

An Open-Label, Multicenter Study Evaluating the Efficacy and Safety of a New 10% Liquid Intravenous Immunoglobulin in Patients With Primary Immune Thrombocytopenia (ITP)

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ABSTRACT

BACKGROUND AND AIMS

This single-arm, open-label, multicenter study evaluated the efficacy and safety of a new 10% liquid intravenous immunoglobulin (Intragam[®] 10 NF), in patients with primary immune thrombocytopenia (ITP).

METHODS

Nineteen patients ≥ 18 years of age with a platelet count of $<50 \times 10^9/L$ received ± 2 g/kg 10% liquid intravenous immunoglobulin (Intragam[®] 10 NF) over 2 days. The primary endpoint was the proportion of patients with a platelet response ($\geq 50 \times 10^9/L$ and an increment $\geq 30 \times 10^9/L$ over baseline within 7 days).

RESULTS

In the per protocol analysis, 88.2% of patients ($n = 17$; 95% Confidence Intervals [CI]: 63.6%, 98.5%) achieved the primary endpoint. The median duration of platelet response was 12.2 days and the median time to first platelet response was 4 days. External bleeding events decreased in number and intensity from Day 2. There were no episodes of internal bleeding. All patients experienced at least one treatment emergent adverse event (TEAE). The majority of TEAEs were mild or moderate intensity with no study withdrawals due to TEAEs and no deaths. Headache was the most common TEAE, attributed to treatment in 68.4% of patients. There were four severe TEAEs with a causal relationship to the study drug: three cases of headache and one aseptic meningitis syndrome (AMS).

CONCLUSION

The majority of ITP patients treated with 10% liquid intravenous immunoglobulin (Intragam[®] 10 NF) achieved a rapid platelet response accompanied by a decrease in bleeding events. The efficacy and safety profile of 10% liquid intravenous immunoglobulin (Intragam[®] 10 NF) is similar to other studies with Intragam P; with the added reassurance of a third dedicated virus removal step and the convenience of a 10% formulation.

Keywords: Immunoglobulins, intravenous, primary immune thrombocytopenia, immune thrombocytopenia purpura, autoimmune thrombocytopenia purpura, idiopathic thrombocytopenic purpura, Intragam[®] 10 NF

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INTRODUCTION

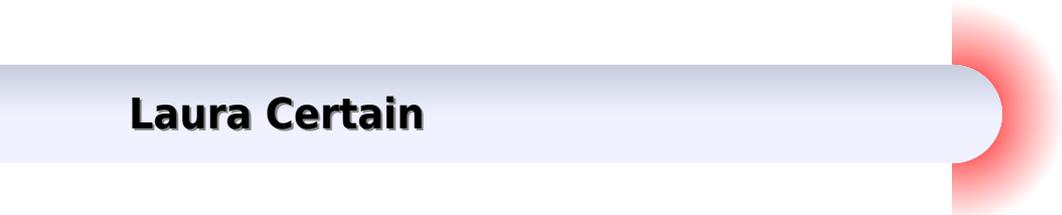
Chronic primary immune thrombocytopenia (ITP) [1] is an autoimmune disorder in which immune-mediated platelet destruction and/or suppression of platelet production results in thrombocytopenia [2–4]. In children, the onset of ITP is typically sudden and the condition is often self-limiting. In contrast, ITP in adults has an insidious onset and a more persistent course [2, 4–6]. The diagnosis of ITP is based principally on the history, physical examination, complete

blood count, examination of the peripheral blood smear, and exclusion of other etiologies [4].

Patients with platelet counts persistently below $10 \times 10^9/L$ are at risk of life threatening bleeding, while petechiae or ecchymoses often develop spontaneously in patients when platelet counts are between 10 and $50 \times 10^9/L$. Patients with platelet counts between 50 and $50 \times 10^9/L$ may experience easy bruising and occasionally more serious bleeding [2]. Guidelines for the management of chronic ITP recommend

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