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Research Article

FORTUNE JOURNAL OF RHEUMATOLOGY

ISSN: 2688-6766

Relapse Rates in Patients with GPA or MPA on Rituximab (RTX) Maintenance Therapy: A Single-Center Experience Observational Study from Saudi Arabia

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Abstract

Introduction: ANCA-associated vasculitis (AAV) is a rare, systematic, small-vessel inflammatory disorder, leading to conditions such as granulomatosis with polyangiitis (GPA), and microscopic polyangiitis (MPA). While glucocorticoids and immunosuppressants are effective in inducing remission, maintaining it remains a challenge. Rituximab (RTX) has become the preferred choice for maintenance therapy.

Objective: To evaluate the effectiveness of rituximab in maintaining remission by analyzing relapse rates among patients with GPA or MPA while receiving RTX.

Methods: An ambispective cohort study was conducted at King Fahad Medical City between 2015 and 2025 which included patients (>14 years old) diagnosed with GPA or MPA. Descriptive statistics were used, and relapse-free survival was estimated using Kaplan–Meier model. The French Vasculitis Study Group Relapse Score (FRS) was incorporated into the study, which includes three variables and a score that ranges from 0 to 3 points: positivity of PR3-ANCA, GFR ≥30 mL/min/1.73 m², and age ≤75 years.

Results: A total of 33 patients were included in the analysis; 81.7% had GPA. Ear, nose, and throat involvement was in 72.7% of patients. At 36 months, relapse-free survival was 76.6%. Six patients (18.2%) experienced relapses. The median steroid dose did not differ between patients with or without relapses. Patients with an FRS score of 1-2 had much higher relapse-free survival, but this was not statistically significant (log-rank test p-value = 0.3).

Conclusion: Rituximab appears to be an effective maintenance therapy for AAV in this Saudi cohort, with relatively low relapse rates and sustained remission in most patients.

Keywords: Rituximab; Relapse; ANCA-associated vasculitis; Maintenance therapy; Saudi Arabia.

Introduction

Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) are a group of heterogeneous, multisystem, necrotizing inflammatory diseases that predominantly affect small-sized blood vessels. Under the umbrella of AAV are three main clinical subtypes: Granulomatosis with Polyangiitis (GPA), Microscopic Polyangiitis (MPA), and Eosinophilic

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Citation: Abdulrahman Alhumaidi, Khalid Qushmaq, Bassim Almatouq, Ahmad Alamer, Abdullah Alosaimi, Reemaz Abdulhameed, Abdulwahab Almansour, Albatool Abodarhem, Huda Draz, Faisal Albalawi. Relapse Rates in Patients with GPA or MPA on Rituximab (RTX) Maintenance Therapy: A Single-Center Experience Observational Study from Saudi Arabia. Fortune Journal of Rheumatology. 8 (2026): 15-22.

Received: April 29, 2026
Accepted: May 07, 2026
Published: May 15, 2026

Alhumaidi A, et al., Fortune J Rheumatol 2026
DOI:10.26502/fjr.26880054

Granulomatosis with Polyangiitis (EGPA). These conditions are characterized by the presence of autoantibodies targeting neutrophil cytoplasmic antigens, primarily proteinase-3 (PR3) and myeloperoxidase (MPO). The autoimmune phenomenon leads to endothelial damage through the generation of reactive oxygen species, formation of neutrophil extracellular traps (NETs), and activation of the complement cascade. Clinically, AAV frequently involves the upper and lower respiratory tracts and kidneys, although other organs may also be at risk [1, 2]. AAV is associated with significant morbidity and mortality, with a high risk of relapses and cumulative organ damage [3-5]. Current therapeutic strategies are divided into two phases. The induction phase aims to control active inflammation using glucocorticoids (GC) in combination with either Cyclophosphamide (CYC) or Rituximab (RTX) [6, 7]. The goal of the maintenance phase is to prevent relapses and preserve the organs' vitality. Rituximab has emerged as the most effective drug for relapse prevention, with additional options including azathioprine, methotrexate, leflunomide, and mycophenolate mofetil [8, 9]. More recently, Avacopan, an oral C5a receptor antagonist, has been approved as a glucocorticoid-sparing agent with demonstrated effectiveness in reducing relapse rates [10]. Despite advancements in the management of AAV, data from Saudi Arabia are lacking. Therefore, the aim of this study is to evaluate the relapse rate among Saudi patients diagnosed with AAV who are receiving rituximab as maintenance therapy.

