Highly active antiretroviral therapy and survival in HIV-infected Injection drug users: implications for the critical role of adherence

Robert Hogg, PhD

BC Centre for Excellence in HIV/AIDS

and Simon Fraser University

British Columbia Centre for Excellence in HIV/AIDS

SFU SIMON FRASER UNIVERSITY
THINKING OF THE WORLD

Learning objectives

- Determine the impact of HAART on life expectancy and survival
- Evaluate the impact of HAART adherence on survival
- Describe barriers to HAART adherence
- Review guidelines for HAART initiation

Life expectancy and survival

Life Expectancy

	Men	Women	Injecting drug users	Non-injecting drug users
Mortality rates (per 1000 person-years)				
Overall	12·9 (12·3–13·6)	9·1 (8·2–10·1)	20·7 (19·0–22·5)	10·5 (10·0–11·0)
Between the ages 20 and 44 years	10·3 (9·7–11·0)	7·4 (7·–8·9)	18·6 (16·9–20·6)	7·8 (7·3–8·3)
Potential years of life lost before age 65 years (per 1000 person-years)				
20–64 years	157·8	214·4	505·5	202·5
Life expectancy (years; adjusted)				
Exact age 20 years	42·8 (SE 0·45)	44·2 (SE 0·55)	32·6 (SE 1·06)	44·7 (SE 0·34)
Exact age 35 years	31·7 (SE 0·32)	32·5 (SE 0·44)	23·4 (SE 0·60)	33·0 (SE 0·22)
Percent surviving from 20 to 44 years	80·2%	83·1%	66·5%	84·1%

Mortality rates are deaths per 1000 person-years (95% CI).

Table 4: Health indicators stratified by sex and injecting drug use

Articles

Life expectancy of individuals on combination antiretroviral therapy in high-income countries: a collaborative analysis of 14 cohort studies

The Antiretroviral Therapy Cohort Collaboration*

Summary

Background Combination antiretroviral therapy has led to significant increases in survival and quality of life, but at a population-level the effect on life expectancy is not well understood. Our objective was to compare changes in mortality and life expectancy among HIV-positive individuals on combination antiretroviral therapy.

retroviral Therapy Cohort Collaboration is a multinational collaboration of HIV cohort studies in h America. Patients were included in this analysis if they were aged 16 years or over and when initiating combination therapy. We constructed abridged life tables to estimate life dividuals on combination antiretroviral therapy in 1996–99, 2000–02, and 2003–05, and stratified D4 cell count, and history of injecting drug use. The average number of years remaining to be lived th combination antiretroviral therapy at 20 and 35 years of age was estimated. Potential years of life years of age and crude mortality rates were also calculated.

914, and 10 854 eligible patients initiated combination antiretroviral therapy in 1996–99, 2000–02, ectively. 2056 (4·7%) deaths were observed during the study period, with crude mortality rates 6·3 deaths per 1000 person-years in 1996–99 to 10·0 deaths per 1000 person-years in 2003–05. life lost per 1000 person-years also decreased over the same time, from 366 to 189 years. Life 0 years increased from 36·1 (SE 0·6) years to 49·4 (0·5) years. Women had higher life expectancies ents with presumed transmission via injecting drug use had lower life expectancies than did those ission groups (32·6 [1·1] years vs 44·7 [0·3] years in 2003–05). Life expectancy was lower in patients e CD4 cell counts than in those with higher baseline counts (32·4 [1·1] years for CD4 cell counts pL vs 50·4 [0·4] years for counts of 200 cells per µL or more).

expectancy in HIV-infected patients treated with combination antiretroviral therapy increased 005, although there is considerable variability between subgroups of patients. The average number of be lived at age 20 years was about two-thirds of that in the general population in these countries.

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tiretroviral drugs of people infected improved significantly since the combination antiretroviral therapy nt-naive patients, first-line combination s generally derived from two different which contains either non-nucleoside se inhibitors (NNRTIs) or protease oth regimens function by suppressing d rapidly increasing CD4 cell counts.[1] scade, combination therapy regimens e effective, better tolerated, and have terms of dosing.[2–4] Clinical trials and ies have shown profound reductions orbidity in patients infected with HIV bination antiretroviral therapy.[5–10] This tality is particularly apparent in h-income countries where access to tiretroviral treatments is more readily

Life expectancy and mortality are universally viewed as important population health indicators. As such, several studies have displayed the negative relation between HIV prevalence and life expectancy at a population level.[11] However, the effect of HIV on life expectancy in the era of combination therapy is not well understood because of the relative novelty of this treatment. The objective of this study was to compare changes in mortality rates and life expectancy among HIV-positive individuals on combination therapy in high-income countries over three separate periods (1996–99, 2000–02, and 2003–05) and in subgroups defined by patient characteristics at initiation of such treatment.

Methods

Participants

The Antiretroviral Therapy Cohort Collaboration (ART-CC) is a multinational cohort study of antiretroviral-naive HIV-positive patients initiating combination antiretroviral therapy.[12–13] The collaboration was estab-

Lancet 2008; 372: 293–99
See Comment page 266

*Members listed at end of paper and contributors to each cohort are listed in webappendix 1

Correspondence to:
Prof Robert Hogg, BC Centre for Excellence in HIV/AIDS, 608-1081 Burrard Street, Vancouver, BC, Canada V6Z 1Y6
bobh.hogg@cfenet.ubc.ca

Hogg et al., 2008, Lancet

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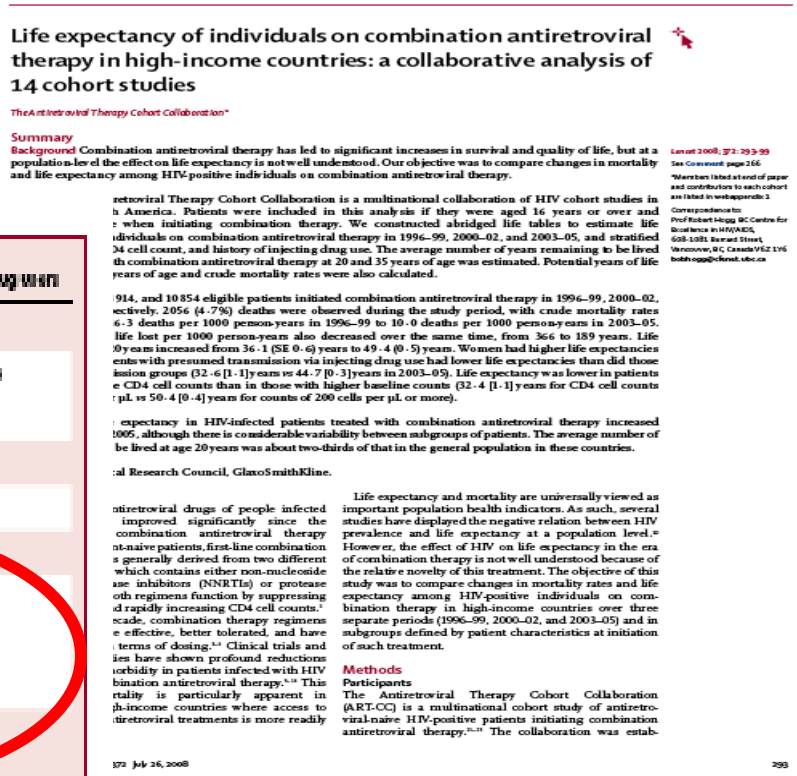
ART
Cohort Collaboration

Life Expectancy



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bobh.cgge@cfenet.ubc.ca

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Mortality rates are deaths per 1000 person-years (95% CI).

