Participation in clinical trials among women living with HIV in Canada

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Abstract

Background: To describe participation in clinical trials among HIV-positive women enrolled since 1993 in the Canadian Women's HIV Study, a prospective open cohort study.

Methods: All HIV-positive women being followed at hospital-based or community-based clinics at 28 sites in 11 Canadian cities were eligible to participate in the Canadian Women's HIV Study. Baseline and follow-up information was collected for 413 women every 6 months by study nurses using standardized questionnaires. Data included sociodemographic variables, HIV exposure group, CD4 count, disease classification, use of antiretroviral therapies and participation in clinical trials.

Results: At study intake 15.0% (62/413) of the women had participated in a clinical trial; an additional 8.5% (35/413) participated during a median follow-up of 18 months. Multivariate analysis revealed that the following factors were independently associated with participation in a clinical trial: white race (adjusted odds ratio [OR] 3.38, $p = 0.001$), current use of antiretroviral therapy (adjusted OR 2.01, $p = 0.008$), completion of secondary school (adjusted OR 1.97, $p = 0.024$) and residence in the Prairies or Atlantic provinces (adjusted OR 1.98, $p = 0.043$).

Interpretation: Although the overall clinical trial participation rate of 23.5% was relatively high among HIV-positive women, injection drug users were underrepresented in this study population, and non-white women, women who did not complete high school and women not receiving antiretroviral therapy were less likely than white women, women of higher education and women receiving antiretroviral therapy to participate in clinical trials in Canada. Because of the importance of trial participants being representative of the population for which therapeutic agents are intended, HIV clinical trials must recruit women with lower literacy levels, non-white women, women not receiving antiretroviral therapy and women who are injection drug users to ensure generalizability of research findings. Further study is needed to assess factors that act as barriers and motivators to women's participation in HIV clinical trials.

Résumé

Contexte : Décrire la participation à des études cliniques des femmes infectées par le VIH inscrites depuis 1993 à l'Étude canadienne femmes et VIH, étude de cohortes ouverte et prospective.

Méthodes : Toutes les femmes infectées par le VIH suivies dans des cliniques hospitalières ou communautaires à 28 endroits de 11 villes canadiennes pouvaient participer à l'Étude canadienne femmes et VIH. Des infirmières participant à l'étude ont recueilli aux six mois des renseignements de base et de suivi sur 413 femmes en utilisant des questionnaires normalisés. Les données portaient notamment sur les aspects suivants : variables socio-démographiques, groupe de sujets exposés au VIH, numération de lymphocytes CD4, classification de la maladie, antirétrovirothérapie et participation à des études cliniques.

Résultats : Au début de l'étude, 15,0 % (62/413) des femmes avaient participé à

Evidence

Études

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This article has been peer reviewed.

CMAJ 1998;159:1359-65

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une étude clinique et 8,5 % (35/413) de plus ont participé au cours d'un suivi médian à 18 mois. Une analyse à variables multiples a révélé qu'il y avait un lien indépendant entre les facteurs suivants et la participation à une étude clinique : race blanche (rapport des cotes [RC] rajusté de 3,38, $p = 0,001$), utilisation courante d'une antirétrovirothérapie (RC rajusté de 2,01, $p = 0,008$), études secondaires terminées (RC rajusté de 1,97, $p = 0,024$) et résidence dans les provinces des Prairies ou de l'Atlantique (RC rajusté de 1,98, $p = 0,043$).

