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BACKGROUND

- It is widely held that volunteer bias and selection bias introduced by clinical trial enrollment criteria result in selected patient samples, leading to improved outcomes in trials (efficacy) relative to routine care (effectiveness)
- Efficacy vs. effectiveness comparisons have been understudied for HIV infection

QUESTIONS

- Are certain patient characteristics associated with greater likelihood for clinical trial participation among treatment-naïve HIV-infected patients starting HAART?
- Following HAART initiation, is the frequency of 6-month virologic failure (<50 copies/mL) different between pts receiving ARV treatment through a trial vs. routine care?

COHORT

- The UAB 1917 HIV/AIDS Clinic Cohort Database Project is a 100% quality controlled, IRB approved protocol that contains detailed sociodemographic, psychosocial, and clinical information for HIV-infected patients receiving care at the clinic, which includes over 6,000 patients since 1988 and >1,500 active patients

RESEARCH DESIGN

- Retrospective cohort study
- Study period: 1 January 2000 - 31 December 2006
- Inclusion criteria: ARV-naïve patients initiating HAART were included in this study and classified according to modality of HAART receipt: clinical trial vs. routine care

MEASURES/ANALYSES

- Descriptive statistics were calculated for all study variables for the study population stratified by HAART treatment modality
- Characteristics associated with clinical trial participation
 - Univariate & multivariable logistic regression
- Efficacy vs. effectiveness
 - Chi-square & T-test
 - Univariate & multivariable logistic regression

TABLE 1

Patient characteristics & multivariable logistic regression model of characteristics associated with HAART receipt through a clinical trial

Characteristic	Routine Care (n=444) M ± SD or N (column %)	Clinical Trial (n=126) M ± SD or N (column %)	Clinical Trial Enrollment OR (95% CI)*
Age (per 10 years)	38.0 ± 10.0	37.1 ± 9.1	0.96 (0.76 - 1.22)
Female	104 (23.4%)	26 (20.6%)	1.56 (0.75 - 3.23)
African American	263 (59.2%)	44 (34.9%)	0.48 (0.29 - 0.79)
HIV risk factor			
Heterosexual	192 (43.9%)	39 (31.5%)	1.00
Men who have sex with men (MSM)	213 (48.6%)	76 (61.1%)	1.62 (0.85 - 3.08)
IVDU	33 (7.5%)	9 (7.4%)	1.53 (0.53 - 4.43)
CD4 cell count			
< 50 cells/mm ³	147 (33.7%)	23 (18.4%)	1.00
50 - 199 cells/mm ³	116 (26.6%)	28 (22.4%)	1.55 (0.81 - 2.95)
200 - 350 cells/mm ³	91 (20.9%)	28 (22.4%)	2.32 (1.19 - 4.50)
> 350 cells/mm ³	82 (18.8%)	46 (36.8%)	3.85 (2.02 - 7.34)
log ₁₀ plasma HIV RNA (copies/mL)	4.6 ± 1.1	4.8 ± 0.9	1.37 (1.07 - 1.76)
Insurance Class			
Private	215 (48.4%)	65 (51.6%)	1.00
Public	70 (15.8%)	11 (8.7%)	0.68 (0.31 - 1.49)
None	159 (35.8%)	50 (39.7%)	1.27 (0.79 - 2.04)
Affective Mental Disorder	199 (44.8%)	67 (53.2%)	1.16 (0.74 - 1.82)
Substance Abuse	103 (23.2%)	26 (20.6%)	0.79 (0.41 - 1.50)
Opportunistic Infection	154 (34.6%)	23 (18.2%)	--
Alcohol Abuse	73 (16.4%)	17 (13.5%)	0.73 (0.37 - 1.42)

* Multivariable logistic regression analysis modeling clinical trial enrollment as the outcome.

TABLE 2

Univariate and multivariable logistic regression analyses evaluating characteristics associated with 6-month virologic failure (>50 copies/mL) following HAART initiation

Characteristic	Crude OR (95% CI) VL>50	Adjusted OR (95% CI) VL>50
Study No vs. Yes	0.88 (0.58 - 1.35)	1.04 (0.65 - 1.66)
Age (per 10 years)	0.82 (0.68 - 0.98)	0.84 (0.68 - 1.04)
Female	1.04 (0.68 - 1.61)	0.73 (0.40 - 1.35)
Black	1.23 (0.86 - 1.76)	1.43 (0.91 - 2.24)
HIV risk factor		
Heterosexual	1.03 (0.49 - 2.18)	0.88 (0.34 - 2.32)
MSM	1.11 (0.53 - 2.32)	0.97 (0.38 - 2.50)
Baseline CD4 count		
< 50 cells/mm ³	0.22 (0.13 - 0.38)	0.19 (0.11 - 0.34)
50 - 199 cells/mm ³	0.31 (0.19 - 0.57)	0.31 (0.17 - 0.55)
200 - 350 cells/mm ³	0.23 (0.13 - 0.43)	0.20 (0.11 - 0.37)
Health insurance		
Uninsured	1.17 (0.79 - 1.73)	1.14 (0.74 - 1.76)
Public	1.86 (1.06 - 3.25)	2.37 (1.26 - 4.44)
Affective disorder	1.16 (0.81 - 1.66)	1.22 (0.81 - 1.82)
Substance abuse	1.08 (0.69 - 1.69)	0.96 (0.53 - 1.74)
OI	0.81 (0.55 - 1.19)	--
Alcohol abuse	0.91 (0.56 - 1.49)	0.74 (0.42 - 1.31)

RESULTS

- Among 570 patients meeting inclusion criteria, HAART was initiated through a clinical trial in 126 patients (22%) and as part of routine care in 444 patients (78%)
- Compared to whites, African Americans had roughly half the odds of participating in a clinical trial
- Patients with a baseline CD4 count >200 cells/mm³ and with higher plasma HIV viral loads were more likely to receive HAART through a trial
- Patients with lower baseline CD4 counts had lower odds of 6-month virologic failure (>50 copies/mL) compared to those with CD4 >350 cells/mm³
- 6-month virologic failure was not significantly different between patients receiving HAART through a trial vs. routine care, but it was more common in patients with public vs. private health insurance

CONCLUSIONS

- In concordance with earlier studies, racial disparities in clinical trial participation were observed with under representation of African Americans
- No differences were observed in 6-month virologic efficacy vs. effectiveness of HAART therapy in ARV-naïve patients initiating treatment through a clinical trial vs. routine clinical care
- Patients initiating HAART at CD4 counts below 350 cells/mm³ were less likely to experience 6 month virologic failure

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