RESEARCH PAPER

Simultaneous HIV and lymphocyte CD4+ testing as an intervention for improving linkage to care – experience of a voluntary counselling and testing facility-based pilot programme

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Abstract

Introduction: Simultaneous lymphocyte CD4+ and HIV testing has been proposed as a method for shortening the time between human immunodeficency syndrome (HIV) diagnosis and combined antiretroviral therapy (cART) initiation, thus improving clinical outcomes. Here, we investigate its impact on the linkage to care in voluntary counselling and testing centers (VCT) in Warsaw.

Material and methods: All clients, who presented at the two VCTs in Warsaw and had positive ELISA tests, were offered the lymphocyte CD4+ test simultaneously with the WB test. All tests were anonymous. Data collected between 2012-2013 from the VCTs were linked with HIV clinic records using the WB test numbers as unique identifiers. Persons registered in HIV clinics were considered linked to care.

Results: In total, during 2012-2013, one hundred and twenty-three clients were tested as HIV-positive in the VCTs. Of these, 30 had their lymphocyte CD4+ count tested, while 42 (65.8%) clients were linked to HIV care. The linkage rate did not differ between the lymphocyte CD4+ test groups (66.7% of tested vs. 65.6% of non-tested for the lymphocyte CD4+; $p = 0.91$). There was also no significant difference in time to linkage, $p = 0.52$. In total, 66 (65.8%) clients started cART – 19 (28.8%) in the lymphocyte CD4+ group, and 47 (71.2%) in other ($p = 0.07$). However, there was a significant difference in the time for starting cART, $p = 0.005$.

Conclusion: In Poland, a resource-rich country, simultaneous lymphocyte CD4+ and HIV testing at counselling and testing centers had no effect on linkage to care, but did have a positive impact on time to starting cART.

HIV AIDS Rev 2018; 17, 1: 8-11
DOI: https://doi.org/10.5114/hivar.2018.74052

Key words: HIV, lymphocyte CD4+, testing, VCT, linkage to care.

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Article history:
Received: 07.04.2017
Received in revised form: 23.11.2017
Accepted: 18.01.2018
Available online: 26.02.2018

International Journal of HIV-Related Problems
HIV & AIDS Review

Introduction

Currently, it is estimated that in some European countries, predominantly in Eastern Europe, the percentage of undiagnosed infections reaches 60% of the total population of these infected with human immunodeficency syndrome (HIV), and in one third of those, the diagnosis is given at a late stage of the infection [1-3]. This constitutes a significant threat to public health and to the individual patient's health, as well as increasing the risk of transmitting HIV infection to sexual partners [4].

Poland is a country with high rates of late presentation. Late presentation is defined as presenting to HIV care at the time when the lymphocyte CD4+ cell count is below 350 cells/μl, or an AIDS defining condition occurs [5, 6]. One of the reasons for this is that Poles rarely decide to test themselves for HIV. As presented by Rosińska *et al*., 87% of Poles do not see themselves or their social environment as being at HIV risk [7].

Free and anonymous tests for HIV are offered in thirty diagnostic and consultation centers in Poland. Every test is combined with pre and post-test counselling [4]. Actively engaged counsellors hold a certificate issued by the National AIDS Centre Agenda of the Minister of Health. However, only 31,000 persons per year use this convenient method of testing, and the number has not substantially increased over recent years [7]. Testing is also offered in public and private care, but very often without counselling. As recently presented in other research, not all the patients with a HIV diagnosis necessarily report to a specialist care. The Test and Keep in Care (TAK) project has shown that one in three persons with a positive HIV test result does not report for further specialist medical care [8]. Factors associated with a lower rate of linkage to care are hetero- and bisexual orientation, a lower level of education, and not using condoms in a stable relationship [9]. The latter factor is especially worrying since these people may continue to be involved in unprotected sex, thus transmitting the infection.

Therefore, any programmes that evaluate methods for further improving the linkage to care are essential in order to improve the cascade of care and meet the UNAIDS goal of 90-90-90 [10]. With this purpose in mind, in 2012, a pilot programme for lymphocyte CD4+ testing centers as a tool to improve linkage to care was initiated.

