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Running title: AIDS patients and late testers in Italy

Abstract

The objective of this study is to define the socio-demographic and behavioral characteristics of people unaware of being HIV-positive at AIDS diagnosis. A multi-center cross-sectional study was conducted in 11 Italian centers of infectious diseases, recruited on a voluntary basis. Each center enrolled individuals diagnosed with AIDS aged ≥ 18 years from May 2003 to December 2005. The patients were classified into two groups based on the amount of time that elapsed from diagnosis of HIV infection to AIDS diagnosis. "Late testers" were defined as those with a time period of ≤ 6 months between first HIV positive test and AIDS diagnosis. In order to evaluate the factors independently associated with being a late tester, a multivariate logistic regression model was performed. The McNemar χ^2 test was used to analyze behavioral changes before and after HIV diagnosis. During study period 245 patients were enrolled, of these 51.8% were late testers. The variables independently associated with being a late testers were: being employed; having acquired the infection through sexual contacts; having taken the HIV test because they didn't feel well; having at least one symptom or illness among those indicating infection; not having had paid sex within the 12 months prior to HIV diagnosis. Before and after HIV diagnosis a significant increase in safe sex behaviors was observed among individuals with no delay in diagnosis. However, the proportion of people who continue not using condoms is still high. This study seems to indicate that sexual transmission is often associated to late testing. Individuals enrolled seem to have a low perception of risk, they do not perform HIV testing and consequently miss the opportunity of early diagnosis.

Keywords: AIDS; HIV; late tester

Introduction

Since 1996, the large-scale use of combination antiretroviral therapy has contributed considerably to reducing the incidence of AIDS and the correlated mortality of the disease in industrialized countries. In Italy, the number of cases of AIDS reported to The National AIDS has decreased from approximately 5,653 cases registered in 1995 to 1,330 cases in 2008 (COA, 2009).

However, the effectiveness of this therapeutic intervention is limited for a significant proportion of people with AIDS (in Italy in 2008, approximately 60%) receiving HIV diagnosis in the same time of AIDS diagnosis, therefore without having adequate time for the necessary treatment (COA, 2009). Lack of knowledge of HIV serostatus is harmful to the individual, since it precludes the possibility of benefiting from the interventions that reduce the risk of clinical progression, and constitutes a public health problem because it doesn't allow for taking the necessary actions that can prevent further spread of the infection (Girardi et al., 2000).

Since the late 90s, numerous studies have been conducted in different countries to highlight the socio-demographic and epidemiological characteristics of people who were unaware of being HIV-positive at AIDS diagnosis. Some of these studies were made on a study population of people with AIDS, others focused on individuals at the time of first HIV diagnosis (Castilla et al., 2002; Schwartz et al., 2006; Porter et al., 1993; Couturier et al., 1998; Hocking et al., 2000; Sabin et al., 2004; Delpierre et al., 2007; Adler et al., 2009).

A study conducted in Italy on patients reported to the National AIDS Registry in 1996-2002 have shown that male gender, come from foreign country and have being infected

through sexual contacts were associated with an HIV diagnosis close to AIDS diagnosis. (Longo et al., 2005). However, in that study only a limited number of patients characteristics could be analyzed, since data were derived from AIDS surveillance forms.

The present study therefore intent to investigate other characteristics of persons with delayed diagnosis, in particular health status, risk perception and the clinical history.

It is important to identify the characteristics of the “late testers”. This will help develop strategies that can give more immediate access to the test for those whose behavior puts them at risk of HIV infection but who are unaware of the risks and therefore do not test (Girardi et al., 2007).

In addition, early diagnosis of HIV in the HAART era guarantees the person who has acquired HIV more efficient management of the disease and the opportunity of defining the optimal time for initiation of antiretroviral therapy. This is where this study can be placed; the objective being to define the socio-demographic and behavioral characteristics of people unaware of being HIV-positive at AIDS diagnosis.

Methods

A multi-center cross-sectional study was conducted in 11 Italian centers of infectious diseases, recruited on a voluntary basis. Each center enrolled individuals newly diagnosed with AIDS aged ≥ 18 in the period from May 2003 – to December 2005.

People newly diagnosed with AIDS were divided into groups of “late testers”, individuals for whom the time between HIV diagnosis and AIDS diagnosis was ≤ 6 months, and “non-late testers”, individuals with the time between HIV diagnosis and AIDS diagnosis was > 6 months. This is useful to having a homogeneous sample of people newly diagnosed with AIDS who access to the Centers for Infectious Diseases.

