Immune thrombocytopenia in adults: a prospective cohort study of clinical features and predictors of outcome

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Appendix

METHODS

ITP diagnosis ascertainment

The primary objective of the PGRx-ITP registry was to establish if vaccination (several types) could be a risk factor for the development of ITP,[1] enabling a strict diagnostic ascertainment process.

First, the diagnosis of incident and non-secondary ITP was systematically ascertained by the research team for all of the patients included, using criteria established by international guidelines:[2] (1) isolated thrombocytopenia, (2) absence of secondary ITP, and (3) incident (i.e., newly diagnosed) ITP. The definitions used for isolated thrombocytopenia, secondary ITP and incident ITP are detailed in Table 1.

Second, the recruiting physicians were systematically requested by email to confirm the diagnosis 3 months after first recruiting a patient. All patients with a non-confirmed diagnosis were excluded.

Case report forms for ITP patients

Upon inclusion, the recruiting physician was responsible for filling in the following information:

- date of first ITP symptoms
- date of diagnosis and inclusion
- mode of onset
- clinical presentation at diagnosis
- blood test results (namely platelet count) at diagnosis
- titration of antinuclear antibodies (ANA), if tested

- results of a bone-marrow examination, if done (recommended in France for patients over 60 years old[3])
- initial therapeutic management of ITP

Twelve months after diagnosis, all recruiting physicians completed data on the outcome of ITP:

- treatments administered to patients over this period
- current platelet count
- recovery or progression to chronic ITP

Statistical analyses

Parametric tests were used to compare patients testing positive for ANA (titer>1/80) and patients testing negative at baseline, regarding age, gender, history of autoimmune disorder in first-degree relatives, bleeding symptoms and platelet count at baseline.

Univariate logistic regression models were used to identify baseline variables associated to the 12-month outcome (chronicity *vs.* recovery), providing Odds Ratios (OR) and 95% Confidence Intervals (95%CI). The potential baseline predictors were determined *a priori*: gender, age, bleeding symptoms, platelet count and positive ANA test. These analyses were performed in all patients and then restricted to patients not managed with any disease-modifying intervention (defined as the use of rituximab and/or splenectomy) during the 12 months as these treatments are thought to modify the natural course of ITP.[4,5]

Univariate conditional logistic regression models were used to determine whether a history of autoimmune disorder in first-degree relatives was a risk factor for developing ITP or not, cases and their matched controls were compared using. These analyses were performed in the entire set of patients and in the sub-group of cases showing positive ANA test at baseline and the sub-group of cases showing progression to chronic ITP at 12 months.

Literature citations

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