Materials and Methods

Study Population

This was an ambispective observational study that included patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) diagnosis seen at King Fahad Medical City (KFMC) in rheumatology and nephrology clinics from 2015 to 2024. Patients are eligible for inclusion if age ≥ 14 years or older with ANCA-positive GPA or MPA diagnosed as per the criteria of the American College of Rheumatology (ACR) 1990 treated with vasculitis treated with rituximab either in induction or maintenance therapy. Patients are excluded if they are ANCA-negative, end stage renal patients on long time dialysis, or ANCA-associated vasculitis induced by infection or drug. In our report, we followed The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki of the World Medical Association and was approved by the institutional review board in King Fahad Medical City Research Center.

Data Collection

Data was extracted from the Electronic Medical Record (EMR) system that included variables such as demographic information, clinical presentation at the time of diagnosis (cutaneous, renal, pulmonary, neurological, ear, nose, and throat (ENT), gastrointestinal, or cardiovascular involvement), biochemical markers like ANCA antibody type, erythrocyte sedimentation rate (ESR), C- reactive protein (CRP), serum creatinine, glomerular filtration rate (GFR), radiological and histopathologic features, Birmingham Vasculitis Activity Score (BVAS), and treatment protocols including induction and maintenance regimens with Rituximab. Other variables were collected such as steroid use, relapse outcome (time to relapse, and type as major or minor relapse), number of infection episodes, incidence of intensive care unit (ICU) admission, need for plasma exchange.

Study outcomes

The primary outcome of the study was to evaluate the relapse rate among patients receiving Rituximab maintenance therapy. Secondary analyses descriptively examined potential factors associated with relapse, including diagnosis type, corticosteroid dose, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR). Additionally, we explored the recently published French Vasculitis Study Group Relapse Score (FRS), which assesses the probability of relapse in patients with GPA and MPA. The FRS includes three variables—PR3-ANCA positivity, estimated glomerular filtration rate (GFR) ≥30 mL/min/1.73 m², and age ≤75 years—each contributing one point, yielding a total score ranging from 0 to 3. Relapse rates were compared between patients with FRS scores of 1–2 and those with a score of 3.

Statistical Analysis

Baseline characteristics were summarized using descriptive statistics. Continuous variables were summarized as median and interquartile range (IQR), and categorical variables were summarized as frequencies and percentages as appropriate.

Comparisons between patients who experienced relapse and those who did not were performed in variables of interest using the Wilcoxon rank-sum test for continuous variables and the χ^2 test or Fisher's exact test for categorical variables, as appropriate. Relapse-free survival (RFS) was defined as the time from initiation of rituximab maintenance therapy to the first documented relapse. Patients without relapse were censored at the date of last follow-up. RFS was estimated using the Kaplan–Meier method, and survival probabilities were reported with 95% confidence intervals (CIs). A p-value of less than 0.05 was considered to be statistically significant for all testing. All statistical analyses were performed using R version 4.5.2.

Results

A total of 33 patients were included in the analysis. The median age was 45.0 years (IQR 34.0–62.0), and 57.6% were male. Granulomatosis with polyangiitis (GPA) was the

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most common diagnosis (81.8%), followed by microscopic polyangiitis (MPA) (18.2%). Median baseline laboratory values included an ANCA level of 119.0 (IQR 81.2–157.0), ESR 44.0 (21.0–78.0), CRP 11.0 (4.5–16.8), and BVAS 10.0 (6.0–13.5). Median estimated glomerular filtration rate was 45.0 (34.0–62.0) mL/min/1.73 m². ENT involvement was present in 72.7% of patients, chest involvement in 51.5%, and renal involvement in 45.5%. Regarding organ involvement, ENT manifestations were the most frequent (72.7%), followed by pulmonary involvement (51.5%) and renal involvement (45.5%). Joint involvement was observed in 42.4%, cutaneous manifestations in 39.4%, ocular involvement in 24.2%, and gastrointestinal involvement in 12.1% of patients. Nearly half of the cohort (48.5%) underwent a diagnostic tissue biopsy. Markers of severe disease were present in a subset of patients. ICU admission at diagnosis occurred in 15.2%, endotracheal intubation in 12.1%, and plasmapheresis was required in 21.2%. Dialysis was initiated in 3.0% of patients (Table 1).