For all eligible individuals demographic and clinical data were abstracted from hospital records.

An *ad hoc* questionnaire was administered at the time of the patient's discharge from the hospital by specifically trained personnel to patients who agreed to enter the study and provided written informed consent. The questionnaire included the following sections: socio-demographic information; information regarding the history of the test and infection; information on drug use, sexual behavior and adherence to antiretroviral therapy, for those who were aware of being HIV positive since more than three months.

Outcome definitions

The patients were classified into two distinct groups based on the amount of time that elapsed from HIV diagnosis to AIDS diagnosis. "Late testers" were defined as those with a time period of ≤ 6 months between HIV diagnosis and AIDS diagnosis. Then, the association of specific information contained in the questionnaire and the two groups of patients with AIDS (late testers and non-late testers) was assessed. In order to evaluate the factors independently associated with being a late tester, a multivariate logistic regression model was performed, including variables associated with late testing with a p-value of <0.10 in univariate analysis, as well as age and gender.

The McNemar χ^2 test was utilized to analyze separately for the late and non-late testers behavioral changes (sexual and drug use) before and after HIV diagnosis. Data analysis was made with SPSS 17.0.

Results

From May 2003 to December 2005, 472 patients were considered for the inclusion in the study, and 245 of these (51.8%) were actually enrolled and completed the questionnaire.

The 227 individuals who did not participate differed from the 245 participating individuals for: main modality of acquiring the infection (among participants: “heterosexual” 45.3%; among non-participants: injecting drug users – IDUs 37.9%); level of CD4+ at AIDS diagnosis (CD4+ \leq 200 cells/ μ l: 89.7% among participants and 83.3% among non-participants) and proportion of late testers (51.8% among participants and 38.8% among non-participants). There were no significant differences between the two groups regarding gender, age, marital status or nationality.

Among the 245 participating individuals, 127 (51.8%) were late testers (Table 1). Table 1 shows the social-demographical characteristics of the late testers compared to the non-late testers and shows the crude (cOR) and adjusted odds ratio (aOR) associated with being a late or non-late tester.

In multivariate analysis, the variables independently associated with being a late testers were: being employed; having acquired the infection through sexual contacts (homosexual and heterosexual); having taken the HIV test because they didn't feel well; having at least one symptom or disease among those indicating infection; not having had paid sex within the 12 months before to HIV diagnosis.

The same variables are significantly associated with being a late tester, both for individuals who acquired the infection through sexual contact and those who acquired it through injecting drug use (data not shown).

Among the late testers, there was a significantly higher percentage (15.7%) of individuals with two or more AIDS defining diseases compared to the non-late testers (5.1%). The most frequent disease, in both later testers and non-late testers was *Pneumocystis jirovecii* pneumonia (22.8% and 20.3%, respectively). In the late testers vs. non-late testers, there was a greater proportion of diagnosis of Cerebral toxoplasmosis (11.8% vs. 5.9%), Cytomegalovirus disease (11.8% vs. 4.2%) and Kaposi's sarcoma (9.4% vs. 1.7%) and a

lower proportion of diagnosis of Burkitt's lymphoma (4.7% vs.11.9%) and AIDS Dementia complex (3.1% vs. 10.2%) (Table 2).

Table 3 shows the behavioral analysis (sexual and drug use) before and after HIV diagnosis. Both the late testers and non-late testers had fewer sexual relations with their regular partners after HIV diagnosis. Among the non-late testers who continued having sex with their regular partners, the percentage of those always using safe sex measures increased significantly. The percentage of those who had sex with occasional partners before and after HIV diagnosis was significantly reduced in the late testers. No reduction of the number of contacts with occasional partners was observed in those individuals with no delay in diagnosis, but there was a significant increase in safe sex behaviors. In both groups, after six months of HIV diagnosis, there was a significant decrease in drug use and in injected drug use specifically.

