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Biologic Immunotherapy with Human Intravenous Immunoglobulin Ivig in Inflammatory and Autoimmune Disorders: Experiences During the Last 30 Years

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The first publication on intravenous immunoglobulin (IVIG) administration for children with immune thrombocytopenia ITP (Imbach et al., *The Lancet* 1981;1:1228-1231) evoked targeted immunomodulation in patients with inflammatory and autoimmune disorders. We update the development of the immunomodulatory effects of IVIG over the last 30 years. The biologic, human IVIG is extracted from the pooled plasma of 10'000 – 60'000 blood or plasma donations. The safety of IVIG is controlled by ongoing careful selection and deferral of donors, by testing and validation of donated blood and plasma as well during the steps of production including the purification process. The key observation/discovery was made in a boy with severe bleeding immune of ITP. Following administration of IVIG the boy's platelet counts started to increase and in a subsequent pilot study the same phenomenon was observed of 12 consecutive children with ITP. Since then, there have been controlled clinical trials of IVIG in patients with ITP as well as in other inflammatory or autoimmune disorders. Examples of documented immunomodulation are today: in hematology: graft versus host disease, allograft recipients, autoimmune lymphoproliferative syndrome and others, in neurology: Guillain-Barré syndrome, dermatomyositis, myasthenia gravis, multifocal motor neuropathy, remitting-relapsing multiple sclerosis and others, in dermatology: autoimmune mucocutaneous blistering diseases, pemphigus, Stevens-Johnson syndrome and others. Extensive studies on the mechanisms of action of IVIG have documented the immunomodulatory interaction in the disturbed immune response in these patients, although the mechanisms of actions remain far from being clear. Today, the clinical efficacy of IVIG has resulted in high demand for the product. The peer reviewed scientific, original articles on "IVIG" (see PubMed) listed at total of 32'251 publications until 2010. The worldwide annual use of IVIG increased remarkably, from 300 kg to 70,000 kg over the last 30 years. Thus, the human derived product IVIG challenged therapeutic approaches from immunosuppression to biologic immunomodulation in many inflammatory and autoimmune disorders.