Table 1: Patients' Characteristics

Variable	N=33
Age in years, median (IQR)	45.0 (34.0–62.0)
Diagnosis, n (%)	
MPA	6 (18.2)
GPA	27 (81.8)
ANCA level, median (IQR)	119.0 (81.19 – 157.0)
ESR, median (IQR)	44.0 (21.00 – 78.00)
CRP, median (IQR)	11.0 (4.50, 16.80)
BVAS, median (IQR)	10.0 (6.00, 13.50)
eGFR, median (IQR)	45.0 (34.0– 62.0]
General symptoms, n (%)	14 (42.4)
Cutaneous symptoms, n (%)	14 (42.4)
Mucocutaneous involvement, n (%)	6 (18.2)
Eye involvement, n (%)	7 (21.2)
ENT involvement, n (%)	24 (72.7)
Chest involvement, n (%)	17 (51.5)
Cardiovascular involvement, n (%)	5 (15.2)
Gastrointestinal involvement, n (%)	10 (30.3)
Renal symptoms, n (%)	15 (45.5)
Nervous system involvement, n (%)	7 (21.2)
Any biopsy performed, n (%)	16 (48.5)
Lung biopsy, n (%)	2 (6.1)
ENT biopsy, n (%)	5 (15.2)
ICU admission at diagnosis, n (%)	5 (15.2)
Intubation required, n (%)	4 (12.1)
Plasmapheresis (PLEX) performed, n (%)	7 (21.2)
Dialysis required, n (%)	1 (3.0)

MPA = Microscopic polyangiitis; GPA = Granulomatosis with polyangiitis; ANCA = Antineutrophil cytoplasmic antibody; ESR = Erythrocyte sedimentation rate; CRP = C-reactive protein; BVAS = Birmingham Vasculitis Activity Score; ENT = Ear, nose, and throat; ICU = Intensive care unit

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Table 2: Pharmacological interventions and rate of infections during treatment course.

Variable	N=33
Rituximab induction, n (%)	10 (30.3)
Cyclophosphamide, n (%)	6 (18.2)
Methotrexate (Induction), n (%)	7 (21.2)
Azathioprine (Induction), n (%)	5 (15.2)
Steroids while on Rituximab, n (%)	22 (66.7)
Azathioprine while on Rituximab, n (%)	8 (24.2)
Methotrexate while on Rituximab, n (%)	4 (12.1)
Infections, n (%)	12 (36.4)
TMP/SMX use, n (%)	9 (27.3)

Abbreviations: TMP/SMX = Trimethoprim/sulfamethoxazole

Relapse-Free Survival Over Time

Time (Months)	Survival Probability (95% CI)	Cumulative Events (n, %)
12	0.871 (0.761–0.997)	4 (12.1%)
24	0.829 (0.703–0.979)	5 (15.2%)
36	0.766 (0.609–0.962)	6 (18.2%)
48	0.766 (0.609–0.962)	6 (18.2%)
60	0.766 (0.609–0.962)	6 (18.2%)
72	0.766 (0.609–0.962)	6 (18.2%)

