Comparison of Low-Dose versus Conventional-Dose Prednisolone in the Treatment of Idiopathic Thrombocytopenic Purpura (ITP)

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Objective: To assess the efficacy of low-dose prednisolone in patients with ITP.

Design: A Prospective Randomized Controlled Trial.

Setting: Salmaniya Medical Complex, Kingdom of Bahrain.

Method: A randomized controlled trial was conducted comparing the conventional-dose to a low-dose of prednisolone (0.25 mg/kg/day).

Forty-one patients with ITP were enrolled in the study; 21 patients were randomized to low-dose prednisolone (group I) and 20 patients received the conventional-dose (group II).

Result: The overall remission rate (OR) for both groups was 78.05%. There was no statistically significant difference between both groups in terms of group overall remission 17 (81%) versus 15 (75%), group complete remission 11 (52.4%) versus 10 (50%) or partial remission rate 6 (28.6%) versus 6 (25%). In addition, failure rate, relapse rate, and splenectomy rate were similar and not statistically significant. Two (10%) patients developed complications related to steroids therapy, both were in group II, but were not statistically significant.

Conclusion: Although the study had a small number of patients, it revealed that low-dose of prednisolone (0.25 mg/kg/day) is as effective as the conventional-dose (1 mg/kg/day) and probably safer.

Accordingly, we recommend the use of low-dose prednisolone as initial therapy for ITP rather than the high-dose.


Idiopathic thrombocytopenic purpura (ITP) is a relatively common disease, with an incidence of 2.25-6.6/100,000/year1-3. Until recently, the main pathology of ITP was thought to be due to autoantibodies attached to the platelets causing their destruction by reticuloendothelial systems, particularly the spleen; however, defective thrombopoiesis and T-cell mediated platelets destruction have been discovered4-6. The natural history of ITP is scantily defined, but some studies showed that they had a good outcome and mortality equal to the general population while having more morbidity from the treatment rather than the disease7-12.

Bleeding is usually uncommon in ITP except in severe cases (platelets count<30x10^9/l) and clinical presentation varies from asymptomatic, mild bleeding or serious bleed like intracranial hemorrhage. Patients with platelet counts >50x10^9/l need no treatment except if they are undergoing procedures expected to induce blood loss. Steroids and immunoglobulins are considered as first-line therapy, although there are no randomized trials addressing their use versus no treatment7,8,13. Splenectomy is reserved for those who fail steroid therapy. Few randomized trials comparing the conventional-dose of prednisolone (1 mg/kg/day) versus the low-dose (0.25-0.5 mg/kg/day) showed no significant difference1,3,8,12,14-17. Although, prednisolone in the conventional-dose is still recommended as the initial therapy2.

The aim of this study is to assess the efficacy of low-dose prednisolone (0.25 mg/kg/day) compared to conventional-dose (1 mg/kg/day) in patients with ITP.

METHOD

Patients diagnosed with ITP from January 2003 to December 2005 were recruited in the treatment protocol. ITP was diagnosed according to the accepted criteria: isolated thrombocytopenia with platelets count below 150×10^9/l, normal hemoglobin level, white blood cell counts, differentials, and peripheral blood smear. In addition, history and physical examinations were not suggestive of any other diseases. Bone marrow examination was not routinely performed. Written informed consent was obtained from each patient. The study was approved by the local ethical committee.