Table 4: Health indicators stratified by sex and injecting drug use

IDUs live significantly less than non-IDUs

Hogg et al., 2008, Lancet

.

ART Cohort Collaboration

HAART survival in IDUs

Highly Active Antiretroviral Therapy and Survival in HIV-Infected Injection Drug Users

Evan Wood, MD, PhD
Robert S. Hogg, PhD
Viviane Dias Lima, PhD
Thomas Kerr, PhD
Benita Yip, BSc (Pharm)
Brandon D. L. Marshall, MSc
Julio S. G. Montaner, MD, FRCPC

Context Highly active antiretroviral therapy (HAART) is often withheld from injection drug users (IDUs) infected with the human immunodeficiency virus (HIV) based on the belief that their unstable lifestyles may predetermine a markedly inferior outcome with HAART. However, long-term evaluations of HIV treatment outcomes among IDUs in comparison with other risk groups are not available.

Objective To compare survival rates among HIV-infected patients initiating HAART with and without a history of injection drug use.

Design, Setting, and Patients Population-based, prospective cohort study (HAART Observational Medical Evaluation and Research [HOMER]) of 3116 antiretroviral-naive HIV-infected patients in a province-wide HIV/AIDS treatment program in British Columbia, Canada. Of the 3116 patients, 915 were IDUs (29.4%), 579 were female (18.6%), and the median age was 39.4 years (interquartile range, 33.3-46.4 years). Treatment with HAART was initiated between August 1, 1996, and June 30, 2006. The median duration of follow-up was 5.3 years (interquartile range, 2.8-8.3 years) for IDUs and 4.3 years (interquartile range, 2.0-7.6 years) for non-IDUs. Patients were followed up until June 30, 2007. Data were analyzed between November 1, 2007, and May 26, 2008.

Main Outcome Measure All-cause mortality.

Results Overall, 622 individuals died (20.0%) during the study period (232 IDUs and 390 non-IDUs), for a crude mortality rate of 20.0% (95% confidence interval [CI], 18.4%-21.5%). At 84 months after the initiation of HAART, the product limit estimate of the cumulative all-cause mortality rate was similar between the 915 IDUs (26.5%; 95% CI, 23.2%-29.8%) and 2201 non-IDUs (21.6%; 95% CI, 16.9%-26.2%) (Wilcoxon $P = .47$). In multivariate time-updated Cox regression, the hazard ratio of mortality was similar between IDUs and non-IDUs (1.09; 95% CI, 0.92-1.29).

Conclusion In this study population, injection drug use was not associated with decreased survival among HIV-infected patients initiating HAART.

JAMA. 2008;300(5):550-554 www.jama.com

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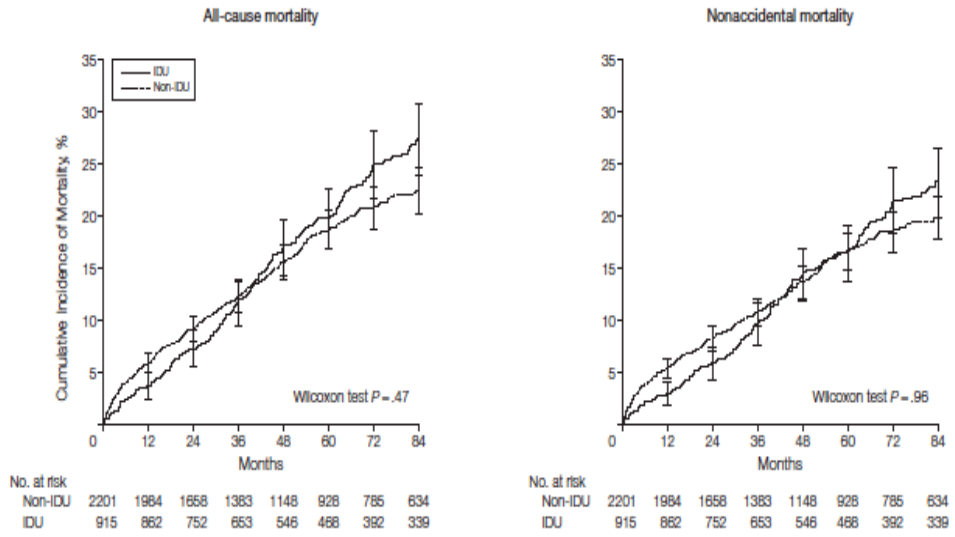
Figure. Mortality Rate Among 3116 Antiretroviral-Naive Patients Initiating HAART



Overall, there were 622 deaths and the analysis of nonaccidental mortality censored 87 deaths (14.0%) as nonevents among which 62 deaths (71.2%) were accidental poisonings, 16 were suicides (18.3%), 6 were traumas (<0.1%), and 3 were classified as other (<0.1%). Survival curves were compared using the Wilcoxon test and all follow-up data for all participants. Error bars indicate 95% confidence intervals; HAART, highly active antiretroviral therapy; IDU, injection drug user.

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HAART survival in IDUs

No difference in survival between IDUs and non-IDUs

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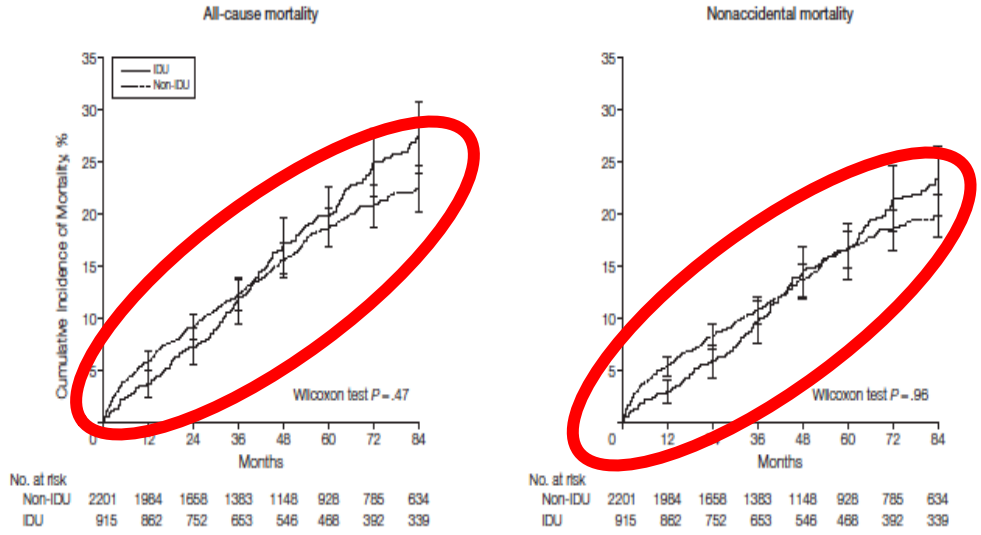