Interprétation : Même si, à 23,5 %, le taux global de participation à l'étude clinique était relativement élevé chez les femmes infectées par le VIH, les consommateurs de drogues injectées étaient sous-représentés dans la population de l'étude et les femmes non blanches, les femmes qui n'avaient pas terminé leurs études secondaires et les femmes qui ne suivaient pas une antirétrovirothérapie étaient moins susceptibles de participer à des études cliniques au Canada que les femmes blanches, les femmes plus instruites et les femmes qui suivaient une antirétrovirothérapie. Comme il importe que les participants à des études représentent la population à laquelle sont destinés les agents thérapeutiques, les études cliniques sur le VIH doivent recruter des femmes moins alphabétisées, des femmes non blanches, des femmes qui ne suivent pas une antirétrovirothérapie et des consommatrices de drogues injectées afin d'assurer que les résultats de la recherche soient généralisables. Une étude plus poussée s'impose pour évaluer les facteurs qui nuisent à la participation des femmes à des études cliniques sur le VIH et ceux qui les incitent à y participer.

During the 1990s an important debate has taken place concerning differential access to health care and inequality of medical treatment for women.[1–4] Recognizing the effects of decades of sex-exclusive research[5] and the inequitable participation of women in clinical trials,[6] the US Food and Drug Administration adopted a new policy and published guidelines in 1993 requiring specific analyses of data concerning female participants in clinical trials, increased numbers of clinical trials involving women subjects and improved efforts by researchers to recruit more women into clinical trials.[7,8] The Medical Research Council of Canada has stated that an urgent need exists for studies of the factors that impede or enhance the recruitment of women into clinical trials.[9] We report here the initial results of research assessing the level of participation in clinical trials among Canadian women enrolled in a national prospective cohort study of HIV infection.[10]

Methods

Since 1993 HIV-positive women have been recruited into the Canadian Women's HIV Study by their attending physicians in community-based and hospital-based clinics in 11 cities (28 sites) across Canada. The objective of the study is to gain a better understanding of the clinical and behavioural impact of HIV infection and, in particular, to assess gynecologic illness, more specifically the link between human papillomavirus infection and cervical dysplasia, in Canadian women with HIV infection. All women with confirmed HIV infection, regardless of clinical stage, who are capable of providing fully informed consent are eligible to participate in this open cohort. Ethical approval to document reasons for nonparticipation was not granted, so the profile of nonparticipants is unknown.

Participants agree to return for follow-up visits every 6 months after the initial (baseline) encounter. Information is recorded by study nurses on baseline and follow-up questionnaires. All study instruments were developed in English, translated into French and verified for comparability by 2 francophone clinicians. Information collected includes participants' sociodemographic characteristics, HIV exposure group, disease symptomatology, sexual and reproductive behaviour, drug and alcohol use, and use of medications, including antiretroviral agents (at the time of this analysis these were restricted to AZT [zidovudine], ddI [didanosine], ddC [zalcitabine], 3TC [lamivudine], d4T [stavudine], saquinavir, indinavir and ritonavir). Women are specifically asked whether they have participated in a clinical trial, the name of the study, the agents assessed, and the participation start and end dates. If the trial has ended, the trial arm of participation is recorded, if known. Missing information is extracted from the patient's chart. A sample of venous blood is obtained and sent for determination of the CD4 count to local laboratories participating in a national flow cytometry quality-assurance program. At the time of our analysis 97 women (23.5%) were lost to follow-up; the reasons were death (46), move away from any study site (18), illness becoming too severe (3), incarceration (2) and other (28).

In our analysis potential associations between participation in clinical trials and patient characteristics were evaluated in univariate analysis using the χ^2 test for proportions, the χ^2 test for linear trend, and the *t*-test, median test and Wilcoxon rank test for continuous variables. Variables found to be statistically significant were included in a multiple logistic regression model along with potential confounding variables. For time-dependent variables such as age and duration of knowledge of HIV status, information recorded at the most recent visit was used for women who did not report participation in a clinical trial, and information recorded at the time of first participation in a clinical trial was used for trial participants. Possible interactions were investigated by adding plausible multiplicative interaction terms one at a time to the model. The level of significance was set at a p value of 0.05.