Discussion

In our sample, more than half of the individuals studied were unaware of having HIV infection before AIDS diagnosis. This is a higher proportion than what can be found in an Italian study (Longo et al., 2005), but still corresponds to the national average registered by COA/ISS (COA, 2009). This diversity can also be explained by the characteristics of the sample being studied which consists entirely of people newly diagnosed with AIDS, defined as late testers, with a time interval of ≤ 6 months between HIV and AIDS diagnosis. In fact, other studies took into account the time interval between the first positive test and AIDS diagnosis which was extremely variable, ranging from 1 to 12 months (Girardi et al., 2000; Castilla et al., 2002; Schwartz et al., 2006; Porter et al., 1993; Couturier et al., 1998; Hocking et al., 2000; Chadborn et al., 2006; Wortley et al., 1995; Brännström et al., 2005). Other studies refer to the CD4 cell count where $CD4 \leq 200$ cells/ μ l (Chadborn et al., 2006).

Therefore, it is important to consider which population is being studied: people newly diagnosed with HIV, people recently infected with HIV, people newly diagnosed with AIDS in order to compare data from different countries (Adler et al., 2009). Our study population consists of people newly diagnosed with AIDS.

The results of the present study are consistent with those of a previous analysis conducted in an Italian AIDS study (Longo et al., 2005) and provide additional information on other risk factors for late diagnosis including being employed, having being tested because of feeling ill, not reporting paid sexual intercourses.

Unlike other studies (Delpierre et al., 2008), our study shows that being employed is associated with being a late tester. Analyzing the characteristics of this person, the information that emerges is that employed people compared to non-employed people are more frequently male, with a high level of education who have acquired the infection through heterosexual sexual contacts and tested for HIV because they had symptoms such as fever of long duration, weight loss, and before knowing that they were HIV+ had more frequently been diagnosed with syphilis and gonorrhoea.

Probably the socio-economic status of the employed person did not lead their doctor to suggest taking the HIV test despite the presence of symptoms and sexually transmitted diseases. In fact, less than one-third of the workers took the test on the advice of their specialist doctor.

As also reported in other studies (Schwartz et al., 2006; Porter et al., 1993; Couturier et al., 1998; Hocking et al., 2000; Longo et al. 2005), this study seems to indicate that sexual transmission is often associated to late testing while injecting drug use is more common among the non-late testers. It is possible that, a number of information campaigns focused on sexual transmission have been conducted in Italy (Fрати et al., 2002), there is still a low perception of the risk of acquiring infection through sexual contacts. In addition, IDUs are

more easily identifiable by health care workers due to the fact that these people access drug addiction services and are therefore strongly urged to take the test whereas it is not as easy for people who engage in risky sexual behavior who could have fewer opportunities to access services of prevention, diagnosis and treatment of HIV infection (CDC, 2003; Castelnuovo et al., 2003).

Even the different distribution of the AIDS defining pathologies in the individuals participating in the study seems to indicate that sexual relations are the main means of transmitting the virus among late testers. In fact, it is known that Kaposi's sarcoma is the most common pathology among AIDS patients who contracted the virus through sexual contact (Dal Maso et al., 2009).

The high proportion of late testers who had contracted HIV through sexual contacts (heterosexual and homo/bisexual) raises great concern since these two modes account for almost 70% of the new cases of AIDS registered by the National AIDS Registry in 2008 (COA, 2009). Moreover, not having had paid sexual relations within the 12 months prior to HIV diagnosis is associated to being a late tester. Some studies show that among heterosexuals, late testers are more frequently people with a stable relationship and less frequently people with a higher number of sexual partners (Castelnuovo et al., 2003, Borghi et al., 2008). Probably, people who did not have occasional sexual contacts or paid sexual contacts had a lower risk perception. In addition, it would seem that healthcare providers do not consider them a priority target for offering the test (Girardi et al., 2007).

Taking the test because one did not feel well and having at least one symptom or illness among those suggesting infection are variables associated with being a late tester. Individuals seem to have a low risk perception, they do not perform HIV testing and consequently miss the opportunity of early diagnosis (Girardi et al., 2000; Brännström et al., 2005; Girardi et al., 2004).

Lastly, behavioral analysis made before and after HIV diagnosis has allowed for identifying late testers as tending to reduce sexual relations with steady or occasional partners while non-late testers only reduce sex with occasional partners but increase condom use in all sexual practices. However, the proportion of people who continue not using condoms is still high (Sudarshi et al., 2008; Camoni et al., 2009). It must be stressed that the importance of this result is limited by the low number of answers provided by the late testers in this part of the questionnaire.

