Objective: 24-month stability data of immunoglobulin intravenous 10% protein solutions containing either 0.25M glycine or 0.25M L-proline with a target pH of 4.8 are provided.

Methods: Three lots of IGIV process intermediates were used as the starting materials. Each intermediate was divided into two parts and further processed to the final IGIV 10% formulated with either 0.25M glycine or 0.25M L-proline. The final IGIVs were stored at 25°C/60% relative humidity for 24 months. Immunoglobulin monomers, dimers, aggregates and fragments were measured by high-performance size-exclusion chromatography, anti-Hepatitis B surface (anti-HBs) antigen antibodies by an enzyme immunoassay. The data were analyzed using the "paired t-test".

Results: There were no statistical significant differences in total "monomers+dimers" (96.5% vs. 96.1%, p=0.618), in aggregates and fragment content (0.29% vs. 0.26%, p=0.750, 3.20% vs. 3.63%, p=0.537) and in the protective anti-HBs antigen antibody level (3.73 IU/mL vs. 3.81 IU/mL, p=0.532) between the formulations in glycine and L-proline after 24 months storage. Dimer level in both formulations was found to be well below 10% (7.52% in glycine, 5.80% in L-proline), considered to be the upper limit for good tolerability.

Conclusion: The results obtained from IGIVs formulated in 0.25M glycine or 0.25M L-proline after 24 months storage at 25°C indicate that both amino acids provide a similar stabilization of the IgG molecule in liquid formulations at low pH.

283 QUANTIFYING TOTAL IGG AND IGG SUBCLASSES (PEAK AND TROUGH) IN PRIMARY IMMUNODEFICIENCY PAEDIATRIC PATIENTS TREATED WITH INTRAVENOUS IMMUNOGLOBULIN (MULTIGAM®) AND RELATION WITH SEROSPECIFIC ANTIPNEUMOCOCCAL ANTIBODIES

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Introduction: Primary immunodeficiency diseases (PID) are associated with an increased susceptibility to recurrent severe bacterial infection, mainly related to S.pneumoniae. Intravenous immunoglobulin (IVIG) replacing functionally deficient or absent immunoglobulin, is the mainstay treatment to reduce mortality and morbidity.

Objective: Target IgG trough levels including specific antipneumococcal antibodies (APAbs), required to minimize infection risk is not established. We reported the results of a multicenter, prospective, open-label, non-interventional study in 22 PID paediatric patients, without modification of the doctor-patient relationship.

Methods: Trough and peak total IgG and IgG subclasses were measured in the patient plasma over a period comprising 6 consecutive IVIG infusions (BN Prospec System, Siemens).

APAbs against serotypes 1, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 12F, 14, 18C,19A, 19F, 23F were determined by individual 22F-ELISA according WHO13.

Results: 22 PID patients (mean age: 9.18±5.42 y; range 0.7-17.2 y) were treated with a mean IVIG weekly dose 0.400±0.008g/kg. Mean study duration was 227 ± 119 days. For all visits, trough mean in g/L were respectively 7.77± 0.28 (total IgG), 4.88± 0.27(IgG1), 2.23±0.06 (IgG2), 0.21± 0.01 (IgG3), 0.14 ± 0.01 (IgG4). Peak total IgG level was 13.92 ± 0.35g/L. A good relation was found between the available dose and the peak level ($p < 0.001$). The relation dose/ next trough level was weaker. No relation was found between the dose and the next trough APAb content.

Conclusion: Total IgG and IgG subclasses levels are within the expected values established for all age group healthy children.

306 EFFICACY AND TOLERABILITY OF PRIVIGEN® (IGPRO10) IN PRIMARY AND SECONDARY IMMUNODEFICIENCIES - A MULTICENTER OBSERVATIONAL STUDY

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Introduction: Privigen® (IgPro10) is a 10% polyvalent human IgG preparation for intravenous administration (IVIG) using L-proline as stabiliser.