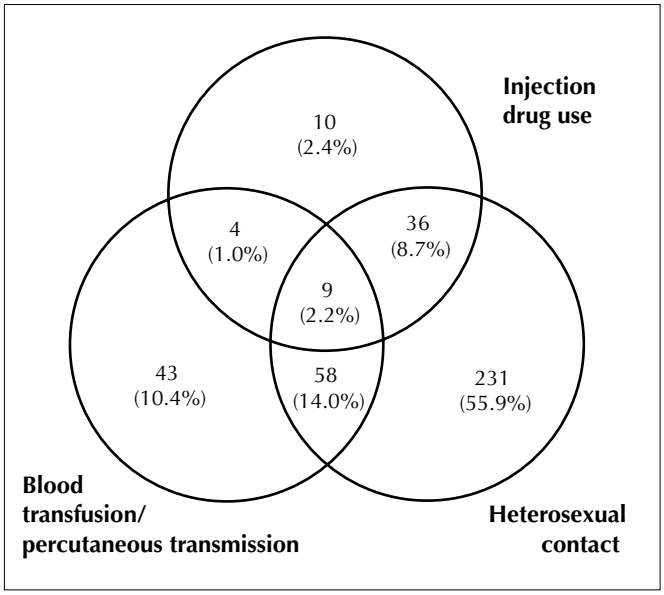

Fig. 1: Source of HIV acquisition for 413 women enrolled in the Canadian Women's HIV Study. [Data are not included for 22 women (21 missing, 1 refusal).]

Results

At the time of our analysis, there were 413 women enrolled in the Canadian Women's HIV Study; 283 (68.5%) were anglophone and 130 (31.5%) francophone. White women represented 62.4%, black women 32.9%, aboriginal women 3.7% and Asian women 1.0% of the cohort. At baseline, the median age was 32.7 (range 16.6–77.3) years. The median number of years of schooling was 12.0 (range 3.0–22.0). For 64.4% (257/399) of the women the annual family income was less than $20 000. The median duration of knowledge of HIV status was 23 (range 0–120) months.

The risk factors for HIV acquisition of the women are shown in Fig. 1. The standard AIDS case surveillance hierarchy[11] attributes cases to one exposure category only and assumes, for example, that women who have injected drugs were infected through this route regardless of possible exposures through unprotected sexual activity. By applying AIDS case surveillance definitions to the study participants we attributed 70.0% (289) to infection through sexual transmission, 14.3% (59) through injection drug use and 9.2% (38) through the receipt of infected blood or blood products. For 5.3% (22) the source of infection was unknown, and for 1.2% (5) it was reported to be percutaneous transmission (3 attributed to injection, 1 to tattoo and 1 to an accident). These figures are comparable to those of cumulative AIDS cases among females 15 years and older in Canada (Table 1) but significantly underrepresent injection drug users, who accounted for 24.7% of AIDS cases diagnosed among women in 1996 ($p = 0.017$).

The median CD4 count at baseline was 0.30 (range 0.001–1.719) $\times 10^9$/L, with 32.1% ($n = 126$) having a count of less than 0.20×10^9/L and 47.1% ($n = 185$) having a count of $0.20–0.499 \times 10^9$/L. The median for lowest observed CD4 count was 0.26 (range 0–1.719) $\times 10^9$/L, with 40.3% ($n = 163$) and 44.3% ($n = 179$) having a count of less than 0.20 and of $0.20–0.499 \times 10^9$/L respectively. Of 306 women with a CD4 count below 0.50×10^9/L,

Table 1: Sources of HIV acquisition among women in Canada

Exposure category	Source; no. (and %) of cases					
	Canadian Women's HIV Study*		Cumulative AIDS cases†		1996 AIDS cases†	
Injection drug use	59	(14.3)‡	177	(18.1)	21	(24.7)‡
Heterosexual contact	289	(70.0)	620	(63.3)	53	(62.4)
Recipient of blood or blood product	38	(9.2)	115	(11.7)	5	(5.9)
Percutaneous exposure	5	(1.2)	1	(0.1)	0	(0)
No identified risk	22	(5.3)	67	(6.8)	6	(7.1)
Total	413	(100.0)	980	(100.0)	85	(100.0)

*For multiple sources, source was attributed by order of AIDS case surveillance categories.
†Source: *AIDS in Canada: quarterly surveillance update.*[11]
‡$p = 0.017$.

