission induction therapy.

Relapse is still a clinical program and many patients require ongoing GC therapy in order to maintain remission. Organ damage and infection risk remain a problem in AAV maintenance and there is a significant negative impact on patients functional status over time.

There is an ongoing need for more targeted therapies to improve clinical outcomes in AAV.

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