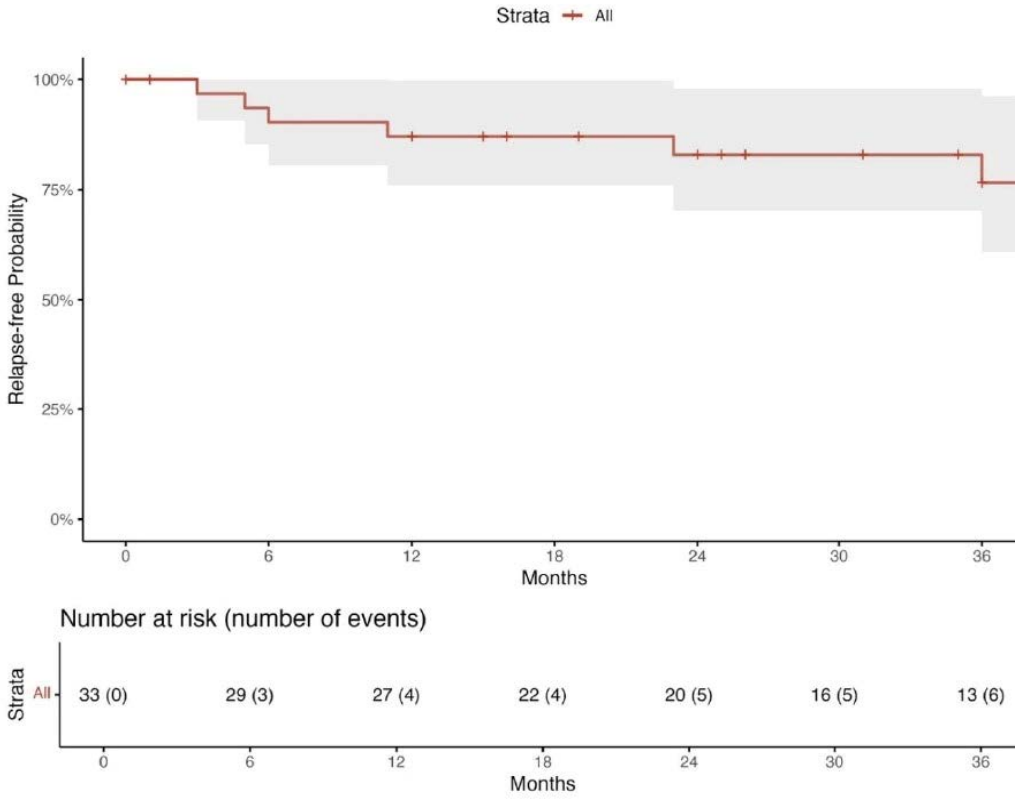

Figure 1: Kaplan–Meier estimate of relapse-free survival during rituximab maintenance therapy.

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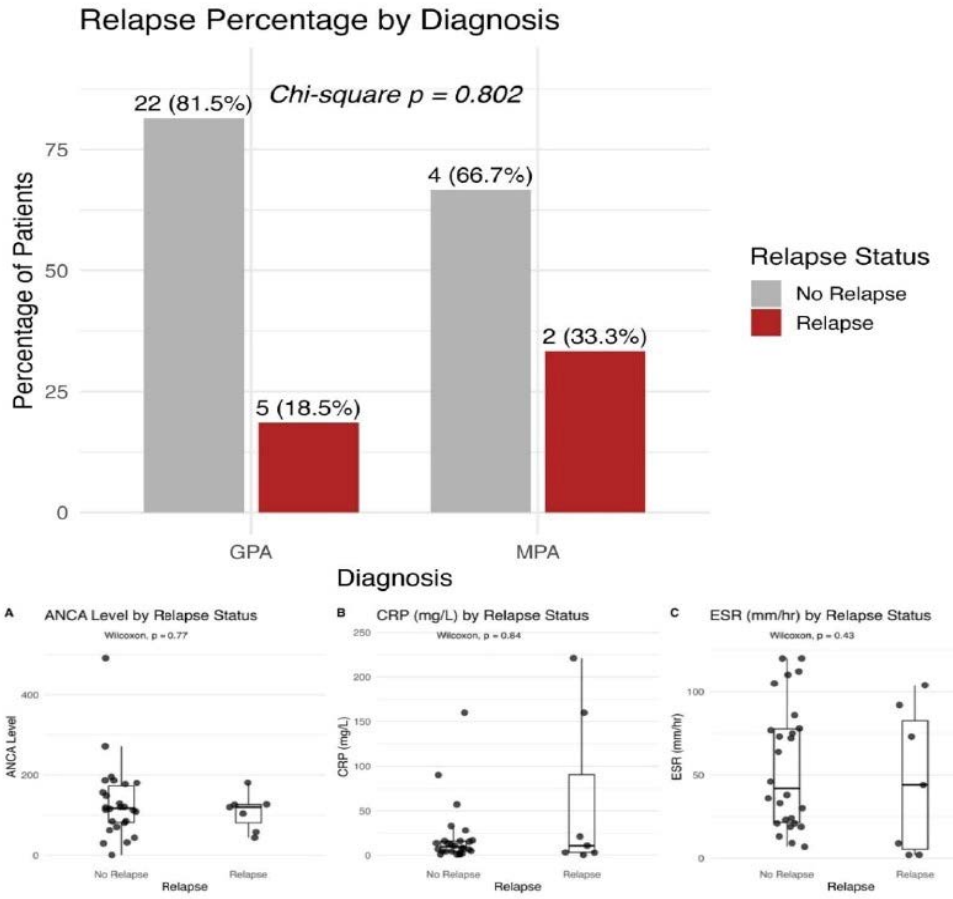

