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# PHARMACO-SURVEILLANCE AND ADVERSE EVENTS IN THE TREATMENT OF PEDIATRIC RHEUMATIC DISEASES: A RETROSPECTIVE COHORT

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**BACKGROUND**

Treatment of autoimmune rheumatic diseases includes disease-modifying antirheumatic drugs, immunosuppressants and biological agents; however these medications can cause many adverse events (AEs) whose severity depends on many factors, such as medication doses, route of administration, use duration, drug association, or presence of other risk factors. This study describes the AEs of the treatment of autoimmune rheumatic diseases, reporting their severity, associated factors, procedures and follow-up in patients with juvenile idiopathic arthritis (JIA), juvenile systemic lupus erythematosus (JSLE) and juvenile dermatomyositis (JDM) in a specialized pediatric rheumatology center.

**MATERIALS AND METHODS**

Retrospective descriptive and analytical study of a cohort. We described all AEs and the aggravating factors in children and adolescents treated at a specialized pediatric rheumatology center. The associations between the aggravating factors for the AEs, such as patient age, dose, route of administration, and use duration of medication were evaluated.

**RESULTS**

This study found 951 AEs in 547 patients. Methotrexate was the leading cause (63.3% of cases), characterized specially as gastrointestinal intolerance and increased liver enzyme levels, followed by high doses of oral glucocorticoids. It was observed that more AEs were associated with use of disease-modifying antirheumatic drugs, immunosuppressants and intravenous immune globulin than with biological medications (96.4% x 3.6%). Two patients (0.2%) had life-threatening AEs and 35 (3.7%) had severe AEs. No death related to medication was registered. The aggravating factors related to methotrexate were younger age of the patients, use of subcutaneous route or both subcutaneous and oral routes, and the presence of JIA, whereas the aggravating factors for glucocorticoids were female sex, younger age of patients, oral use, higher doses and presence of JSLE. The most frequent medical procedures for the AEs were withdrawal or reduction of medication (23.9%), change in route of administration, use of other medications, or orientations to the patients.

**CONCLUSION**

This research is the largest retrospective study in the literature focusing on the AEs for medications used in the treatment of childhood autoimmune rheumatic diseases. It was concluded that the AEs are frequent and need constant monitoring. The occurrence of AEs may be related to the disease itself or other associated treatments.