World Academy of Science, Engineering and Technology
International Journal of Medical and Health Sciences
Vol:18, No:12, 2024

Efficacy and Safety Profile of Biosimilar PEG-Asparaginase (Asviia) in Patients with Acute Leukaemia: A Retrospective Study from Kashmir

Authors : Faisal Guru Rashid, Syed Nisar, Mohammad Hussain Mir, Ulfat Ara, Richa Tripathi

Abstract : Background: Biosimilar pegylated L-asparaginase is a potential alternative to the innovator version for treating acute lymphoblastic leukaemia (ALL) in Indian children, addressing issues of availability and cost. Biosimilar offers a viable solution, ensuring wider access to essential treatment in resource-limited settings like India. With this in mind, we conducted a study to assess the efficacy and toxicity of Biosimilar Pegaspargase (Asviia) in patients with Acute Leukaemia at our centre. Materials and methods: A retrospective study was conducted to assess the efficacy and safety of biosimilar PEG-asparaginase (Asviia) in newly diagnosed paediatric acute lymphoblastic leukaemia patients at the Paediatric Oncology unit of Department of Medical Oncology at Sher-I-Kashmir Institute of Medical Sciences, SKIMS Srinagar. The study included patients of ALL treated at our centre between January 2021- and December 2023. Each patient received 2 induction doses of pegaspargenase. Results: 45 patients (16 females and 29 males) were included in the study who received biosimilar PEG-asparaginase (Asviia) as a part of the treatment protocol. The age range of patients was between 1 and 16 years with a median age was 7.5 years. Median PEG Asparaginase dose received was 1175 IU (1125-3750 IU). The majority of patients were Pre-B ALL. There was considerable improvement in the haematological parameters, like haemoglobin levels rising by 1.39 and platelet counts rising by 30,402 after the patients received the first dose of Peg-ASP. Biosimilar Pegaspargase in Acute Leukaemia patients showed a tolerable safety profile with no life-threatening events. 13% of patients exhibited allergic reactions, and 17% had sepsis. Two patients (4.4%) had pancreatitis and Transaminitis events. At the end of induction, out of 45 patients, 40 (88.89%) patients had complete remission with Minimal Residual Disease (MRD) negativity, while 5 patients were MRD positive. Conclusion: Biosimilar PEG-Asparaginase (Asviia) demonstrated a tolerable safety profile and good efficacy, with nearly 90% of patients having complete Remission with MRD negativity.

Keywords : acute lymphoblastic leukaemia, biosimilar, PEG-asparaginase, minimal residual disease, remission
Conference Title : ICH 2024 : International Conference on Hematology
Conference Location : Goa, India
Conference Dates : December 09-10, 2024