72.5% (n = 222) had a history of having received antiretroviral treatment and 55.2% (n = 169) were currently receiving antiretroviral therapy.

At baseline, 62 (15.0%) of the 413 women reported having participated in a clinical trial. During a median follow-up of 18 months (range 4–38.8) an additional 35 women enrolled in a clinical trial, for a total participation rate of 23.5% (97/413). Women had been recruited into a total of 43 trials; these were designed to evaluate antiretroviral agents (20 trials), prophylactic agents for opportunistic infections (12) or treatment of opportunistic infections (6) or were pharmacokinetic studies (4) or vaccine studies (1).

The univariate analysis, which compared clinical trial participants with nonparticipants, revealed that participation was associated with older age (p = 0.004), white race (p = 0.001), completion of secondary school (p = 0.001), no history of injection drug use (p = 0.016), residence in the Prairies or Atlantic provinces (p = 0.02) and current use of antiretroviral treatment outside of a clinical trial (p = 0.002) (Table 2).

For the logistic regression analysis, 11 covariates were included in the model either on the basis of significance in the univariate analysis (race, education, exposure category, region of residence, current use of antiretroviral treatment) or on the basis of either potential confounding with other variables or potential eligibility or exclusion criteria for clinical trial participation (age, CD4 count, place of birth, family income, disease classification and duration of knowledge of HIV status). The latter 3 variables were removed because their addition did not change the adjusted odds ratios of other variables. Crude and adjusted odds ratios for the factors found to be significantly associated with clinical trial participation are shown in Table 3. The odds of participating were 3 times higher among white women than among black, aboriginal and Asian women. The odds of participating were twice as high among women currently receiving antiretroviral therapy (v. those not receiving it), women who had completed secondary school (v. those who had not) and women residing in the Prairies or Atlantic provinces (v. those living in the more populated provinces of Quebec, Ontario and British Columbia). Because none of the interaction terms examined was statistically significant, they were not included in the final model, which had very good explanatory power. The influence of a history of injection drug use was of borderline significance.

Interpretation

Our finding that 23.5% of the 413 women enrolled in the Canadian Women's HIV Study had participated in a clinical trial compares favourably with the rates of 22.3% of 260 ambulatory care HIV patients of both sexes in a Boston hospital cohort who had ever participated in a clinical trial[12] and the 10% of 4604 AIDS patients in the United States who were currently in trials.[13] The associations observed between clinical trial participation and race and education are supported by a US study that found that men and women with AIDS were less likely to participate in an experimental drug trial if they were black, had fewer than 12 years of education and did not have regular health care.[13] Although a history of injection drug use was of borderline significance in our study, research examining the determinants of accrual of women to large multicentre clinical trials in the United States found that participants were less likely to have a history of injection drug use than women with AIDS.[14] Study centres headed by female principal or coprincipal investigators enrolled more than twice as many women as did study centres headed by male investigators, a finding not confirmed by our study. Although participation in clinical trials was not associated with having a clinician who was hospital-based (where research trials are more commonly conducted), versus community-based, the independent association we observed for location of residence suggests that physician factors may play a role. Clinicians' and patients' general interest in new developments in the rapidly evolving field of HIV medicine[15] may be reflected in the association we observed between antiretroviral use and trial participation. Conversely, women not taking antiretroviral treatments may be reticent to expose themselves to potential side effects, both within and outside the clinical trial context.[16]

In our analysis women who had not completed high school were less likely to participate in clinical trials than those with a higher level of education. This indicates a need to adapt clinical trial procedures for women with lower literacy levels, including those whose mother tongue is not English or French, to assist them in grasping the significance and complexities of clinical trials, which are reflected in the detailed explanations found in most clinical trial consent forms today. If physicians who propose clinical trials have a better understanding of patients' perceptions of the advantages and disadvantages of trial participation,[17–20] they may be better prepared to clarify issues and thus assist potential subjects in their decision-making.

