(a control group to compare for effects specifically related to the switch from IVIG to SCIG); prior therapy for 1 patient was not stated.

Methods. Patients received weekly SCIG infusions at home over a period of 10 months (43 infusions). Questionnaires were administered at baseline and at 6 and 10 months. For assessment of HRQOL in children, parents completed the Child Health Questionnaire-Parental Form 50; adults used the Short Form 36. For assessment of treatment satisfaction, the authors adapted a Life Quality Index instrument previously developed in a study of antibody-deficient patients receiving IVIG.

Results. On the Child Health Questionnaire-Parental Form 50, the children demonstrated significant improvement in 6 of 14 concepts analyzed: “role/social-emotional, behavioral,” “general health perceptions,” “parental impact-emotional,” “parental impact-time,” “family activities,” and “global health.” On the Short Form 36, adults had improvements in vitality, mental health, and social functioning. These differences were found only in those adults who switched from IVIG to SCIG, not in those who were already receiving SCIG, suggesting that the improvement resulted from the change in therapy. Both children and adults had significant improvements in Life Quality Index. Again, in the adults, no change was seen in the group that was already receiving SCIG at enrollment. At study end, all children/parents, the 10 adults on SCIG at enrollment, and 73% of the adults who switched preferred to continue SCIG at home. Two expressed a preference for SCIG regardless of setting, 1 expressed a preference for home regardless of method, 1 expressed no preference for anything, and only 1 expressed a preference for IVIG in the hospital.

Conclusions. Home therapy with SCIG in children and adults with antibody deficiency is generally self-perceived as superior to in-hospital therapy with IVIG with respect to several validated measures of HRQOL.

Reviewer’s Comments. IVIG has been a major mode of therapy for immunodeficiency for 30 years. Many primary care providers have 1 or a few patients who receive this therapy. Less widely recognized, SCIG has also been used with safety and efficacy equivalent to IVIG and has been the major mode of immunoglobulin delivery in some countries (although this is an off-label use in the United States). For a variety of reasons, SCIG is gaining in popularity and may replace IVIG for many patients with immunodeficiency diseases.

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HUMAN IMMUNODEFICIENCY VIRUS

PERFORMANCE CHARACTERISTICS OF HIV-1 CULTURE AND HIV-1 DNA AND RNA AMPLIFICATION ASSAYS FOR EARLY DIAGNOSIS OF PERINATAL HIV-1 INFECTION


Purpose of the Study. The diagnosis of HIV infection in a newborn exposed to HIV in utero is a challenge. In the early years of the epidemic, HIV clinicians monitored the decline of HIV antibody levels for up to 2 years after birth to confirm that a child was not HIV-infected. HIV infection in infants is now typically made by the detection of viral DNA sequences in peripheral blood mononuclear cells by means of a DNA polymerase chain reaction (PCR). Plasma HIV-RNA measurements with PCR may also be valuable but has the theoretical limitation of false-negative reactions resulting from early treatment of the mother and infant. The purpose of this study was to evaluate the performance of HIV DNA PCR, HIV RNA PCR, and HIV culture to identify infected infants exposed to the virus in utero.

Study Population. Infants participating in the Pediatric AIDS Clinical Trials Group protocol 185.

Methods. Specimens from the infants (24 infected and 100 uninfected) obtained prospectively were studied with standard nucleic acid–amplification assays and peripheral blood mononuclear cell microcultures. The sensitivities, specificities, and positive and negative predictive values were calculated for each of the 3 assay systems.

Results. At birth the sensitivity of culture, DNA PCR, and RNA PCR were 21%, 11%, and 27%, respectively. By 6 weeks, the sensitivity had improved to 90%, 83%, and 95%. The specificity was 99% to 100% for all assays at all times.

Conclusions. The authors concluded that the diagnostic performance of the RNA PCR assay matched or exceeded that of culture and DNA PCR. Because RNA assays require less blood volume and often can be performed more quickly at reference laboratories, it is suggested that RNA assays may be used for early diagnosis of HIV infection in infants.

Reviewer’s Comments. This study demonstrates that RNA PCR assays are effective for the diagnosis of HIV infection. However, it must be noted that cryopreserved specimens were used for these PCR assays and may have impacted the sensitivity of the DNA PCR. Additionally, we have had 3 false-positive RNA PCR assays in 2 newborns and 1 adolescent exposed to HIV. A negative RNA PCR at or after 6 weeks of age strongly indicates that an infant is not infected.

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GROWTH HORMONE IN T-LYMPHOCYTE THYMIC AND POSTTHYMIC DEVELOPMENT: A STUDY IN HIV-INFECTED CHILDREN


Purpose of the Study. Growth hormone (GH) plays a role in thymic function, and decreased hormone secretion has been reported in HIV-infected children. Highly active antiretroviral therapy suppresses HIV replication and results in increases in CD4+ T cells in HIV-infected patients. The aim of this study was to determine if the level of immune reconstitution associated with antiretroviral therapy is influenced by the status of the GH insulin-like growth factor 1 axis.

Study Population. HIV-infected children (n = 26) were studied. Half of them had GH deficiency as defined by a reduced peak GH response to GH-releasing hormone and arginine-stimulation test. These patients were matched to 13 patients of similar age, pubertal status, and clinical findings but with normal GH-response tests.

Methods. Thymic volume was measured with magnetic resonance imaging. Peripheral blood lymphocyte subsets were evaluated with standard monoclonal antibody techniques. Serum interleukin 7 levels were measured with an enzyme-linked immunoabsorbent assay.

Results. The 2 patient populations did not differ in age, weight, height, body mass index, pubertal status, clinical or immunologic stage of disease, or number and percentage of CD4+ T cells before beginning antiretroviral therapy. After antiretroviral therapy, children with GH deficiency had reduced CD4+ T-cell numbers and percentages, reduced interleukin 7 concentrations, and reduced thymic...
Performance Characteristics of HIV-1 Culture and HIV-1 DNA and RNA Amplification Assays for Early Diagnosis of Perinatal HIV-1 Infection

Joseph A. Church

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Performance Characteristics of HIV-1 Culture and HIV-1 DNA and RNA Amplification Assays for Early Diagnosis of Perinatal HIV-1 Infection

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