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Potential explanations

- Population-based
- HAART available free of charge
- Few barriers (financial or other) to care
- Complete reporting of deaths (thru linkages to Vital Statistics and reporting by physicians)
- Better adherence support

Adherence and survival

Intermittent use of HAART

Intermittent use of triple-combination therapy is predictive of mortality at baseline and after 1 year of follow-up

Robert S. Hogg[a,b], Katherine Heath[a,b], David Bangsberg[c], Benita Yip[a], Natasha Press[a], Michael V. O'Shaughnessy[a,d] and Julio S.G. Montaner[a,e]

Table 3. Univariate and multivariate analysis of the baseline factors associated with survival among 1282 persons first prescribed any triple-combination antiretroviral therapy.

Variable	Risk ratio (95% CI)	
	Crude	Adjusted[a]
Age (years) (continuous)	1.02 (1.00–1.04)	–
Sex (male versus female)	1.17 (0.66–2.10)	–
Protease inhibitor use (yes versus no)	2.12 (1.16–3.88)	1.52 (0.82–2.82)
Injecting drug use (yes versus no)	0.99 (0.63–1.54)	–
Physician experience (per 100 patients per physician)	0.77 (0.59–0.99)	0.86 (0.67–1.12)
AIDS diagnosis (yes versus no)	2.15 (1.38–3.34)	1.44 (0.88–2.35)
CD4 cell count (per 100×10^6 cells/l decrease)	1.36 (1.21–1.53)	1.31 (1.16–1.49)
Plasma viral load (per $\log_{10}$ copies/ml increase)	1.79 (1.28–2.52)	1.34 (0.95–1.87)
Intermittent antiretroviral use (< 75% of the time in the first year)	2.35 (1.60–3.46)	2.90 (1.93–4.36)

[a]Including all prognostic variables that were statistically significant in the univariate analysis. CI, Confidence interval.

Objective: To characterize the impact of intermittent use of triple drug antiretroviral therapy on survival.

Design, setting and participants: Population-based analysis of 1282 antiretroviral therapy naive HIV-positive individuals aged 18 years and older in British Columbia who started triple-combination therapy between August 1996 and December 1999. Therapy use was estimated by dividing the number of months of medications dispensed by the number of months of follow-up. Intermittent therapy was defined as the participant having obtained less than 75% of their medication in the first 12 months.

Main outcome measure: Cumulative all-cause mortality rates from the start of triple drug antiretroviral therapy to 30 September 2000.

Results: As of 30 September 2000, 106 subjects had died. Cumulative mortality was 3.9% (± 0.5%) at 12 months. In a multivariate model, after controlling for other variables that were significant in the univariate analyses each 100 cell decrement in baseline CD4 cell count and the intermittent use of antiretroviral drugs were associated with increased mortality with risk ratios of 1.31 [95% confidence interval (CI), 1.16–1.49; $P < 0.001$] and 2.90 (95% CI, 1.93–4.36; $P < 0.001$), respectively. In order to control for downward drift, intermittent use of therapy was measured over the first year whereas other factors were measured at the end of year 1. After adjusting for

Hogg et al., AIDS, 2001

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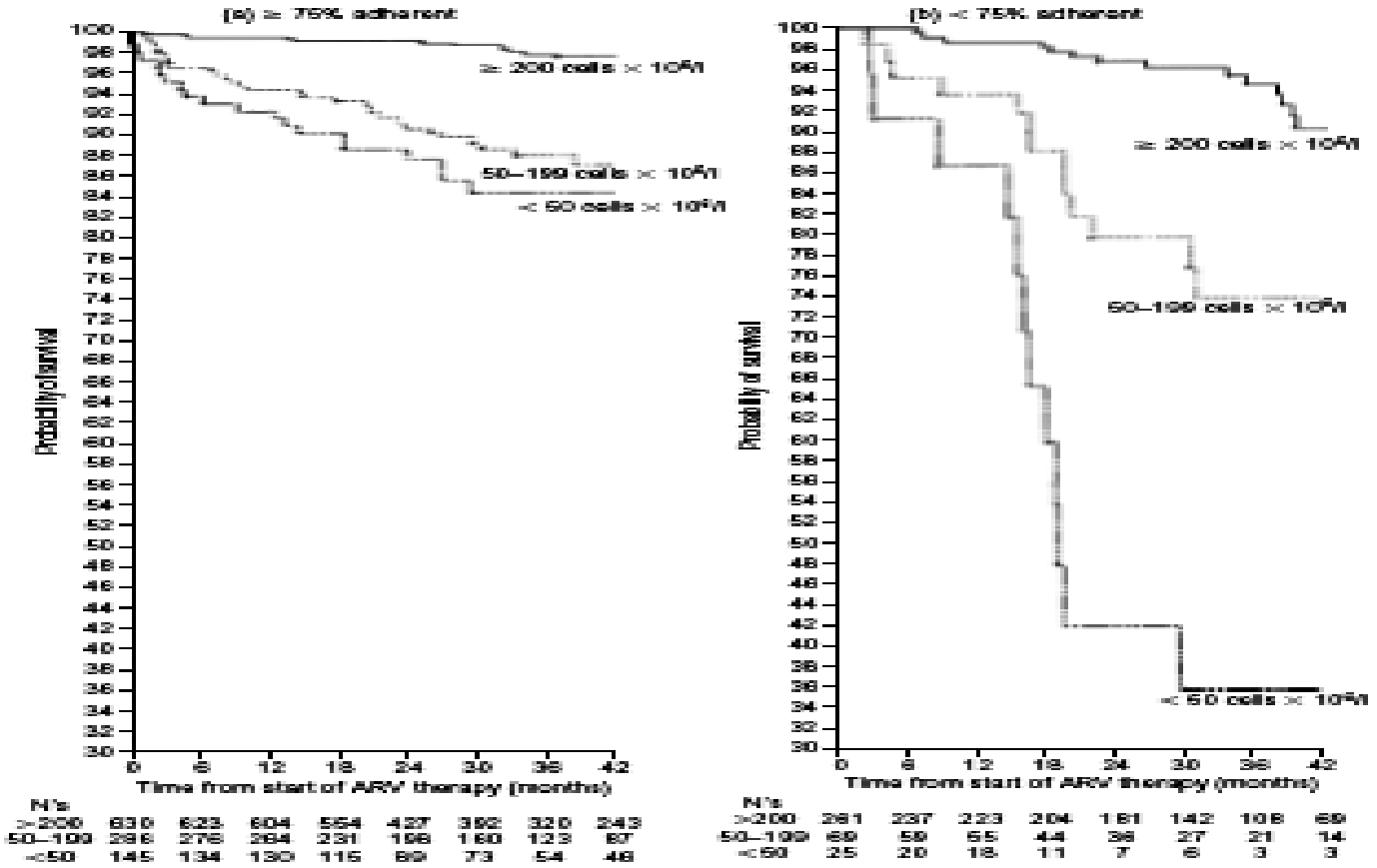
3 fold increase in survival among adherent people