Inclusion criteria such as CD4 count, clinical status and exposure to therapeutic and prophylactic agents, as well as exclusion criteria such as a history of injection drug use, can affect participation rates. Injection drug users may have difficulty adhering to study protocols,[14] and active drug use raises the issue of drug interactions. Multiple hurdles must be overcome for injection drug users to receive appropriate HIV care,[21] a fact perhaps reflected in the underrepresentation of users in our study. Since the proportion of AIDS cases among Canadian women that are at-

Table 2: Univariate analysis of factors assessed for potential association with participation by women in HIV clinical trials

Factor	Group; no. (and %) of patients* Participants *n = 97*	Nonparticipants *n = 316*	*p* value
Age, yr	*n = 97*	*n = 313*	
Mean	36.7	34.3	0.015†
Median	36.9	33.1	0.004‡
Range	18.8–77.3	17.0–70.9	0.003§
Age group, yr	*n = 97*	*n = 313*	
< 25	7 (7.2)	24 (7.7)	0.003
25–29	15 (15.5)	73 (23.3)	
30–34	18 (18.6)	103 (32.9)	
35–39	29 (29.9)	52 (16.6)	
40–44	17 (17.5)	31 (9.9)	
≥ 45	11 (11.3)	30 (9.6)	
Race	*n = 97*	*n = 313*	
White	75 (77.3)	181 (57.8)	0.001
Black	22 (22.7)	113 (36.1)	
Other	0 (0.0)	19 (6.1)	
Education	*n = 97*	*n = 310*	
Completed secondary school	76 (78.4)	184 (59.4)	0.001
Exposure category	*n = 97*	*n = 312*	
History of injection drug use	9 (9.3)	62 (19.9)	0.016
Region of residence	*n = 97*	*n = 316*	
Ontario/Quebec/British Columbia	77 (79.4)	280 (88.6)	0.02
Prairies/Atlantic provinces	20 (20.6)	36 (11.4)	
Currently receiving antiretroviral therapy	*n = 92*	*n = 308*	
Yes	64 (69.6)	158 (51.3)	0.002
Family income	*n = 95*	*n = 304*	
≥ $20 000	39 (41.1)	103 (33.9)	0.203
Disease classification	*n = 97*	*n = 315*	
Stage A	40 (41.2)	170 (54.0)	0.07
Stage B	34 (35.1)	79 (25.1)	
Stage C	23 (23.7)	66 (21.0)	
Sex of treating physician	*n = 97*	*n = 316*	
Female	32 (33.0)	120 (38.0)	0.373
Clinician status	*n = 97*	*n = 316*	
Hospital-based	90 (92.8)	275 (87.0)	0.122
Community-based	7 (7.2)	41 (13.0)	
Duration of knowledge of HIV status, mo	*n = 97*	*n = 310*	
Mean	46	42	0.282†
Median	40	34	0.400‡
Range	2.5–112.7	0.2–134.0	0.152§
Lowest recorded CD4 count, $\times 10^9$/L	*n = 96*	*n = 308*	
Mean	0.261	0.299	0.190†
Median	0.225	0.270	0.160‡
Range	0.001–1.530	0–1.719	0.045§
Lowest recorded CD4 count, $\times 10^9$/L	*n = 96*	*n = 308*	
< 0.200	43 (44.8)	120 (39.0)	0.27
0.200–0.499	43 (44.8)	136 (44.2)	
≥ 0.500	10 (10.4)	52 (16.9)	
Place of birth	*n = 97*	*n = 310*	
Canada	62 (63.9)	174 (56.1)	0.131
Currently receiving complementary therapies	*n = 97*	*n = 316*	
Yes	83 (85.6)	264 (83.5)	0.634
Children < 18 yr old	*n = 97*	*n = 316*	
None	45 (46.4)	120 (38.0)	0.139
≥ 1	52 (53.6)	196 (62.0)	
Current injection drug use	*n = 97*	*n = 315*	
Active user	2 (2.1)	20 (6.3)	0.101

