
Pilot Study to Assess Subjective and Objective Reporting of Potential Adverse Drug Reactions in Older Versus Younger HIV-Infected Patients Using Antiretroviral Therapy

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Limited data exist on tolerability of antiretroviral therapy (ART) in older HIV-infected patients compared to their younger counterparts. There is also concern for overlap of ART toxicities with concomitant conditions potentially leading to an increased burden of ART-related adverse drug reactions (ADRs). A prospective, descriptive-comparative study was conducted to compare incidence and severity of ADRs secondary to ART in older (≥ 50 years) versus younger (< 50 years) HIV-infected patients. No differences were found in the presence or severity of subjective or objective ADRs between groups. The burden of intolerance appeared to be high for certain ADRs in both age groups. Regardless of age, subjects with certain concomitant illnesses had higher rates of potential ADRs. Providers need to be aware of patient characteristics that lead to increased rates of ART intolerance; for patients with an increased comorbidity burden, providers need to be attentive to the potential impact on ART tolerability.

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As the therapy for HIV has evolved, so has our understanding of antiretroviral therapy (ART), yet

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new questions regarding tolerability develop with their long-term use. ART-associated adverse drug reactions (ADRs) are common in patients taking ART and represent a major concern amongst people living with HIV. ADRs and HIV symptoms have been associated with a decreased quality of life (QOL) in HIV-infected patients (Bader et al., 2006; Lorenz, Cunningham, Spritzer, & Hays, 2006; Malan et al., 2010). In a sample of HIV-infected subjects, using the Medical Outcomes Study-HIV Survey (MOS-HIV) QOL rating scale, Bader and colleagues (2006) found that improved QOL was significantly correlated with fewer physical symptoms and fewer adverse drug reactions. These investigators and Gay and colleagues (2011) showed that ART-related ADRs had a negative impact on adherence.

However, little data exist regarding the age-related tolerability of ART. This is an unfortunate oversight because the most recent surveillance data suggest that persons ages 50 and older accounted for 17% of new HIV diagnoses in 2009 (CDC, 2011). In 2009, individuals older than 50 years made up 37% of those living with HIV in the United States, up from 24% in 2005 (CDC, 2008, 2011).

Although the reasons for the increase in incidence in older Americans are likely multifactorial, an important factor is the sharp decline in mortality with the advent of ART. With the rising rates of HIV in older individuals and the need for long-term, continuous ART, research directed at the impact of HIV treatment on older patients is of increasing importance to guide clinical management for improving QOL (Effros et al., 2008). Several aspects must be taken into consideration when treating older HIV-infected patients, many of which could predispose them to ADRs. Medication pharmacokinetics and pharmacodynamics may be altered because of age-related physiologic changes. These changes, for example, can result in prolonged drug half-lives and increased free drug concentrations, possibly resulting in untoward clinical consequences. Typically, older patients have higher rates of concomitant conditions and consequently a larger number of medications to treat these conditions, both of which could also contribute to symptom and side effect burden (Cassel, 2003). Non-ART medications combined with ART may result in more potential drug interactions, which may also impact ART tolerability. One

question specific to older HIV-infected patients yet to be answered is, does cumulative exposure from ART result in higher rates of ADRs in older patients? These concepts underline the importance of evaluating whether there are age-related issues to help inform how best to monitor and manage older patients for ADRs secondary to ART.

A cross-sectional study conducted in the late 1990s (Zingmond et al., 2003) sought to evaluate age-related differences in HIV symptom expression in two cohorts of patients, the HIV Cost and Service Utilization Study (HCSUS) and the Veterans Aging Cohort 3 Site Study (VACS 3). Patient surveys, provider surveys, and patient interviews were utilized to collect data on symptoms associated with HIV disease and/or opportunistic infections (e.g., diarrhea, weight loss, headache). This investigation demonstrated that subjects who were 50 years of age or older were more likely to identify symptoms of peripheral neuropathy, weight loss, and hair loss, and were less likely to report diarrhea, decreased mood, and white oral patches compared to their younger counterparts (ages <50). While this study was one of the first to evaluate age-related differences in subjective symptom expression, most symptoms may have been related to HIV and not specific side effects of currently recommended ART, making it difficult to determine how to improve clinical management.

Silverberg and colleagues (2007) evaluated age-related differences in the incidence of laboratory abnormalities occurring in the first year of ART therapy. This retrospective cohort study used a database from a large health care system. Compared to patients in the two younger age strata (18–39 years and 40–49 years), patients who were older than 50 years of age were more likely to have abnormalities in serum creatinine, hemoglobin, absolute neutrophil count, low density lipoprotein (LDL) cholesterol, and glucose. In a similar study of a large cohort from the United Kingdom, Sabin and colleagues (2009) found that patients 50 years of age or older had higher total cholesterol levels and lower hemoglobin levels in the first year of ART.

While these retrospective studies give an idea for how commonly patients experience laboratory toxicities in the first year of ART, they do not provide information on the typical burden of intolerance to ART experienced by older patients compared to

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