Hogg et al., AIDS, 2001

Adherence and initial CD4



Wood et al., AIDS, 2003

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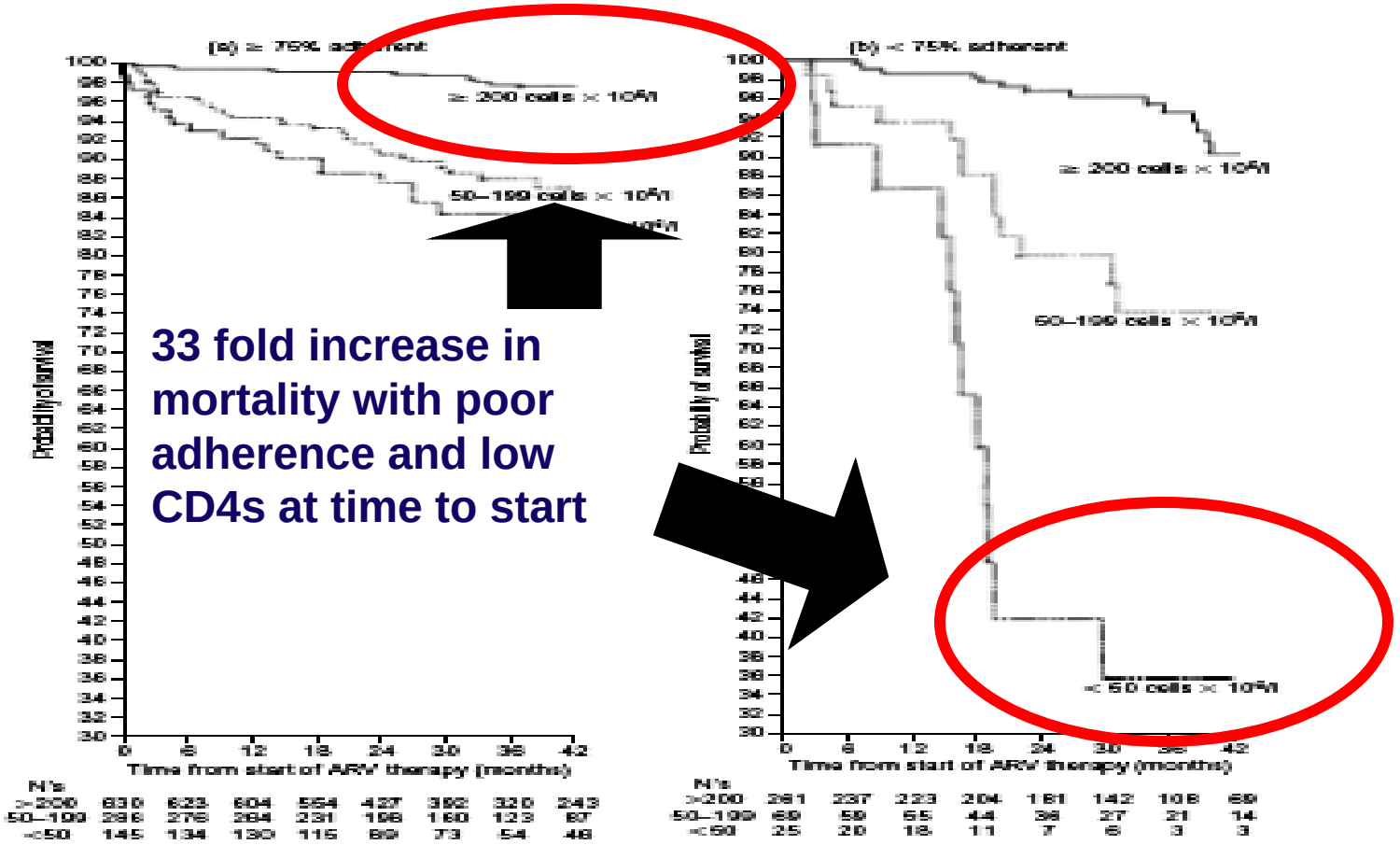


