The Safety of Rituximab and Immunoglobulin Combination Therapy in the Home Infusion Setting

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Background

Rituximab is an anti-CD20 monoclonal antibody that results in B-cell depletion.[1] Immune diseases are associated with the autoantibodies that are assumed to be B-cell driven.[2,3] Therefore, it would be beneficial to use an agent that causes B cell depletion such as rituximab in immune diseases. It is known that rituximab may cause rituximab-associated hypogammaglobulinemia.[1, 4, 5]

Purpose

There is a gap in literature describing the safety and dosing separation of rituximab in conjunction with immunoglobulin (Ig) therapy.[2,3] The primary objective of this study was to review dosing patterns, hospitalizations, and adverse events of combination therapy.

Methods

This study is a multicenter, retrospective, descriptive analysis of patients receiving rituximab and immunoglobulin. Safety data therapy included hospitalizations and adverse drug reactions. The inclusion criteria are patients receiving immunoglobulin and rituximab therapy from this organization between January 2020 through September 2022. Patients who did not receive rituximab and immunoglobulins within the same time frame were excluded.

Results

A total of 68 patients met the inclusion criteria to be evaluated for this retrospective analysis. There were 43 (63.2%) females, and the average patient age was 49 (14 – 79 years) *(Table 1)*. Most of the patients (88.2%) had an inflammation-mediated diagnosis *(Figure 1)*. There were 11 patients who received at least one dose of immunoglobulin and rituximab on the same day. The average dosing separation was immunoglobulin 7.84 days before rituximab and 5.99 days after rituximab *(Figures 3 and 4)*.

About half of the patients experienced a missed or delayed dose of immunoglobulin, with 22 (3.1%) patients possibly impacted by the rituximab dosing schedule. During therapy, 18 (26.5%) patients had a record of at least one hospitalization, with 19 (27.9%) patients having adverse events. Of the reported adverse events, 6 (7.9%) were infusion-related reactions *(Figure 2)*. There were no reports of an acute kidney injury based on the available labs.

Table 1: Patient Demographics

Rituximab and Immune Globulin Patients *(n = 68)*	
Gender	
Female	43 (63%)
Male	25 (37%)
Average Age *(years)*	49 (14 - 79)

Figure 1: Patient Diagnosis
(n = 94)

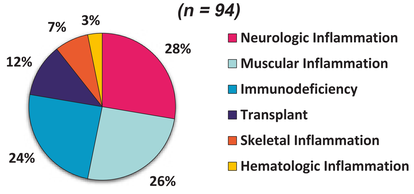


Figure 2: Tolerability of Rituximab and Immunoglobulins
(n = 76)

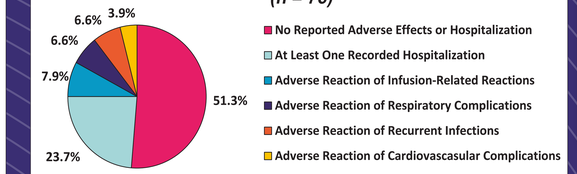


Figure 3: Average Days Between Rituximab and Ig Administrations
(Ig Administration BEFORE Rituximab)

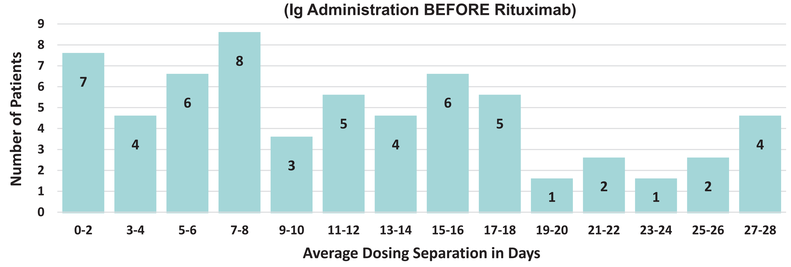
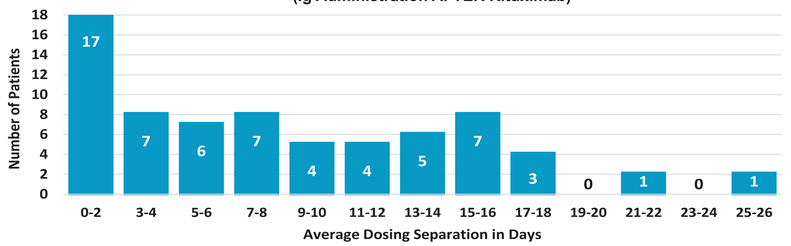


Figure 4: Average Days Between Rituximab and Ig Administrations
(Ig Administration AFTER Rituximab)



Discussion

This study focused on the safety of rituximab and immunoglobulin combination therapy. There were 13 patients who initiated rituximab prior to immunoglobulin therapy, with 3 that started the immunoglobulin therapy due to possible rituximab-associated hypogammaglobinemia.

Of the 11 patients who received at least a dose of immunoglobulin on the same day as rituximab, only one patient had a hospitalization and a missed dose of immunoglobulin. The patient was hospitalized due to a stroke which was deemed unrelated to the rituximab and immunoglobulin dosing. Potential limitations include the dependence of hospitalization documentation and accessibility of lab results. There appears to be no correlation between hospitalizations or adverse events with dosing separation.

Conclusion

The current data does not demonstrate guidelines for dosing of immunoglobulin therapy with rituximab. The findings of this retrospective analysis may help guide practitioners with evidence to safely dose immunoglobulin therapies with rituximab. The benefit of same day infusion may include not only a cost savings, but convenience of time saved by nursing and patient thus the potential for further study of dosing parameters of efficacy based upon separation of dosing.

For future research, studies should be done to evaluate an optimal time to dose immunoglobulin therapy and rituximab to achieve the desired clinical outcome.

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Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Tatum Speicher; Maria Giannakos; Craig Gardner; Julia Cowell; Olivia Hanley. Nothing to disclose.

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