Some limitations of this study need to be mentioned. In the first place, the significance of the sample is limited to the enrolment procedure which was not uniform among the centers throughout the entire period of the study. In addition, the enrolled patients are only half of those initially included in the study. On the other hand, we must consider that the demographic and epidemiological characteristics of the sample that was studied are similar to the characteristics of the AIDS cases that were reported in Italy during the same period and were also the subject of study which was examined from 1996 to 2002 (COA, 2009; Castelnuovo et al., 2003). This study might underestimate the percentage of late testers. It was observed that there was a higher proportion of late testers among those patients who refused the interview. The proportion of late testers among enrolled subjects, including those who accepted to participate as well as those who refused to participate is 55%. This could constitute a strong bias that might have affected the relevance of the results.

The study shares the limitations of surveys by questionnaires, especially in the sections investigating sexual behavior and drug abuse. Moreover, the complexity of the questionnaire required a structured interview.

Even taking these limitations in consideration, the study provides useful information and highlights the need to identify a strategy for easier access to the test, especially for the heterosexual population. Finally, the results seem to suggest that it would be opportune to

raise awareness among healthcare providers to put more attention to clinical symptoms and promote greater awareness regarding the need for HIV testing, not only as a response to high risk behaviors for acquiring HIV infection.

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Table 1 – Factors associated with being a late tester (crude and adjusted odds ratios).

	total	late tester	%	cOR	95% CI	aOR	95% CI
Total	245	127	51.8				
Gender							
Male	201	110	54.7	2.04**	1.04-4.02	1.79 ns	0.57-5.59
Female	43	16	37.2	1.00		1.00	
Age (mean±ds)							
	42.3±8.7						
Age							
<35	41	28	68.3	3.00**	1.42-6.35	1.99 ns	0.68-5.80
35-44	122	51	41.8	1.00		1.00	
≥45	77	45	58.4	1.96**	1.10-3.49	1.88 ns	0.80-4.42
Area of origin							
Outside Italy	40	26	65.0	1.91*	0.94-3.87	1.34 ns	0.44-4.04
Italy	205	101	49.3	1		1	
Education							
< 8 years	136	60	44.1	1.00		1.00	
> 8 years	105	66	62.9	2.14**	1.27-3.61	1.24 ns	0.55-2.76
Being employed							
No	89	23	25.8	1.00		1.00	
Yes	154	104	67.5	5.97***	3.33-10.68	4.60 ***	1.98-10.66
Mode of acquisition the infection							
IDUs	80	11	13.8	1.0		1.00	
Homo/bisexual contacts	66	48	72.7	16.7***	7.25-38.56	9.22 ***	3.19-26.63
Heterosexual contacts	82	57	69.5	14.3***	6.48-31.54	14.41 ***	4.85-42.85
Not reported	17	11	64.7	11.5***	3.53-37.45	9.01 **	1.91-42.38
Place where the first HIV+ test was performed							
Public outpatient clinic	122	65	53.3	1.00		1.00	
During hospitalization	74	49	66.2	1.72*	0.94-3.13	1.49 ns	0.60-3.71
Drug addiction center/prison	27	1	3.7	0.03***	0.00-0.26	0.16 ns	0.02-1.48

Private outpatient clinic	16	9	56.3	1.13 ns	0.39-3.22	1.20 ns	0.29-4.89
Reasons for HIV testing							
Feeling bad	108	76	70.4	7.52***	3.48-16.23	4.98 **	1.75-14.17
At risk behavior	50	12	24.0	1.00		1.00	
Prescribed by doctor	82	36	43.9	2.48***	1.13-5.42	2.63 *	0.89-7.80
Who suggested HIV test							
Specialist doctor	160	97	60.6	3.21***	1.79-5.73	0.96 ns	0.34-2.68
Other (partner, friend, self-prescribed)	74	24	32.4	1.00		1.00	
At least one symptom or illness							
No	57	20	35.1	1.00		1.00	
Yes	188	107	56.9	2.44***	1.32-4.52	4.13 **	1.63-10.46
Hospitalization 12 months before the first HIV+ test							
No	183	91	49.7	1.00		1.00	
Yes	49	31	63.3	1.74*	0.91-3.33	1.17 ns	0.43-3.18
Occasional partners 12 months before HIV diagnosis							
No	107	65	60.7	1.94**	1.16-3.26	1.97 ns	0.82-4.67
Yes	133	59	44.4	1.00		1.00	
Paid sexual intercourses 12 months before HIV diagnosis							
No	176	102	58.0	2.69***	1.47-4.93	6.45 **	1.62-10.29
Yes	62	21	33.9	1.00		1.00	