Figure 2: Relapse Patterns and Inflammatory Markers in Patients with ANCA-Associated Vasculitis. The upper panel shows the proportion of patients with and without relapse stratified by diagnosis (granulomatosis with polyangiitis [GPA] vs microscopic polyangiitis [MPA]); percentages and absolute numbers are displayed. Group comparisons were performed using the chi-square test.

Lower panels display inflammatory markers stratified by relapse status:

(A) ANCA levels, (B) C-reactive protein (CRP), and (C) erythrocyte sedimentation rate (ESR). Boxplots represent medians and interquartile ranges, with individual data points overlaid. Comparisons were conducted using the Wilcoxon rank-sum test.

Rituximab induction therapy was received 30.3% of patients, 18.2% cyclophosphamide, 21.2% methotrexate, and 15.2% azathioprine. During rituximab maintenance, 66.7% of patients were receiving concomitant corticosteroids. Infectious complications occurred in 36.4% of patients during follow-up, and 27.3% received trimethoprim–sulfamethoxazole (Table 2).

Over the follow-up period, 6 patients (18.2%) experienced disease relapse. Kaplan–Meier analysis demonstrated a relapse-free survival probability of 87.1% (95% CI 76.1–99.7) at 12 months, 82.9% (95% CI 70.3–97.9) at 24 months, and 76.6% (95% CI 60.9–96.2) at 36 months. No additional relapses were observed beyond 36 months, with relapse-free survival remaining unchanged through 72 months of follow-up (Figure 1).

Steroid doses on rituximab were compared by relapse status. In the no-relapse group, the median steroid dose was 5 mg (IQR 5–5), while in the relapse group it was also 5 mg but the 75th percentile higher (IQR 2.5–15) with no statistical significance difference between the groups (p-value = 0.44). Relapse by diagnosis showed that among patients with granulomatosis with polyangiitis, 22 (81.5%) had no relapse and 4 (18.5%) relapsed. Among those with microscopic polyangiitis, 4 patients (66.7%) had no relapse and 2 (33.3%) relapsed. The chi-square p-value was 0.802. Laboratory values by relapse status showed ANCA level with a p-value of 0.77, CRP with a p-value of 0.84, and ESR with a p-value of 0.43 (Figure 2).

Relapse-free survival was numerically higher in patients with FRS 1–2 compared with those with FRS 3 throughout the follow-up period. At 36 months, patients with lower FRS scores maintained a higher probability of remaining relapse-free. However, this difference did not reach statistical significance (log-rank p = 0.3), See (Figure 3).

