compensation in the range of $500-$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Novartis. The institution of Dr. Krysko has received research support from Biogen Idec. The institution of Dr. Krysko has received research support from National MS Society.

Spinal Cord Neurosarcoidosis: A Clinical-Radiological Correlation of 39 Cases

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Objective

Present radiological and clinical data of spinal cord neurosarcoidosis and response to treatment.

Background

The diagnosis of neurosarcoidosis is challenging. Stern et al. have used histopathological data, clinical scenarios, and response to treatment to propose diagnosis criteria for definite, probable, or possible neurosarcoidosis. There is no definitive confirmatory test except sample biopsy, which is not a preferred test for the central nervous system due to potential complications. MRI studies can help detect nervous system involvement; however, it is neither sensitive nor specific.

Design/Methods

Retrospective analysis with descriptive statistics.

Results

Our cohort consisted of 39 patients with spinal neurosarcoidosis. On MRI, 62% of the patients had a longitudinally extensive intramedullary lesion, 21% had one or multiple patchy intramedullary lesions, 31% had leptomeningeal involvement, and 18% had nerve roots enhancement. The cervical spine was most commonly affected (85%), followed by the thoracic (38%) and lumbar (15%). Thirty-seven patients were treated with oral or IV corticosteroids at first presentation, followed by maintenance with oral steroids and maintenance immunosuppressive agents. The three most used agents were Methotrexate (49%), Azathioprine (31%), and Mycophenolate mofetil (18%). Thirty-four patients had MRIs during follow-up, and twenty-nine patients had documented improvement during follow-up, with a median improvement time on MRI of 10.8 months (95% CI = 6.1 to 17 months). Thirty-one patients had enhancement on MRI at presentation, and 18 (58%) had complete enhancement resolution during follow-up, with a median time for resolution of enhancement of 51.8 months (95% CI = 24.9 to 83.4 months).

Conclusions

The diagnosis of spinal neurosarcoidosis can be challenging; however, we found that resolution of MRI enhancement can require a few years of immunosuppression, which is longer compared to other spinal neuroimmunological pathologies. The current knowledge about the treatment and prognosis of neurosarcoidosis is limited, and there is no FDA medication approved nor clinical trials data regarding the treatment of neurosarcoidosis.

Disclosure: Dr. Al-Hader has nothing to disclose. Dr. Schultz has nothing to disclose. Dr. Nofar has nothing to disclose. Dr. Rai has nothing to disclose. Dr. Cerghet has nothing to disclose.

Serum Autoantibody Lowering by the Anti-FcRn Monoclonal Antibody, Nipocalimab, Correlates With Clinical Improvement in Generalized Myasthenia Gravis Patients

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Objective

To evaluate the relationship between clinical improvement in Myasthenia Gravis-Activities of Daily Living (MG-ADL) scores and the pharmacodynamic effects of IgG autoantibody lowering induced by nipocalimab in the Vivacity MG Phase 2 study.

Background

Nipocalimab is a fully human, aglycosylated, effectorless IgG1 anti-FcRn monoclonal antibody that targets the neonatal Fc receptor (FcRn) with high affinity, thereby lowering IgG pathogenic antibodies in autoimmune disease.

Design/Methods

The relationship between the reduction in acetylcholine-receptor (AChR)- and Muscle-Specific-Tyrosine-Kinase (MuSK)- autoantibodies with improvement in MG-ADL scores were explored across the four nipocalimab dose arms in the Vivacity MG Phase 2 Study in generalized myasthenia gravis (gMG) patients.

Results

Of the 68 patients enrolled, 54 were randomized to one of the four nipocalimab dosing arms. 51 (94%) were seropositive for anti-AChR, 3 (6%) for anti-MuSK. Nipocalimab was well-tolerated and achieved substantial, dose-dependent and rapid reductions in serum total IgG, including all IgG subtypes and anti-AChR autoantibodies. These reductions were associated with dose-dependent, durable and rapid MG-ADL responses in all nipocalimab-treated groups. A similar trend in IgG4 reduction was noted, though the sample size of MuSK positive patients was small.

Conclusions

The results support the rapid, dose-dependent and predictable effect of nipocalimab in lowering pathogenic autoantibodies and inducing clinical improvement in patients with gMG. In addition, the close correlation between serum IgG, anti-AChR and clinical response suggest the potential of using serial serum IgG levels as a biomarker in management of gMG patients treated with nipocalimab; this will be tested in the ongoing Phase 3 gMG trial.

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or an ownership interest from Johnson & Johnson. Dr. Sun has received personal compensation for serving as an employee of Janssen.

Long-term Safety and Efficacy of Efgartigimod in Patients With Generalized Myasthenia Gravis: Interim Results of the ADAPT+ Study

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Objective

To evaluate the safety and efficacy of efgartigimod in patients with generalized myasthenia gravis (MG) enrolled in the ADAPT+ long-term extension study.

Background

Treatment with efgartigimod, a human IgG1 antibody Fc-fragment that blocks neonatal Fc receptor, resulted in clinically meaningful improvement (CMI) in MG-specific outcome measures in the ADAPT phase 3 clinical trial. All patients who completed ADAPT were eligible to enroll in its ongoing open-label, 3-year extension study, ADAPT+.

Design/Methods

Efgartigimod (10 mg/kg IV) was administered in cycles of once-weekly infusions for 4 weeks, with subsequent cycles initiated based on clinical evaluation. Efficacy was assessed during each cycle utilizing Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scales.

Results

Ninety-one percent of ADAPT patients (151/167) entered ADAPT+. As of February 2021, 106 AChR-Ab+ and 33 AChR-Ab– patients had received at least 1 dose of open-label efgartigimod (including 66 ADAPT placebo [PBO] patients). The mean (SD) study duration was 363 (114) days, resulting in 138 patient-years of observation. Similar incidence rates per patient year (IR/PY) of serious adverse events were seen in ADAPT (efgartigimod: 0.11; placebo: 0.29) compared to ADAPT+ (0.25). Five deaths (acute myocardial infarction, COVID-19 pneumonia/septic shock, bacterial pneumonia/MG crisis, malignant lung neoplasm, and unknown [multiple cardiovascular risk factors identified on autopsy]) occurred; none were considered related to efgartigimod by the investigator. AEs were predominantly mild or moderate. CMI was observed in AChR-Ab+ patients during each cycle (up to 10 cycles) at magnitudes comparable to improvements observed at week 3 of cycle 1 (mean[SE] improvements: MG-ADL, –5.1[0.34]; QMG, –4.7[0.41]). Clinical improvements mirrored maximal reductions in total IgG and AChR-Abs across all cycles.

Conclusions

This analysis suggests the efficacy of long-term treatment with efgartigimod was consistent across multiple cycles. No new safety signals were identified, despite being conducted before vaccine availability during the COVID-19 pandemic.

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