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An Analysis of Safety and Tolerability Data on 10%, 16%, and 20% Formulations of Subcutaneous Immunoglobulin (IGSC)

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Abstract:

RATIONALE: Research regarding the role of IGSC in immune replacement/modulation and preferred concentrations for IGSC formulations is ongoing. We analyzed the safety and tolerability of 2 new 10% products (Gammagard [IGSC10%] and Gamunex[®] [IVIG-C10%]) and 16% and 20% solutions.

METHODS: Parameters included dose adjustment IV/SC, total volume per site, infusion site number, infusion time, adverse-event (AE) profiles, and improvements in tolerability over time.

RESULTS: The factor used to obtain equivalent AUC levels IVIG to IGSC was 137% for 10% and 16% formulations and 153% for IGSC20%. Maximum volume infused was 30mL/site for IGSC10%, 20mL/site for IVIG-C10%, ≤15mL/site for 16%, and 25mL/site for IGSC20%. The maximum number of simultaneous infusion sites is unlimited for IGSC10%, 6 for IGSC16%, and 4 for IGSC20%. Infusion time ranged from 0.6 to 3.7 hours for IGSC10%, 0.8 to 8.3 for IVIG-C10%, and 1.6 to 2 for IGSC20%. Percent of local AEs was 44.7%, 32%, 92%, and 100% for IGSC10%, IVIG-C10%, 16%, and 20%, respectively. Local AE rates per infusion were 2.8% for IGSC10%, 25% for IVIG-C10%, 49% for 16%, and 59.1% for IGSC20%. Decreased local AE incidence over time was noted for IGSC10%, IVIG-C10%, and IGSC16%, but not for IGSC20%.

CONCLUSION: Subcutaneous immunoglobulins are associated with different features and benefits. More infusion sites are possible with IGSC10%, so infusion time can be similar to that of higher concentration products. IGSC10% is associated with the lowest rate of infusion site reactions. Further research needs to be done to evaluate the benefits of higher concentrations on the immunomodulation effect.

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