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Rapid ART initiation using BIC/FTC/TAF and TDF+3TC+EFV in people with HIV in China

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BACKGROUND

The benefits of rapid antiretroviral therapy (rapid ART) has been widely proven among people with HIV, but evidence is limited in China. This study examined virological outcomes and the treatment retention rate at 24 weeks after rapid versus non-rapid ART initiation, and analyzed the efficacy and safety of Bictegravir 50mg/Emtricitabine 200mg/Tenofovir Alafenamide 25mg (BIC/FTC/TAF) comparing with Efavirenz 400 mg + Lamivudine 300 mg + Tenofovir disoproxil fumarate 300 mg (EFV+3TC+TDF) for rapid ART.

METHODS

This was a national, open lable, pragmatic randomized controlled trial. We enrolled all the HIV-1 infected adult (age ≥18 years) men who have sex with men (MSM) diagnosed from March 2021 to April 2022 across eight sites in China. The participants chose to start ART within 14 days after HIV diagnosis were randomly assigned(1:1) to the EFV group (A) and BIC group (B); those who refused to rapid ART used EFV (C) or BIC (D) voluntarily. The primary endpoint was the percentage of viral suppression (<50 copies/ml) after 24 weeks.

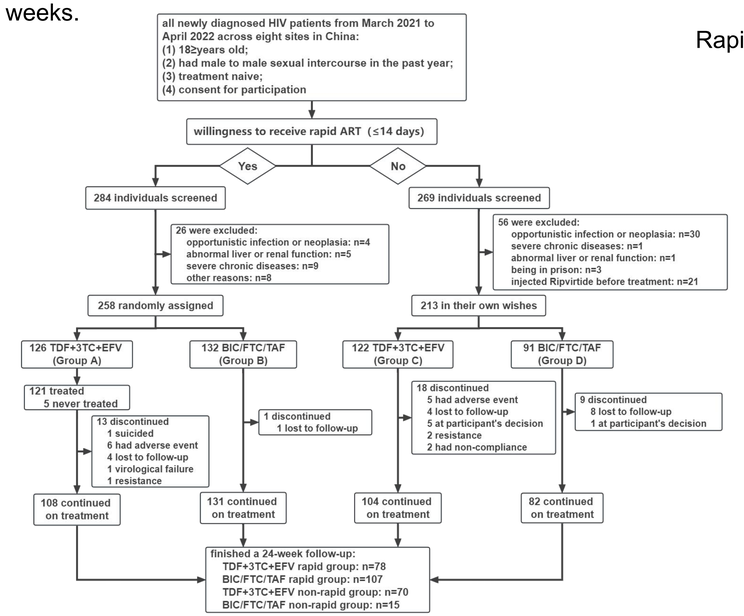

Fig.1 Study flowchart

Rapid ART was applicable to people with HIV in China with a higher engagement rate, less lost to follow-up and better viral suppression. BIC/FTC/TAF was safe and effective in rapid ART.

CONCLUSION

Rapid ART was associated with a good retention rate of care, BIC/FTC/TAF was effective for rapid ART.

RESULTS

A total of 495 participants were enrolled,including 126, 132, 122 and 91 participants in A, B, C, D group respectively. In the rapid (group A and B) and non-rapid ART (group C and D) groups, 92.6% and 86.9% (P=0.053)participants retained in care (Figure 1). Viral suppression rate was higher in group B than in group A(93.5% Vs 74.7%, p< 0.001) but similar between group A and group C (74.7% vs 76.1%, p-0.16) per FDA snapshot. In group B, 33.3% patients changed from underweight (BMI < 18.5) at baseline to normal weight (18.5≤BM<25) after 24 weeks,10% patients and 18.0% patients changed from normal weight to overweight (25≤BMI<30) in group A and B, 5.3% patient in group A and 8.1% patients in group B changed from overweight to obese (BMI>30) respectively. Total serum cholesterol levels increased in both groups (+0.03 VS +0.47 mmol/L, P=0.001). The level of LDL was reduced in group A, while increased in group B after 24weeks compared to baseline (-0.22 VS +0.27 mmol/L, P< 0.001). Changes of HDL (+0.10 VS +0.12 mmol/L, P=0.135), triglycerides(+0.04 VS +0.09mmol/L, P=0.881) and cholesterol/HDL(-0.24 VS -0.15mmol/L, P=0.147) betweenthe two groups were not statistically significant.

Table 1 Baseline patient Characteristics

Characteristic	Group A (n=126)	Group B (n=132)	Group C (n=122)	P value*	Pvalue**
Age (year), IQR	29.0 (25.0, 35.0)	29.0 (25.0, 38.3)	35.0 (27.8, 44.3)	0.488	0.025
Race (Han), n (%)	109 (86.5)	110 (83.3)	113 (92.6)	0.056	0.199
BMI (kg/m^2), IQR	23.2 (20.2, 25.3)	22.9 (20.3, 24.8)	23.1 (20.8, 24.8)	0.552	0.800
Number of comorbidities > 0, n (%)	11 (8.7)	12 (9.1)	16 (13.1)	0.952	0.377
Number of medications > 0, n (%)	10 (7.9)	12 (9.1)	16 (13.1)	0.762	0.549
HBs antigen positive, n (%)	7 (5.6)	6 (4.5)	6 (4.9)	0.679	0.822
HCV antibody positive, n (%)	1 (0.8)	1 (0.8)	4 (3.3)	0.966	0.164
RPR positive, n (%)	22 (17.5)	31 (23.5)	35 (28.7)	0.188	0.036
Baseline viral load (lg copies/mL), IQR	4.4 (4.0, 4.8)	4.3 (3.8, 5.0)	4.3 (3.6, 4.7)	0.444	0.017
Viral load > 100000 (copies/mL), n (%)	19 (15.1)	27 (20.5)	12 (9.8)	0.249	0.212
Baseline CD4 count (cells/μL), IQR	342.0 (243.0, 448.6)	342.0 (241.0, 449.6)	350.0 (207.5, 459.5)	0.913	0.978
Baseline CD4 count < 200 cells/ul, n (%)	22 (17.5)	22 (16.7)	27 (22.1)	0.907	0.356
CD4/CD8, IQR	0.3 (0.2, 0.5)	0.4 (0.2, 0.5)	0.3 (0.2, 0.5)	0.779	0.433
Time from diagnosis to treatment (day), IQR	6.0 (3.0, 8.0)	5.0 (2.0, 7.0)	28.0 (21.0, 51.3)	0.064	<0.001

P value* stands for *P* value of Group A VS B and *P* value** stands for *P* value of Group A VS C. Continuous and categorical variables were compared by the Mann-Whitney U test and the chi-square test, respectively.

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