Material and methods

This pilot project was performed in two consultation and diagnostic testing centers in Warsaw that are run by the Foundation for Social Education. All clients who presented at the two voluntary counselling and testing centers (VCTs) in Warsaw to collect their positive HIV test (4th generation anti-HIV/Ag p24 ELISA test, Vidas HIV duo Quick, BioMerieux) had also been offered a lymphocyte CD4+ count test at the same time, along with a Western blot confirmatory test, but using an extra blood sample. The project began on 1st of July 2012 and ended on 1st of July 2013. In accordance with VCT standards, all tests were anonymous. The lymphocyte CD4+ test results were given at the same time as Western blot test result. Additional counselling was provided to explain the meaning of the lymphocyte CD4+ count test results.

Detailed methodology of the TAK project have been published elsewhere [9]. This research is a part of TAK cohort group. Briefly, the data collected in the VCTs from 2010-2013 were linked to HIV clinic records using the Western blot test number as a unique identifier. Individuals were followed from the day of their VCTs visit, until their first clinical visit or until 4.06.2014. Persons registered in Warsaw HIV clinics were considered linked to care.

The TAK study obtained approval from the Bioethical Committee of the Medical University of Warsaw (AKBE/99/16). Due to the anonymous character of the CBVCT testing, an informed consent forms were not collected.

Results

In total, between 1st of July 2012 and 1st of July 2013, one hundred and twenty-three clients were tested HIV-positive in VCTs.

Of these, 115 (93.5%) were male having sex with men (MSM), and holding higher education (76.4%). 20.3% had a HIV-positive partner, and 11.6% were in a stable relationship. 30.9% had never been tested before. The median age was 30.0 years (range, 26.2-35.2). The median for the first lymphocyte CD4+ tests at HIV clinic was 389 (IQR, 284-509), and the median for the first HIV RNA tests at HIV clinic was 25,344 (IQR, 5,324-117,082).

The general characteristics, both preclinical and clinical, were comparable between the groups except the fact that persons who were tested for lymphocyte CD4+ at VCTs were more likely not to have been tested before for HIV (Table 1).

Thirty patients (24.4%) had a lymphocyte CD4+ test. The median lymphocyte CD4+ count, as measured at VCTs, was 453 cells/μl (interquartile range, IQR: 247-624).

Eighty-one (65.8%) persons were linked to HIV care: 20 (66.7%) of the patients with lymphocyte CD4+ count and 61 (65.6%) of those without lymphocyte CD4+ that were tested a VCT. The linkage rate did not significantly differ between the groups ($p = 0.91$). There was also no significant difference in time to linkage between the groups, $p = 0.52$ (Table 2).

Sixty-six (65.8%) persons started antiretroviral therapy during follow-up; 19 (28.8%) in the lymphocyte CD4+ group and 47 (71.2%) in the other group ($p = 0.07$).

There was a significant difference in the time to starting cART ($p = 0.005$). In general, 75% of patients from lymphocyte CD4+ group started cART within the first 2.5 months of their first visit to a VCT, and 75% of the patients without lymphocyte CD4+ started the treatment within 16 months of their VCT visit. The characteristics of lymphocyte CD4+ and no- lymphocyte CD4+ groups are presented in Table 1.

Table 1. The characteristics of lymphocyte CD4+ and no-lymphocyte CD4+ groups

Characteristic	Lymphocyte CD4+ tested at VCT *n* = 30	Lymphocyte CD4+ not tested in VCT *n* = 93	*p* value
Age in years, median (IQR)	30.2 (25.4-36.3)	30.0 (26.4-34.2)	0.84
Male gender, *n* (%)	29 (96.7)	86 (92.5)	0.68
MSM, *n* (%)	24 (80.0)	74 (79.6)	0.96
Higher education, *n* (%)	26 (86.7)	68 (73.1)	0.27
HIV-positive partner, *n* (%)	5 (16.7)	20 (21.5)	0.57
Never tested for HIV before, *n* (%)	14 (46.7)	24 (25.8)	0.04
First lymphocyte CD4+ at HIV clinic, median (IQR)	363 (163-496)	391 (310-509)	0.17
First HIV RNA at HIV clinic, median (IQR)	23,023 (11,656-92,293)	25,344 (4,238-11,7082)	0.66
Hemoglobin, g/dl	14.6 (13.6-15.4)	14.6 (13.9-15.3)	0.84

Table 2. Comparison of time to linkage and time to starting combined antiretroviral therapy between the study groups

Characteristic	All, *N* = 123	Lymphocyte CD4 tested at VCT, *n* = 30	Lymphocyte CD4 not tested in VCT, *n* = 93	*p* value
Time to first visit at HIV care in months	0 (0-14)	0 (0-8)	1 (0-15)	0.520
Time to starting antiretroviral therapy in months (for those who started)	3 (1-14)	1 (0-2.5)	6 (1-16)	0.005

Discussion

The objective of introducing the pilot programme for the lymphocyte CD4+ count testing was to check whether knowledge about the level of lymphocyte CD4+ cell count would increase the number of HIV-positive persons reporting to HIV clinic. Poland is one of the few European countries where HIV-positive individuals are diagnosed late. Late presenters were most common in Central Europe (49.8%), followed by Northern Europe (48.8%), Southern Europe (45.8%), and finally, Eastern Europe (38.3%); $p < 0.0001$ [11]. The pilot project was planned as an intervention to decrease the percentage of people who present late.

