ABSTRACT: A Chart Review Methodology to Characterize Treatment Patterns and Clinical Outcomes in Patients with Multicentric Castleman’s Disease

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Background

Little is known about usual care treatment patterns and associated outcomes in Multicentric Castleman Disease (MCD). Information on the management of this disease can inform clinical practice, treatment guidelines and elucidate areas of unmet medical need.

Objectives

The design and execution of a retrospective chart review study of patients with MCD are described, highlighting general methodological considerations for conducting chart review studies in rare diseases.
Methods

A multi-center, retrospective, chart review study of 59 MCD patients (61.0% male; mean age 53.3 ± 16.3 years) was conducted in 2 centers in the United States. All MCD cases within a defined eligibility period were identified. For eligible patients, medical record data were abstracted by site study staff; up to 6 months pre-index diagnosis date and up to 3 years of post-diagnosis. Anonymized data were recorded on paper case report forms (CRF) and entered into an electronic data capture (EDC) system.

Results

Key design challenges and lessons learned include: 1) site recruitment: limited number of participating treatment centers resulting in small study population; 2) CRF design: disease complexity and lack of published literature necessitated the involvement of MCD clinical experts with management knowledge 3) data abstraction: patients only seen at the site for a one-time consultation or second opinion resulting in minimal and missing data, making MCD diagnosis confirmation and eligibility criteria difficulty to confirm and underreporting of data and; 4) EDC system design: data from multiple clinical tests, exams and physicians visits were collected so the EDC system must permit large volumes of data with a validation plan to ensure quality data.

Conclusions

Acquisition of clinical outcomes, resource utilization and treatment pattern data through retrospective chart review study in a rare disease population such as MCD is challenging and requires an innovative approach, disease knowledge, and a sufficient treatment centers to optimize external validity.