33 fold increase in mortality with poor adherence and low CD4s at time to start

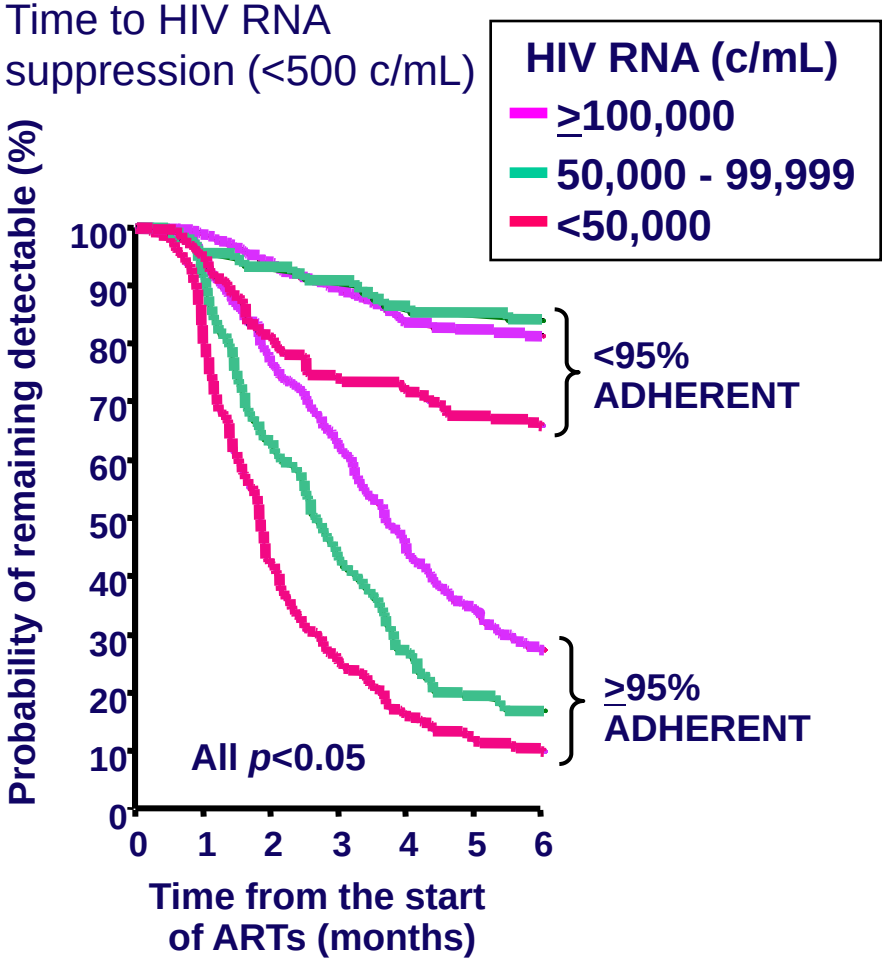
Wood et al., AIDS, 2003

Baseline RNA and adherence

- Is poor prognosis for patients with high HIV RNA confounded by poor adherence?
- Adjusting for adherence, HIV RNA >100,000 associated with HIV-related mortality (ARH 1.81, 95% CI 1.15-2.84)

