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REAL WORLD CLINICAL OUTCOMES IN ANCA ASSOCIATED VASCULITIS (AAV) – UNMET NEEDS IN ACHIEVING AND SUSTAINING REMISSION AND AVOIDING CUMULATIVE ORGAN DAMAGE

RUTHERFORD, P*[1], Goette, D[1]
[1]Vifor Pharma Medical Affairs Zurich Switzerland

Introduction: AAV is a severe systemic vasculitis and rapid induction of remission is desirable and then maintenance treatment required to avoid relapse. However, response to therapy can be variable and treatment-related infections and adverse events are common leading to high acute mortality and long term organ damage. This retrospective study examined AAV remission and maintenance and AEs in incident and maintenance AAV patients managed in routine clinical practice

Methods: Two retrospective real world studies were performed. Firstly, 929 incident AAV patients (54% of patients had granulomatosis with polyangiitis, remainder microscopic polyangiitis) from 4 EU countries (399 physicians) were diagnosed between 2014-17 and data collected at baseline, 1, 3, 6 and 12 months following start of induction therapy was reviewed. Secondly 1478 AAV patients (49% of patients had granulomatosis with polyangiitis) from 4 EU countries (493 physicians) who completed induction therapy for organ/life threatening AAV and initiated maintenance therapy between 2014-16 were studied. Data were collected at the time maintenance was determined to begin by the physician and then at 6, 12, 18 and 36 months

Results: Incident patients had mean age of 56.82 yrs (SD 14.2) with 53.7% male. Birmingham vasculitis activity score (BVAS) was used in only 12%. Induction therapy varied with 59% receiving CYC, 24% RTX and 3% a combination, whilst 83% received GCs. As BVAS was not used routinely, clinical response was assessed as full (no AAV activity and GC taper on track), partial (reduction in AAV activity), or no response (no improvement in AAV). Table 1 shows that response rate varied, most patients required longer term GCs and adverse therapy impact was common. Full response at 1 month was associated with good 12-month outcomes (81% full response) whereas partial response at 1 month (56%) was less favourable (58% full response at 12 months). 78% of patients did not relapse over 12 months, 17% had 1 relapse, 3% had 2 relapses, and 2% had more than 2 relapses.

Table 1 – Response to remission induction therapy in 929 incident patients

	1 month	3 months	6 months	12 months
Full response %	18	43	61	59
At least one AE %	45	42	35	30
Infection %	27	28	23	20
Still receiving GC %	82	79	67	53
Dialysis %	16	3	1	1

Maintenance patients had mean age 54 years with 56% male. 49% were studied from incident and 51% from time of a relapse. Physicians defined maintenance start with mean of 5.7 months from induction start on basis of fixed time point 40%, start of new drug for maintenance 26%, reaching full remission 26% and no specific criteria 8%. Treatment at start of maintenance as GCs 69%, Azathioprine 34%, Rituximab 21%, Mycophenolate 17%, Cyclophosphamide 16% and methotrexate 8%. After 36 months (Table 2) of maintenance, 81% were alive and in remission but 10% had major relapse requiring re-induction therapy and left follow up, 4% died (in 2/3 of cases at time of relapse). AEs and infection were common and many patients required long term GCs

Table 2 – Maintenance therapy outcomes in 1478 maintenance patients

	Maintenance start	6 months	12 months	18 months	36 months
Remission full/partial %	43 / 50	59 / 38	67 / 30	72 / 25	74/ 22
Minor / major relapse %		6/3	4/3	3/2	5/2
Receiving GC%	65	61	53	46	39
At least one AE %	66	52	48	43	42
At least one infection %	54	42	32	27	26

Conclusions: Response to remission induction therapy in AAV patients is still variable with many patients not achieving a full response over the first 12 months of therapy. Infections and treatment-related adverse events are common, especially in the first 3 months. Maintenance period is variably defined but typically around 6 months when many patients are still not fully in remission and the majority are still receiving GCs. Relapse, major and minor, are still common and patients are still faced with treatment AE burden. Unmet need in AAV remains high and there is a need for targeted therapy to improve clinical outcomes.