We have identified that information about the lymphocyte CD4+ cell count did not make any greater impact on the number of persons linked to care; however, it is important to note that this was a small pilot group in Warsaw. Comparing our findings with other studies is difficult because the majority of studies in this area come from resource-poor countries. Testing for lymphocyte CD4+ cell count did not affect linkage to care, but 75% of patients from the lymphocyte CD4+ group started cART within first 2.5 months of their first visit to a VCT, and 75% of patients without lymphocyte CD4+ started the treatment within 16 months of their VCT visit. This implies that patients who had had additional consultations in respect to lymphocyte CD4+ cell count testing, understood better their medical situation and could be appropriate prepared for their next step of care. Similar observations were published in a study with point of care based CD4+ count testing, showing an increase in the retention of patients in care prior to starting treatment, and a reduction in time to cART eligibility assessment [12].

A systematic review (mainly from Africa) and meta-analyses [13] were made to identify the extent to which point of care improves linkages to HIV care and time of cART initiation. This showed that the time between HIV diagnosis and the lymphocyte CD4+ cell test was reduced from a pooled mean of 10.5 days using conventional laboratory-based testing, to a pooled mean of 0.1 days using point of care CD4+ testing. Therefore, it is a useful tool to perform lymphocyte CD4+ cell testing and expedite delivery results. Point of care technologies CD4+ increase patient retention and reduce the amount of time spent, along testing and treatment cascades compared to conventional laboratory-based testing [13]. Patients need time to understand their new situation after diagnosis. The HIV/AIDS stigma has an important role in negatively-impacted self-care strategies for those already affected, and simultaneously hinder prevention efforts to discourage the appearance of new infections [14].

There is a growing body of evidence indicating that opportunities are being missed in diagnosing HIV infections in EU member states. A total of 24 studies were published in international peer-reviewed journals that met the review's eligibility criteria [15]. The research presented here shows that strengthening the information about a positive lymphocyte CD4+ test result does not influence the decisions made about taking HIV

care. This is especially interesting considering the generally low lymphocyte CD4+ count, measured at both VCT and HIV clinics. A worrying fact is that in this research, the median lymphocyte CD4+ count dropped by over 100 cells/μl between the VCT visit and the first visit to the HIV clinic.

Our study underlines the importance of further studies in this area in Poland, as well as the challenges in meeting the goal of 90% linkage, as postulated by UNAIDS.

Testing for HIV is not just a medical test. It can be understood as being a choice between living with uncertainty, and the perceived impact of ascertaining HIV status. It includes many complex medical, psychological, and social factors. The reporting of positive test results should be accompanied by the introduction of different forms and methods of support, i.e., psychological or peer support [16]). Only in VCTs, pre- and post-counselling are mandatory.

There are some important limitations that need to be addressed. First, information about the general acceptance rate of lymphocyte CD4+ testing was not designed to be collected. An additional blood sample could be a barrier to clients who decide to have CD4+ testing. Another important aspect worth mentioning is that people who first receive information about a positive HIV test are in shock, and sometimes do not understand what the lymphocyte CD4+ test means. Being informed of a positive HIV test result creates a vulnerable situation for individuals, as well as a difficult subject for research. This is an area where there is an interplay between sociology, psychology, and clinical medicine that intersect in a very unique way concerning each and every individual [17].

Conclusions

In Poland, a resource rich country, simultaneous lymphocyte CD4+ and HIV testing at counselling and testing centers had no effect on linkage to care, but did have a positive impact on time to starting cART.

Financial disclosure

The TAK project received unrestricted research grants from Research Development Foundation in Hospital for Infectious Diseases, Abbvie Poland and Gilead Sciences Poland. The funders had no role in the study's design, data collection and analysis, decision to publish, or preparation of the manuscript. Furthermore, the authors of this paper declare no conflict of interest.

Conflict of interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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