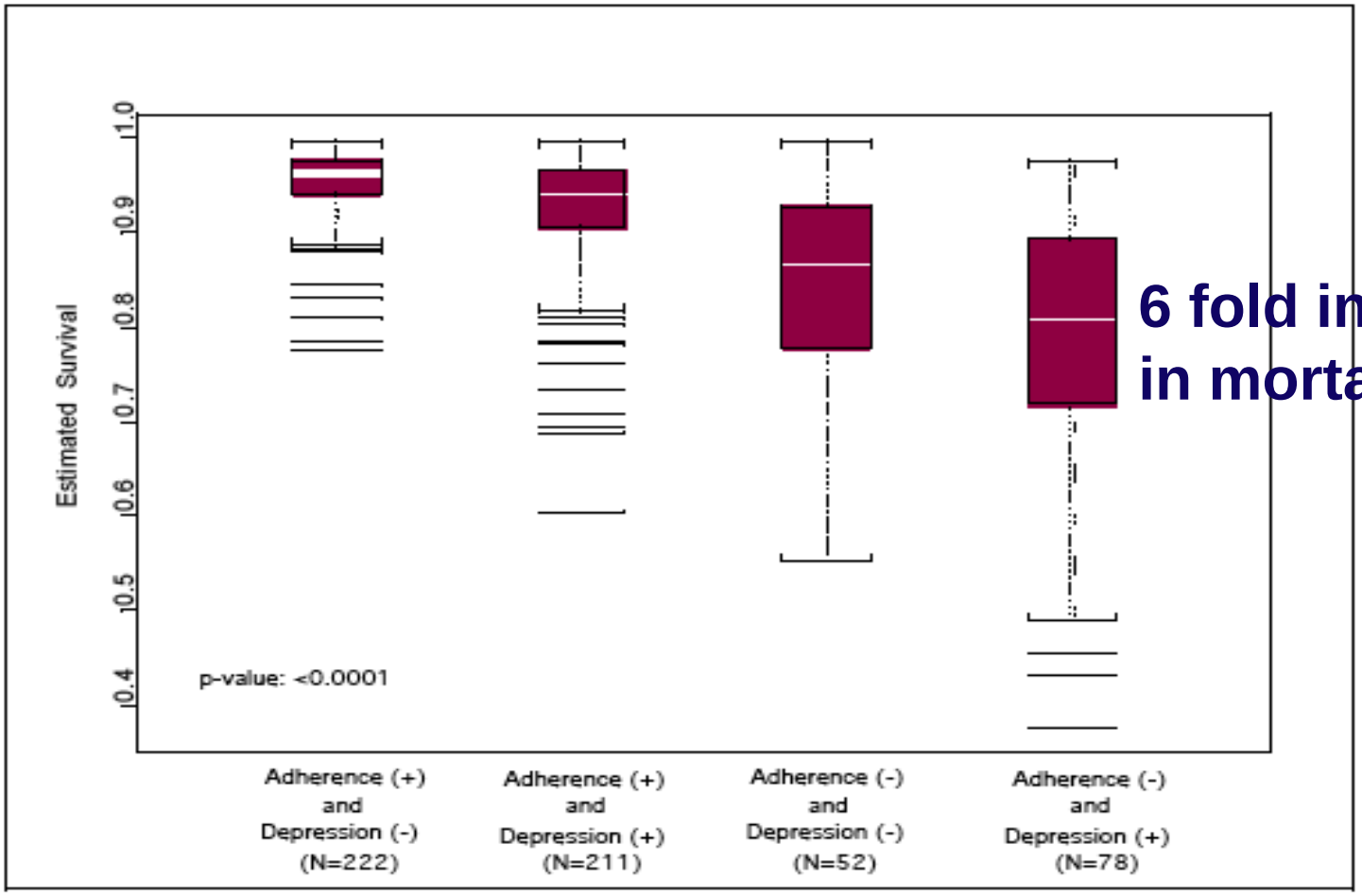
Conclusion

- Even when controlling for adherence, VL >100,000 confers a worse prognosis



Wood E, *et al. 10th CROI*, Boston 2003, #182

Adherence and depression



6 fold increase in mortality

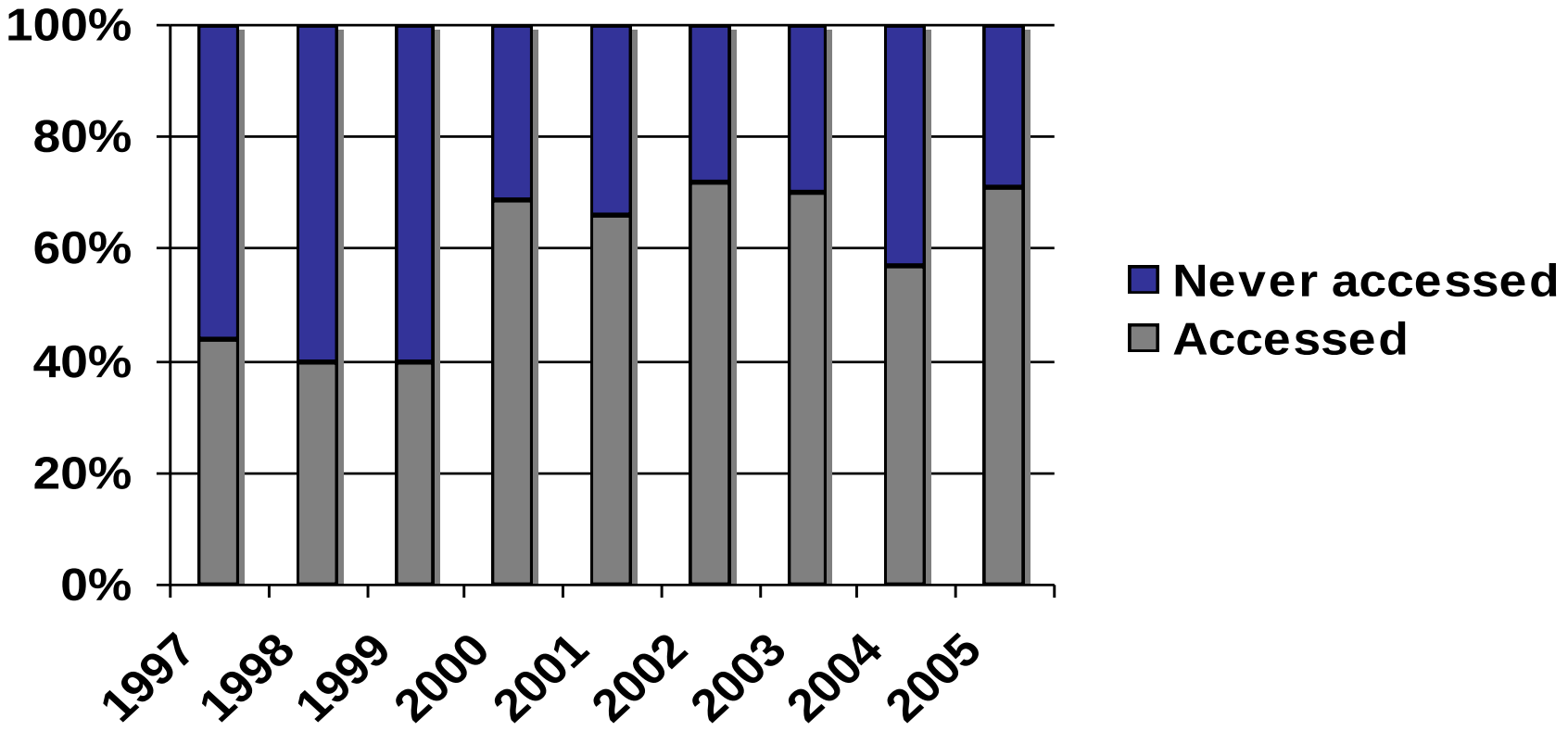
Lima et al., AIDS 2006

Barriers to adherence

Barriers to adherence

- Misinformation about HAART
- Drug dependency
- Mental illness, Hep C & other co-infections
- Poor access to medical care
- Criminal enforcement
- Unstable housing

Ever accessed HAART



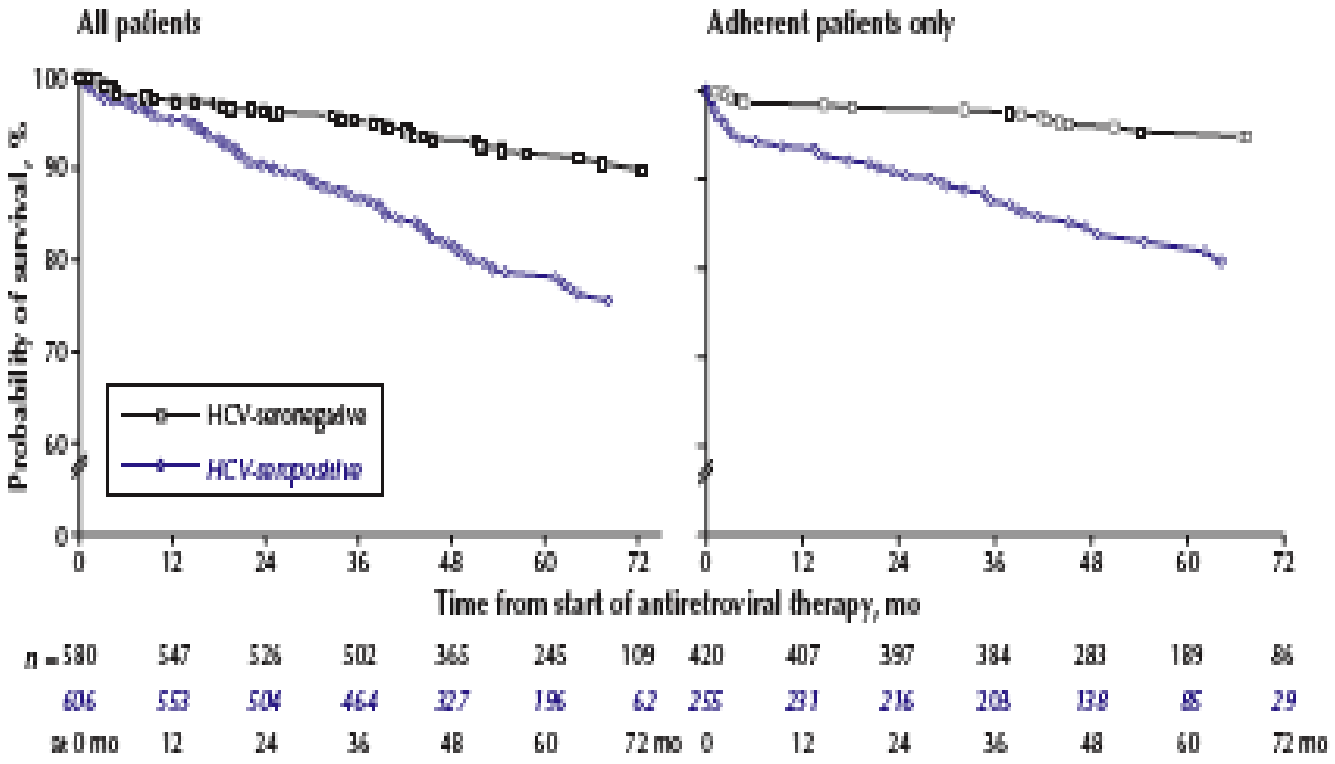
Note: Based on 1,436 HIV-related deaths from 1997 to 2005 in BC

