A Retrospective Chart Review of the Amount of IV Fluids Administered and Infusion Reactions Occurring in Patients Receiving Alemtuzumab Course One for Relapsing MS

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Poster # SX07

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Introduction

Alemtuzumab received FDA approval for treatment of relapsing forms of Multiple Sclerosis in late 2014. In clinical studies, 92% of patients receiving alemtuzumab 12 mg experienced Infusion Associated Reactions (IAR)[4]. Serious IAR's occurred in 3% of patients receiving alemtuumab[4]. Recommendations have been made to minimize severity and frequency of these reactions, including hydration and premedication with corticosteroids[1,2,3]. Corticosteroids are associated with risk of sodium retention, potassium loss, and resultant edema.

Materials & Methods

Thirty-nine patients received Course One alemtuzumab at Carolinas HealthCare System Multiple Sclerosis Center between the dates of 2/1/15 and 1/31/17. A retrospective chart review identified basic clinical data such as daily total of concurrent IV Fluid administration, dosages of corticosteroids, and the presence and severity of IAR's.

All patients were instructed to increase hydration and premedicate with ranitidine 150 mg and cetirizine 10 mg daily starting three days prior to infusion day one. This regimen was continued throughout Course One. Additionally, all patients were premedicated with Benadryl 50 mg IV, acetaminophen 1000 mg PO, and Solumedrol 1000 mg IV on infusion days one through three. Twenty-six patients received Solumedrol 500 mg days four and five.

Patients were initially hydrated with NS 250 ml/hr concurrent with medication infusion. We felt fluid volumes were contributing to IAR's, so volumes were gradually reduced.

Objective

Determine if differing rates of concomitant IV Fluid administration influences frequency and severity of IAR's.

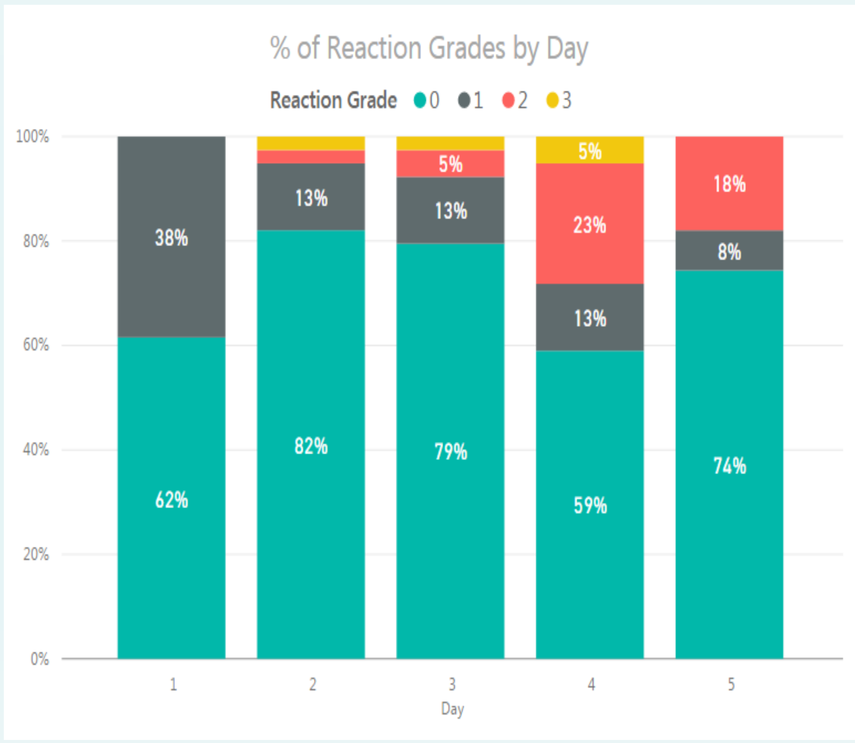
Results

Analysis

Several mixed effect models were fit and the final model was selected based on AIC. The parameters of the final model were obtained using the method of maximum likelihood. "Unstructured" correlation structure between the repeated measures was found to be best fit for this data. SAS 9.4 was used for statistical analysis.

Patient Demographics

Number of females (%)	**21 (53)**
Age at time of treatment (years) (median (range))	40(22-67)
Number of patients with EDSS of 4 or greater (%)	27 (69)
Number of patients (%) receiving IV Fluid amounts:	
0-500 mL	13(33)
501-1000 mL	8(21)
Over 1000 mL	18(46)



Discussion

We saw far fewer IAR's in our patient population than were reported in the clinical trial data, perhaps due to the aggressive premedication regimen our patients were prescribed. None of the factors identified were significantly associated with the presence or grade of an IAR. Odds of a reaction were approximately three times more likely on day 4 than day 1, but this was not statistically significant. Odds of a reaction were greater when concurrent IVF amounts were greater than 500 ml, but this was not statistically significant. The study was limited by small sample size.

Conclusions

More research is needed to determine the optimal amount of hydration for patients receiving alemtuzumab for RMS. We believe that patient education regarding hydration and premedication prior to infusions has contributed to lower rates of IAR than expected. Though not statistically significant, we saw a trend towards less reactions in patients receiving lesser amounts of concurrent IVF.

References

[1]**McEwan L, Caon C, Chieffe C, Mayer L, Saldana-King T, and Miller CE**. *Journal of Infusion Nursing.* 2016;39(2):93-104.
[2]**Caon C, Ma yer L, and Smith MS.** *Int J MS Care.* 2013; 15:159-168.
[3]**Caon C, Namey M, Meyer C, Mayer L, Oyuela P, Margolin DH, and Rizzo M.** *Int J MS Care*. 2015; 17: 191-198.
[4]**Lemtrada Package Insert**
[5]**Methylprednisolone Package Insert**.

Disclosures

Ms Moore and Dr Graves have received honoraria from Genzyme as a consultant for advisory boards and as a member of the speaker's bureau. Mr Clifford has received honoraria from Genzyme as a consultant for advisory boards. Dr Raheem has no disclosures.