*Unless otherwise specified.
†*t*-test.
‡Median test.
§Wilcoxon rank test.

tributed to injection drug use has now risen to 25%,[22] extra effort must be made to assist injection drug users in actively participating in clinical trials if studies are to provide results that can be generalizable to the overall population of HIV-positive women. An added benefit is the collection of information on the interactions of antiretroviral agents and currently illegal drugs such as heroin, cocaine, amphetamines and ecstacy as well as methadone and potential opiate substitutes such as buprenorphine, naltrexone and LAAM (L-alpha-acetylmethadol).

Other barriers to clinical trial participation by women include the fear of legal liability related to the desire to protect fetuses and future childbearing ability,[23] the concern that variations in hormonal status will affect laboratory test results and the possibility that fluctuations in the response of surrogate markers in women at various stages of the menstrual cycle, or while taking oral contraceptives, might affect inferences about treatment effects.[5] In the case of life-threatening conditions, since 1977 it has been judged that the compelling possibility of prolonging the life of the mother overrides the potential risk to the fetus.[7,24] Nevertheless, pregnancy and inadequate birth control often result in the exclusion of women from clinical trials. Further research is required among Canadian women with HIV infection to determine the extent to which clinicians discuss clinical trials with all women who meet eligibility criteria.

Clinical and research staff can identify and develop innovative strategies to overcome recruitment, retention and adherence barriers, and they can help women make informed choices about clinical trial participation when it is proposed.[25,26] In our study, women were not directly asked why they did or did not participate in clinical trials and whether the availability of child care, the distance from treatment centres and transportation costs were important factors. These remain important questions for investigations using qualitative methods such as in-depth interviews or focus groups.

Women have been an absent term in the AIDS research equation for too long.[27] Barriers to clinical trial participation among women require further exploration, particularly for disadvantaged women, if trial participants are to represent the population of HIV-positive women adequately. In addition to clinical trials addressing gynecological concerns in HIV-positive women, disaggregated sex-specific analyses might bring to light circumstances and interrelationships among variables that are unique to women.[28,29]

We thank Thang Tran for data analysis, Susanne Schlichtherle for literature searches, Lisa Hum for manuscript proofing, Johanne Samson for comments, Sylvie Gauthier and Karina Pourreaux for manuscript formatting, and the study nurses for data collection.

This research was supported by the National Health Research and Development Programme and the Medical Research Council of Canada (grant 6605-4164-AIDS).

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Table 3: Multivariate logistic regression analysis* of factors found to be significantly associated with clinical trial participation by women

Factor	Crude OR	Adjusted OR	95% CI	*p* value
Race				
Non-white	1.00	1.00		
White	2.54	3.38	1.61–7.12	0.001
Currently receiving antiretroviral therapy				
No	1.00	1.00		
Yes	1.94	2.01	1.20–3.36	0.008
Education				
Did not complete secondary school	1.00	1.00		
Completed secondary school	2.60	1.97	1.09–3.54	0.024
Region of residence				
Quebec/Ontario/British Columbia	1.00	1.00		
Prairies/Atlantic provinces	2.02	1.98	1.02–3.82	0.043
History of injection drug use				
Yes	1.00	1.00		
No	2.53	2.24	0.99–5.08	0.054

Note: OR = odds ratio, CI = confidence interval.
*Hosmer and Lemeshow goodness-of-fit = 8.3307 (8 degrees of freedom); $p = 0.402$. Adjusted for age (by 10-year increments), CD4 count (< 0.200 v. $\geq 0.200 \times 10^9$/L) and place of birth (Canada v. elsewhere).

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