Source: Joy et al., JAIDS, 2008

Case study: drug dependency and mental health

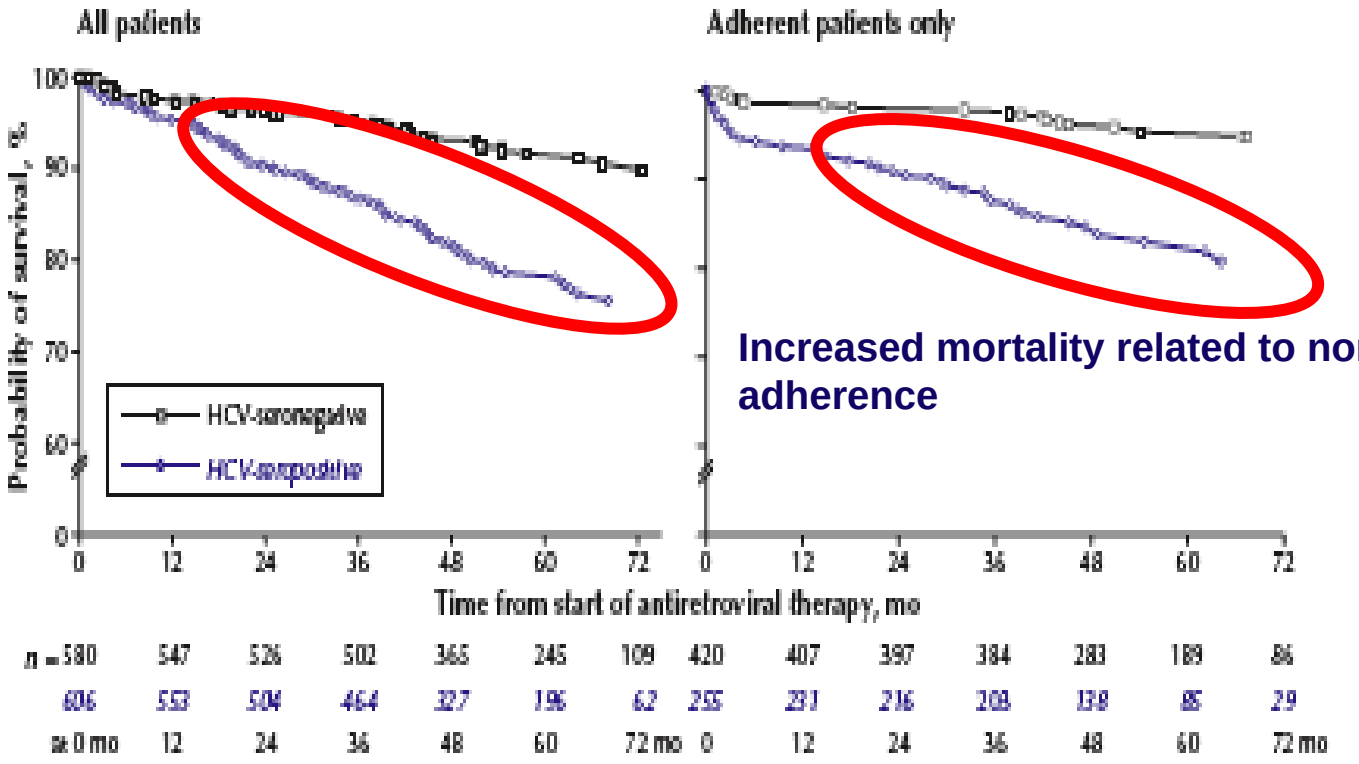
- **Towards Aboriginal Health and Healing** (**TAHAH**) program stabilizes all psycho-social, legal and economic crises and immediate primary health issues. For instance,
- 25 year old woman, homeless, FASD, IVDU, HCV+, PTSD, Paranoid Delusions. HIV+ at age 17; CD4 Nadir 230; pVL over 100,000; recurring opportunistic infections.
- Referred to **TAHAH** 2007: immediate survival needs addressed, then gradual initiation of antipsychotic meds.
- 2008: PWD application (line by line), started depo-provera, stabilized housing
- 2009: initiation of methadone, then HAART
- Dec 2009 = CD4 390, VL = 188
- Client had over 20 contacts with staff per month

Adherence and hepatitis C



Braitstein et al., CMAJ, 2005

Adherence and hepatitis C

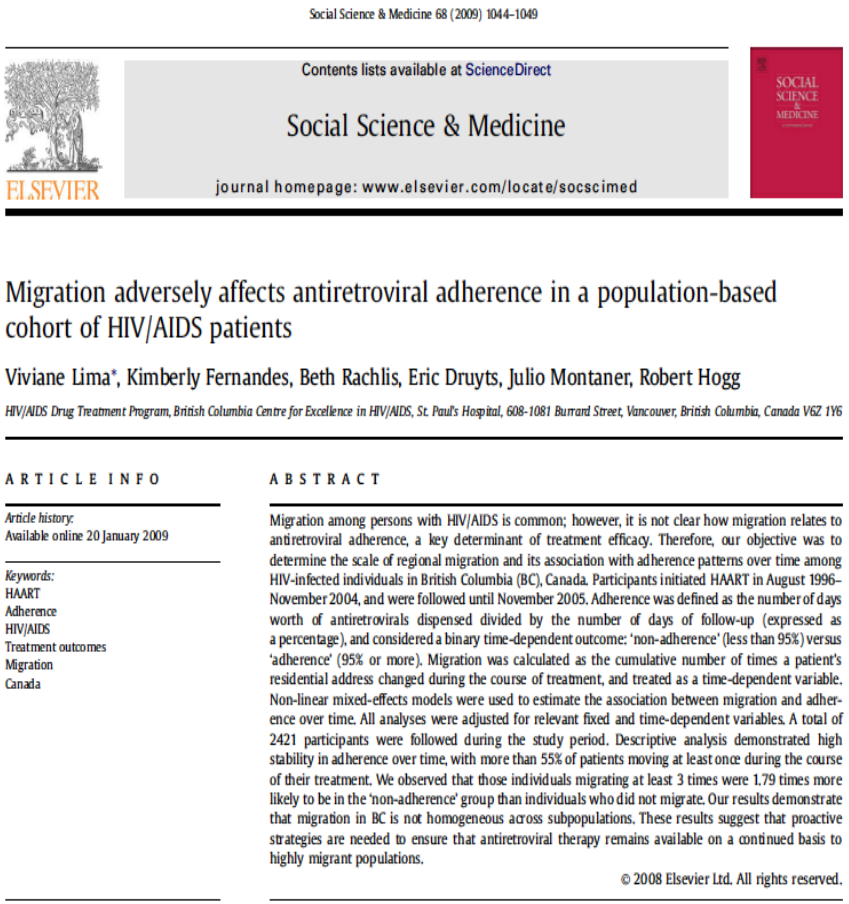


Increased mortality related to non-adherence

Braitstein et al., CMAJ, 2005

Migration and adherence

- People on HAART who migrated at least 3 times were 1.8 times more likely to be non-adherent than those who did not.