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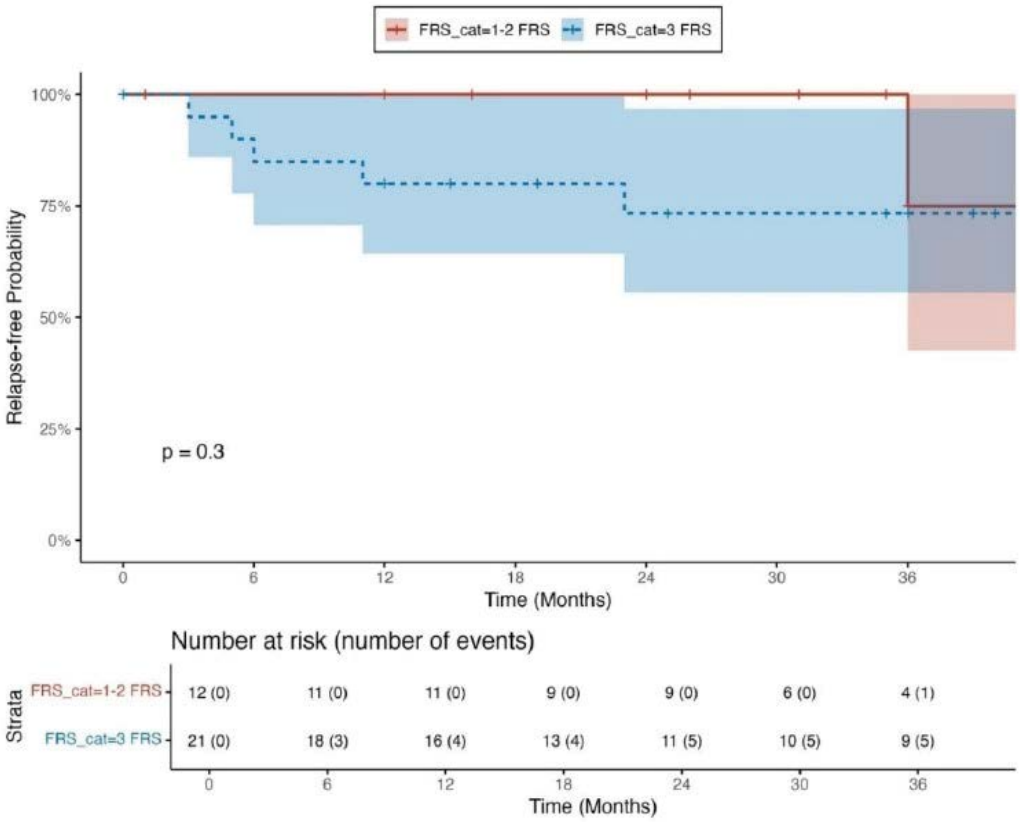

Figure 3: Kaplan–Meier curves depicting relapse-free survival stratified by French Vasculitis Study Group Relapse Score (FRS). Patients were categorized into two groups: FRS 1–2 and FRS 3. Shaded areas represent 95% confidence intervals. Tick marks indicate censoring events. The table below the plot shows the number of patients at risk and the cumulative number of relapse events at each time point. Comparisons between groups were performed using the log-rank test

Discussion

Although ANCA-associated vasculitis (AAV) is rare disease, its burden is overwhelming since the complications, and the inflammatory activity of the disease would be life threatening if untreated. In this observational study, we established the effectiveness of rituximab to maintain remission among patients diagnosed with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA). Our data indicates that Rituximab was successful in obtaining long-term disease control, as relapse-free survival was noted to be 87.1% in 12 months, 82.9 % in 24 months, while it was 76.6% in 36 months and beyond, respectively. Compared to major trials, our findings agree with the data already published to support the efficacy of Rituximab including MAINRITSAN-2 trial which reported relapse-free survival rate at 24 months to be between 83% - 86% when comparing fixed-schedule versus individually tailored Rituximab infusion administration [11]. Our own 24-month relapse-free survival rate was 82.2.6%, which falls in this range and, therefore, indicates similar efficacy despite a smaller number of real-world patients. In addition, the findings of our study align with RITAZAREM trial which reported a relapse survival rate to fall into the range of 85% - 50% at 24 – 48 months in patients maintained on Rituximab comparatively to the relapse survival rate in our data that ranged between 82.9% - 76% in the same period of time [12].