In this table were reported variables associated with being a late tester in univariate analysis with p-value<0.10.

ns not significant (p-value >0.10)

* p-value <0.10

** p-value <0.05

*** p-value <0.001

Table 2 – Clinical characteristics at AIDS diagnosis: CD4 cell count and most frequent AIDS-defining illnesses

	Total (N=245)		Non- late testers (N=118)		Late testers (N=127)	
	N	%	N	%	N	%
Median CD4 cell count (IQR)	61 (22-174)		103 (35-190)		41(18-99)	
<i>Pneumocystis jirovecii</i> Pneumonia	53	21.6	24	20.3	29	22.8
Oesophageal candidiasis	29	11.8	14	11.9	15	11.8
Pulmonary Tuberculosis	23	9.4	13	11.0	10	7.9
Toxoplasmosis	22	9.0	7	5.9	15	11.8
Wasting syndrome	22	9.0	11	9.3	11	8.7
Burkitt's lymphoma	20	8.2	14	11.9	6	4.7
Cytomegalovirus	20	8.2	5	4.2	15	11.8
AIDS-dementia complex	16	6.5	12	10.2	4	3.1
Kaposi's sarcoma	14	5.7	2	1.7	12	9.4
Multiple concomitant AIDS-defining illnesses	26	10.6	6	5.1	20	15.7

Table 3 - Sexual behavior and drug use before and after diagnosis of HIV infection

	Non- late testers				p-value*	Late testers				p-value*
	Before HIV diagnosis	%	After HIV diagnosis	%		Before HIV diagnosis	%	After HIV diagnosis	%	
Sexual contacts with stable partners					0.002					0.000
No	17	19.1	35	39.3		14	25.9	42	77.8	
Yes	72	80.9	54	60.7		40	74.1	12	22.2	
Total	89		89			54		54		
Condom use in sexual contacts with stable partners§										
-Vaginal sex					0.001					0.375
Never/sometimes	34	87.2	20	51.3		8	88.9	5	55.6	
Always	5	12.8	19	48.7		1	11.1	4	44.4	
Total	39		39			9		9		
-Anal sex					0.031					1.000
Never/sometimes	22	88.0	16	64.0		1	33.3	1	33.3	
Always	3	12.0	9	36.0		2	66.7	2	66.7	
Total	25		25			3		3		
-Performing oral sex					0.031					1.000
Never/sometimes	32	94.1	26	76.5		3	75.0	2	50.0	
Always	2	5.9	8	23.5		1	25.0	2	50.0	
Total	34		34			4		4		
-Receiving oral sex					0.063					1.000
Never/sometimes	30	93.8	25	78.1		3	75.0	2	50.0	
Always	2	6.3	7	21.9		1	25.0	2	50.0	
Total	32		32			4		4		
Sexual contacts with occasional partners					0.585					0.000
No	40	35.4	44	38.9		23	41.1	49	87.5	

Yes	73	64.6	69	61.1	33	58.9	7	12.5
Total	113		113		56		56	

Condom use in sexual contacts with occasional partners**

-Vaginal sex					0.000			nc
Never/sometimes	35	77.8	22	48.9	3	100.0	3	100.0
Always	10	22.2	23	51.1	0	0.0	0	0.0
Total	45		45		3		3	

-Anal sex					0.003			1.000
Never/sometimes	31	77.5	20	50.0	2	50.0	2	50.0
Always	9	22.5	20	50.0	2	50.0	2	50.0
Total	40		40		4		4	

-Performing oral sex					0.002			1.000
Never/sometimes	37	94.9	27	69.2	3	75.0	3	75.0
Always	2	5.1	12	30.8	1	25.0	1	25.0
Total	39		39		4		4	

-Receiving oral sex					0.004			1.000
Never/sometimes	39	95.1	30	73.2	3	75.0	3	75.0
Always	2	4.9	11	26.8	1	25.0	1	25.0
Total	41		41		4		4	

Drug use***					0.000			0.000
No	31	27.4	70	61.9	80	70.8	99	87.6
Yes	82	72.6	43	38.1	33	29.2	14	12.4
Total	113		113		113		113	

Injecting drug use***					0.000			0.031
No	42	40.4	85	81.7	87	91.6	93	97.9
Yes	62	59.6	19	18.3	8	8.4	2	2.1
Total	104		104		95		95	

* Mc Nemar test for paired data

** 12 months before and after HIV diagnosis

*** 6 months before and after HIV diagnosis