Poster # 1039

Real World Community-Based HIV Rapid Start Antiretroviral with BFTAF Versus Conventional HIV Antiretroviral Therapy Start – The RoCHaCHa Study, a Pilot Study

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ABSTRACT

Background
Trillium Health (TH) is a FQHC in Rochester, NY providing primary and specialty care, including HIV prevention and treatment. Rapid Start ART (RSA) has been shown to decrease time to virologic suppression while increasing linkage to and retention in care. However, data on BFTAF with these benefits are limited. We aim to prove RSA with BFTAF is advantageous in time to viral load suppression, linkage to and retention in care, and patient satisfaction and acceptance.
Methods
We included data from ART-naïve newly diagnosed PLWH, 18 years of age and older, enrolled between October 2018 and March 2020 with baseline assessment and started BFTAF. Follow up visits were done per protocol through 48 weeks. The primary study endpoints include median times from: diagnosis to clinic presentation, clinic presentation to ART, and ART to undetectable viral load (VL), < 200 copies/ mL and < 50 c/mL. Retention in care was measured at 3 months. Study results were compared with non-RSA historical control data. Patient reported outcomes will be evaluated at study completion.
Results
Of the 52 participants screened, 31 consented and were deemed eligible for the study. Twenty-six participants have been followed for at least 3 months and have been included in this preliminary analysis. Fourteen received their diagnosis at TH: screening for PrEP (6), community-based HIV/STI/HCV testing (4), community outreach (1), or routine patient screening in primary care (3). Twelve were diagnosed externally: university health centers (2), other health clinic (9), or at-home rapid HIV test (1). All accepted the RSA treatment with BFTAF; three eligible patients declined the study, but accepted RSA. All participants were retained in care on BFTAF through 3 months.
Conclusions
RSA with BFTAF reduced the time to virologic suppression in all participants newly diagnosed with HIV-1 compared with historical non-RSA model.

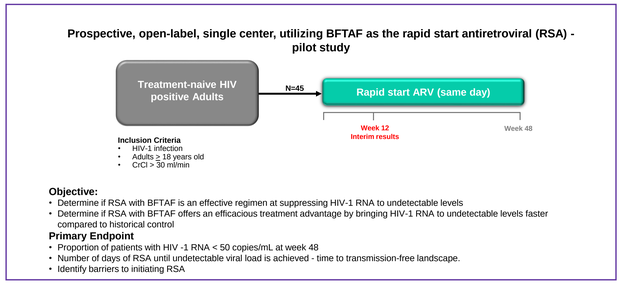
INTRO

Globally, Rapid Start Antiretroviral therapy (RSA) is becoming the standard of care in clinics who have adapted and implemented it in their practice. The DHHS guidelines recommends RSA (same day initiation of HIV treatment) in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for the individual patients, and improve the rate of virologic suppression in PLWH[1]. In primary HIV infection, early viral suppression is achieved faster with INSTI compared to PI/r regimens[2]. However, data on BFTAF with these benefits are limited. Trillium Health (TH) is a FQHC in Rochester, NY providing primary and specialty care, including HIV prevention and treatment, in a one-stop-shop model of care (clinic, case management, pharmacy, lab, etc. all onsite). We aim to prove RSA with BFTAF is advantageous in time to viral load suppression, linkage to and retention in care, and patient satisfaction and acceptance.

METHOD

The study design with the objectives and primary endpoints are illustrated in figure 1. Participants were recruited via person-to-person conversation in the presence of suspected newly diagnosed HIV-1 infection from Trillium Health testing sites and from external referrals such as the Department of Health. Clinical and laboratory evaluations were done on Days 1, 7, 14, 28, 56, 84, 128, 252 and 336. Adherence were assessed by pharmacy refills and patient reported pill count. Statistical analysis was completed to compare baseline characteristics of RSA and non-RSA groups as well as comparison of primary endpoints of both groups. Statistical tests included: Wilcox rank test, Kruskal-Wallis Test and Fisher exact test, depending on variable type. Interim results for the first 26 participants with at least 3 months of follow-up including laboratory analysis are presented here.

Figure 1: Study Design



RESULTS

Baseline characteristics (table 1) are balanced between the two arms except for sex assigned at birth which was 100% male in the RSA group.

Participants of the study who took BFTAF for rapid start and remained on the study for at least 3 months with completion of laboratory analysis were including in these results. Table 2 shows complete findings.