The relapse in our population was estimated to be 18.2% mainly in the first 3 years of being on Rituximab. Otherwise, the curve was stabilized beyond 36 months in comparison to another study with similar sample size to our cohort, that was conducted in Mexican population (by Carranza-Enríquez et al) where the relapse rate was 33% [13]. Thus, such data lend support to the long-term effectiveness of rituximab to prevent relapses and achieve long-lasting control of the disease activity. The plateau beyond 36 months indicates that once patients enter sustained remission, Rituximab achieves durable disease control. Our findings also agree with the results of Alberici et al, who reported long-term follow-up outcomes in patients receiving Rituximab for AAV maintenance. Over a median follow-up of 44 months, only 14% of patients experienced relapses which is relatively similar to the relapse rate in our study (18.2%) over 48 months [14]. The low relapse observed in our cohort parallels these findings, emphasizing Rituximab's capacity in achieving long term disease control, thus reducing the burden and complications of AAV.

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The relapse in our cohort, whose GPA predominance was 81.8%, was classified into life/organ threatening (major) relapse and non-life/organ threatening (minor) relapse. Two major relapses were observed in GPA patients, one of whom developed glomerulonephritis evident from renal biopsy, while the other case had proteinuria despite having limited respiratory involvement in the initial presentation and early initiation of Rituximab therapy. The other five cases had minor disease relapses in the form of developing manifestation affecting the upper respiratory tract (epistaxis), musculoskeletal (2 patients had arthritis), and lower respiratory tract (pulmonary nodules) systems. Moreover, our study found that there was no difference observed in relapse risk between GPA and MPA, or between c-/PR3-ANCA– and p-/MPO-ANCA–positive patients which is agreed by Gialouri CG et al, 2024 [15]. Irrespective of Rituximab being the maintenance agent in all of our patients, it was the first-line induction therapy in use in 30.3% of patients, while others received Cyclophosphamide, Methotrexate, or Azathioprine. In addition, almost two thirds of our population were on Glucocorticoids while maintained on rituximab. We explored the hypothesis in which concomitant steroid use with Rituximab maintenance contributes to the reduction in the relapse rate. We found that there is no statistically significant difference in the relapse rate (P=0.44) which indicates the reduction of relapse could be attributed to Rituximab alone.

Interestingly, The French Vasculitis Study Group Relapse Score (FRS) was incorporated in our study. The FRS is composed of three variables and ranges from 0 to 3 points: positivity of PR3-ANCA, GFR ≥30 mL/min/1.73 m² and age ≤75 years (1 point each) [16]. Our findings showed that patients with FRS 1-2 have a lower rate of relapse during the whole duration of the study, whereas patients with FRS 3 have a higher rate of relapse. Such findings aid the use of the FRS score to be applied in clinical settings and assess the risk of relapses in GPA and MPA patients. Our study has many strengths: using FRS as a predictive tool for relapse rate for the first time, extending the duration of our study that exceeds 36 months and the nature of our study being a prospective and retrospective (ambispective). We have some limitations in our study, such as being from a single center and small number of patients, so we recommend carrying out the study on multi-center level with larger number of patients.

Conclusion

(AAV) is an aggressive inflammatory pathology with a high relapse rate. The current study concluded that Rituximab appears to be a reasonable maintenance agent to reduce disease flares and prevent subsequent organ damage among the Saudi population. Additionally, the use of the FRS score as a tool to assess relapse risk yielded promising results, suggesting its potential utility in clinical practice. However, further studies involving larger and more diverse populations are recommended to confirm its prognostic value and strengthen its role in routine patient assessment.

Acknowledgments

We would like to thank Mr. Jamaan Algrofeen the coordinator of the day care unit (DCU) in King Fahad Medical City, who helped in the enrollment process of the participants.

Competing Interest

The authors declare that they have no competing interests.

Ethical Approval and Consent to Participate

The study was reviewed and approved by the Institutional Review Board (IRB) in the research center of King Fahad Medical City.

Written informed consents were obtained from the participants for enrollment into the study.

Consent for Publication

Written consents were provided by the participants prior to the publication of the study.

Competing Interest

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Funding

This study received no financial support or funding from external agencies or any other sectors.

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