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Migration adversely affects antiretroviral adherence in a population-based cohort of HIV/AIDS patients

Viviane Lima*, Kimberly Fernandes, Beth Rachlis, Eric Druyts, Julio Montaner, Robert Hogg

HIV/AIDS Drug Treatment Program, British Columbia Centre for Excellence in HIV/AIDS, St. Paul's Hospital, 608-1081 Burrard Street, Vancouver, British Columbia, Canada V6Z 1Y6

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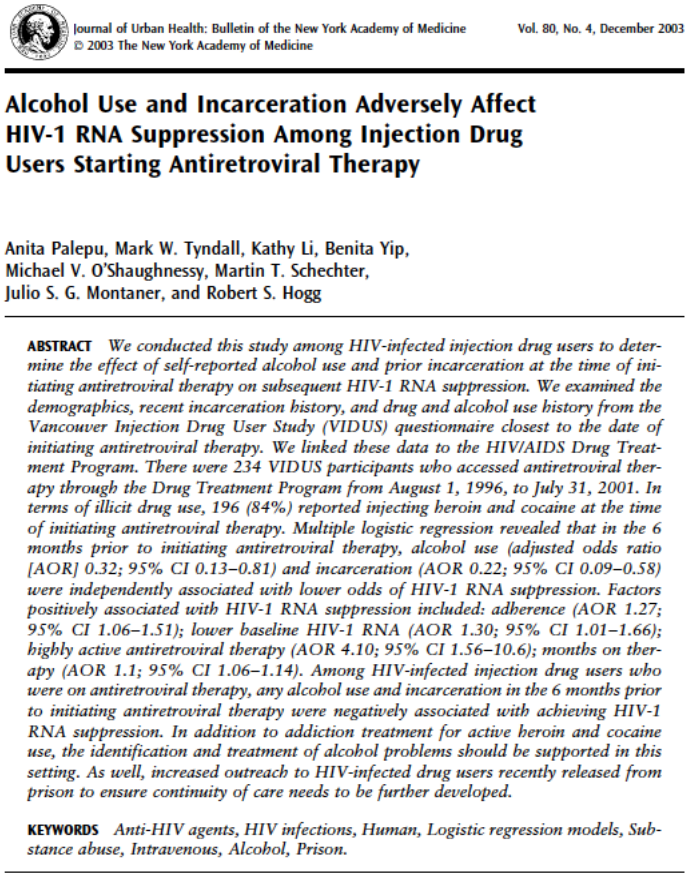
ABSTRACT

Migration among persons with HIV/AIDS is common; however, it is not clear how migration relates to antiretroviral adherence, a key determinant of treatment efficacy. Therefore, our objective was to determine the scale of regional migration and its association with adherence patterns over time among HIV-infected individuals in British Columbia (BC), Canada. Participants initiated HAART in August 1996–November 2004, and were followed until November 2005. Adherence was defined as the number of days worth of antiretrovirals dispensed divided by the number of days of follow-up (expressed as a percentage), and considered a binary time-dependent outcome: 'non-adherence' (less than 95%) versus 'adherence' (95% or more). Migration was calculated as the cumulative number of times a patient's residential address changed during the course of treatment, and treated as a time-dependent variable. Non-linear mixed-effects models were used to estimate the association between migration and adherence over time. All analyses were adjusted for relevant fixed and time-dependent variables. A total of 2421 participants were followed during the study period. Descriptive analysis demonstrated high stability in adherence over time, with more than 55% of patients moving at least once during the course of their treatment. We observed that those individuals migrating at least 3 times were 1.79 times more likely to be in the 'non-adherence' group than individuals who did not migrate. Our results demonstrate that migration in BC is not homogeneous across subpopulations. These results suggest that proactive strategies are needed to ensure that antiretroviral therapy remains available on a continued basis to highly migrant populations.

Prison and HAART response

- Among IDUs, alcohol use and incarceration prior to start of HAART were negatively associated with viral load suppression



Journal of Urban Health: Bulletin of the New York Academy of Medicine Vol. 80, No. 4, December 2003

Alcohol Use and Incarceration Adversely Affect HIV-1 RNA Suppression Among Injection Drug Users Starting Antiretroviral Therapy

Anita Palepu, Mark W. Tyndall, Kathy Li, Benita Yip, Michael V. O'Shaughnessy, Martin T. Schechter, Julio S. G. Montaner, and Robert S. Hogg

ABSTRACT *We conducted this study among HIV-infected injection drug users to determine the effect of self-reported alcohol use and prior incarceration at the time of initiating antiretroviral therapy on subsequent HIV-1 RNA suppression. We examined the demographics, recent incarceration history, and drug and alcohol use history from the Vancouver Injection Drug User Study (VIDUS) questionnaire closest to the date of initiating antiretroviral therapy. We linked these data to the HIV/AIDS Drug Treatment Program. There were 234 VIDUS participants who accessed antiretroviral therapy through the Drug Treatment Program from August 1, 1996, to July 31, 2001. In terms of illicit drug use, 196 (84%) reported injecting heroin and cocaine at the time of initiating antiretroviral therapy. Multiple logistic regression revealed that in the 6 months prior to initiating antiretroviral therapy, alcohol use (adjusted odds ratio [AOR] 0.32; 95% CI 0.13–0.81) and incarceration (AOR 0.22; 95% CI 0.09–0.58) were independently associated with lower odds of HIV-1 RNA suppression. Factors positively associated with HIV-1 RNA suppression included: adherence (AOR 1.27; 95% CI 1.06–1.51); lower baseline HIV-1 RNA (AOR 1.30; 95% CI 1.01–1.66); highly active antiretroviral therapy (AOR 4.10; 95% CI 1.56–10.6); months on therapy (AOR 1.1; 95% CI 1.06–1.14). Among HIV-infected injection drug users who were on antiretroviral therapy, any alcohol use and incarceration in the 6 months prior to initiating antiretroviral therapy were negatively associated with achieving HIV-1 RNA suppression. In addition to addiction treatment for active heroin and cocaine use, the identification and treatment of alcohol problems should be supported in this setting. As well, increased outreach to HIV-infected drug users recently released from prison to ensure continuity of care needs to be further developed.*

KEYWORDS *Anti-HIV agents, HIV infections, Human, Logistic regression models, Substance abuse, Intravenous, Alcohol, Prison.*

Palepu et al., Urban Health, 2006

Homelessness in Vancouver

- Up 171% (since 2002), 52% on street, 48% in shelters
- 30% of homeless are Aboriginal
- 48% report addiction (39% in 2002)
- 33% have co-morbidity of addiction and mental illness
- 40% reported a health condition, 35% reported two or more.
- 30 % welfare, 11% disability, 23% no income, 14% employed, 5% dumpster diving or binning, 5% illegal income
- Reasons for homelessness: 44% low $$, 25% health/addictions, 22% housing cost, 16% abuse/conflict, 13% evicted, 8% moving/ stranded

From City of Vancouver, GVRD & SPARC reports

Conclusions

- IDUs have similar survival rates as non-IDU, at least in BC
- Adherence is an important determinant of HAART survival
- Numerous barriers to HAART adherence exist, especially among IDUs

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The Economist, Sept 2003