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The Monitoring of Lymphocyte Populations may be Optional in Patients with Suppressed Viremia: A Two Years Observational Study

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Commentary

The determination of lymphocyte populations (LPs) traditionally has been included in the routine follow-up of HIV-infected patients as an indicator of the degree of immune suppression and of the need to start treatment, select the type of therapy, or prescribe preventive measures against opportunistic infections. However, the variability of the technique produces variations in patients with undetectable viremias that have no clinical consequences [1] but which nevertheless generate uncertainty among the patients - with the resulting need for additional educational and reassurance measures.

The utility of LP determination in well controlled patients has been questioned [2-4]. In this regard, and based on the our firmly held believe that the technique is of little use, in March 2014 it was removed from the from the routine follow-up of HIV-infected patients, unless specifically ordered.

We describe our cumulative experience with the suppression of LP determination up until April 2016 in a clinic specialized in the management of HIV-infected patients.

A prospective study was made of all patients reporting for follow-up between March 2014 and April 1st 2016. Routine clinical practice in patients with undetectable viremias and no toxicity or adherence problems contemplates a new LP determination 5-6 months after the visit. In our study, LP determination was not repeated in those patients with undetectable viremias and CD4+ counts of > 350 cells/mm^3 in the previous test. Individuals with other causes of lymphopenia such as chemotherapy were not included. On occasion of the first follow-up visit, the patients received an approximately two-minute long explanation of why LP determination was not going to be carried out. We documented the need for further explanations, the need for subsequent LP determination requests, the introduction of prophylaxis, or the appearance of opportunistic infections.

Of the 238 patients seen during the study period, LP determinations were not requested in 146 subjects. The sample characteristics were: 70% males, mean age 47.9 years (SD 9.18), initial CD4+ count 520 cells/mm^3 (SD 140).

A total of 362 LP determinations were not requested – representing 65% of all the tests made in the follow-up of all the HIV-infected patients. In 12 subjects we included LP determination in an immediate second test due to the detection of viremia – though in no case were prophylactic measures due to significant reductions in CD4+ count necessary. In 6 patients LP determination was included in updating the laboratory test results after a period of treatment dropout and failure to perform the scheduled tests. In only one patient of this latter group was prophylactic treatment started with cotrimoxazole, with the reintroduction of antiretroviral therapy due to the presence of a CD4+ count of 157 cells/mm3. No opportunistic infections were identified.

Thus, we performed only 18 (5%) of 362 and 213 (39%) of 557 of the LP determinations that would have been requested in the usual 6-monthly follow-up tests in the group of virologically controlled patients and in the total HIV-infected patients, respectively.

The patients accepted the explanation of why LP determination was not made, and none of them requested testing to be carried out. On occasion of the subsequent follow-up visits, the patients were only informed that their sustained undetectable viremia made LP testing unnecessary for the previously mentioned reasons. The patients accepted this without problems.

The determination of LPs has been used as a marker of disease progression and mortality risk in HIV-infected individuals [5-7], and as an indicator of the need to start preventive treatment against opportunistic infections and (until quite recently) antiretroviral therapy. However, the availability of viral load (VL) quantification tests [8,9] offers better prediction of treatment efficacy and disease progression; as a result, the need for LP monitoring in virologically suppressed patients has been questioned [2-4,10].

The determination of LPs is not without costs, and there is also important variability associated to the technique. In this regard, retrospective observational studies have shown that patients with undetectable viremias present variations in the cell counts that are of scant clinical relevance [1,10]. Some guides therefore view the determination of LPs as being optional, and accept a decrease in the number of annual determinations made [11,12].

To our knowledge, this is the first prospective study on the impact of suppressing the determination of LPs in virologically control individuals in terms of patient acceptance of the decision, reduction of the number of LP determinations made, the need to reintroduce prophylactic treatment, and the appearance of opportunistic

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infections. As limitations of the study, this is a single-center, with a relative small number of patients with no control group in which data collection does not allow us to know the percentage of patients who failed to report for their subsequent laboratory tests or follow-up visits.

Based on the results obtained, we consider that repeated LP determination is not necessary in virologically well controlled and non- immunosuppressed HIV-infected patients. The measure does not imply a risk of adverse events, reduces the number of required determinations (and therefore the associated cost by over 50%) and avoids patient anxiety caused by the variability of the technique. Also only requires simple patient information measures that moreover decrease as the suppression of LP determination becomes accepted as part of routine clinical practice.

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