

Poster presentation

Safety of rituximab in children with auto-immune diseases

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Purpose

Assessment of safety of rituximab in children with auto-immune diseases (AID) in published reports.

Methods

Pooled analysis of the literature using the Medline database until March 2008.

Results

We identified 169 children treated for refractory AID: autoimmune cytopenia (s) (104 patients), systemic lupus erythematosus (SLE) (52 patients), miscellaneous (13 patients). The mean follow-up period was 6 to 36 months. Patients received 2 to 4 rituximab infusions (350–750 mg/m²) associated with immunosuppressive drugs in 49/52 SLE patients. Replacement intravenous immunoglobulins therapy was given to 68/169 patients. Moderate side effects were observed in 50/169 patients: infusion-related reactions, infections, transient neutropenia $> 0.5 \times 10^9/L$ and serum sickness disease. Severe side effects were observed after rituximab infusion in 11/169 (6.6%) patients: severe infusion related hypotension (4 patients), neutropenia $< 0.2 \times 10^9/L$ (3 patients), (2 SLE patients), cerebral vasculitis (1 SLE patient). Two SLE patients who have received cyclophosphamide died from cerebral histoplasmosis and *Staphylococcus aureus* endocarditis, and one boy who underwent autologous bone marrow transplantation for severe thrombocytopenic purpura developed severe enteroviral meningoencephalitis; Ig G level was low at time of infection in 3/4 patients and not available in the fifth.

Conclusion

Severe adverse events were recorded in 6.6% of the rituximab-treated children. Patients who have received previous, concurrent and/or subsequent immunosuppressive drugs may experience severe infections, and must be closely monitored. A cohort study of children treated for auto-immune diseases with rituximab has been initiated in France since March 2008 to better assess the tolerance of this therapy.