- Median of 1 day (0-3.8) from diagnosis to clinic presentation
- 100% of participants started ART same day of clinic visit
- Median time from diagnosis to transmission-free status:
  HIV RNA < 200 copies/mL: 17 days
  HIV RNA < 50 copies/mL : 28 days
- 100% were retained in care through 3 months

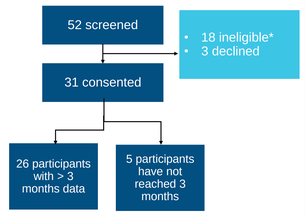
Table 1: Baseline Characteristics

Characteristics	Study RSA n=26	Non-RSA Control n=24	P value
Age at diagnosis, mean (SD)	32.2 (9.8)	36.3 (13.3)	0.398
Race/ethnicity, n (%)			
Black	6 (26.9)	10 (41.7)	0.227
White	16 (61.5%)	11 (45.8)	0.395
Other	3 (11.5%)	3 (12.5%)	1.000
Hispanic/LatinX	7 (26.9%)	4 (16.7%)	0.501
Non-Hispanic/LatinX	16 (61.5%)	20 (83.3%)	0.119
Ethnicity unreported	3 (11.5%)	0 (0.0%)	0.236
Sex at birth, male, n (%)	26 (100%)	19 (79.2%)	0.020
Gender identity, male, n (%)	23 (88.5%)	17 (70.8%)	0.164
Sexual orientation, gay, n (%)	15 (57.7%)	11 (45.8%)	0.572
Baseline HIV 1 RNA VL, median (IQR), copies/mL	22,689 (2,395-55,650)	46,800 (20,825-133,250)	0.091
Baseline HIV 1 RNA VL >100,000, n (%)	4 (15.4%)	9 (37.5%)	0.109
Median CD4 cells/mm3	500 (354-701)	447 (292-648)	0.281
<200 CD4 cells/mm3, n(%)	0 (0.0%)	3 (12.5%)	0.103
IV drug use ever, n (%)	6 (23.1%)	3 (12.5%)	0.467
Mental health diagnoses (%)	11 (42.3%)	7 (29.2%)	0.388
Homeless ever, n (%)	4 (15.4%)	4 (16.7%)	1.000

Table 2: Clinical outcomes

Outcomes (reported in days)	Study RSA n=26	Non-RSA Control n=24	p value
Diagnosis to clinic presentation, median (interquartile range)	1 (0.0 – 3.8)	9.5 (6.0 – 22.25)	<0.001
Clinic presentation to ART, median (interquartile range)	0 (0.0 – 0.0)	35.5 (28.0 – 57.0)	<0.001
ART to VL <200 copies/mL, median (interquartile range)	14 (7.3-27.8)	34 (29.75 – 62.75)	<0.001
ART to VL <50 copies/mL, median (interquartile range)	27 (12.0 – 30.8)	74 (31.75- 200.5)	<0.001
Diagnosis to VL <200 copies/mL, median (interquartile range)	17 (11.0 – 30.5)	94 (83.75 – 199.0)	<0.001
Diagnosis to VL <50 copies/mL, median (interquartile range)	28 (14.0 – 34.5)	187.5 (113.0 – 340.8)	<0.001

Disposition: Study Enrollment



Regimen Non-RSA control	N=24
DTG + FTC/TAF	2
DTG + FTC/TDF	2
EVG/COBI/FTC/TAF	10
EVG/COBI/FTC/TAF + DRV	1
EVG/COBI/FTC/TDF	1
DRV/COBI + FTC/TAF	1
DRV/COBI + DTG	3
DTG/ABC/3TC	4

*10 confirmatory testing revealed HIV negative status; 3 telemedicine; 2 ineligible provider; 1 < 18 years old; 1 started ART in hospital; 1 incarcerated

- 13 of 31 participants have completed day 336 (last study visit)

CONCLUSIONS

This first (real world) data on Rapid Start Antiretroviral therapy with BFTAF highlights many attributes positioning it to be the regimen of choice in a clinic with infrastructure and stakeholder by-in for immediate start of HIV treatment reducing the risk of transmission to others.

- Participants on BFTAF had shorter days from diagnosis to transmission-free status
- 100% of participants started BFTAF same day of clinic visit
- 100% of the participants were retained in care through 3 months
- Median day from diagnosis to clinic presentation was 1 day

This data supports and contributes to achieving the “End the Epidemic” initiative in New York as well as nationally.

REFERENCES

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf.
2. Veil R, et al. Virological and Immunological Impact of Integrase Inhibitor-based Regimen Initiated During Primary HIV-1 Infection. AIDS 2019. DOI: 10.1097/QAD.0000000000002447

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