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Sexual Risk Compensation and Retention in PrEP Care in Korea: An HIV PrEP Demonstration Study

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ABSTRACT

Background: Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) is effective in preventing human immunodeficiency virus (HIV), however, its feasibility has not been evaluated in the Republic of Korea (Korea). Therefore, this study aimed to assess the feasibility of PrEP in men who have sex with men (MSM) in Korea. This is the first demonstration study in Korea, in which PrEP medication, laboratory tests, and clinic visit fees were provided without charge to participants.
Methods: HIV-negative MSM were prescribed daily TDF-FTC and followed up at an outpatient clinic. At each visit, adverse reactions, adherence, and sexual behavior were assessed using a questionnaire, and residual pills and blood and urine samples were collected. Tenofovir diphosphate (TFV) concentrations were measured in plasma and urine.
Results: One hundred participants were enrolled and followed up for a median of 392 days. The retention-in-care was 77%. The incidence of HIV and other sexually transmitted infections (STIs) was 0.98 and 13.67 per 100 person-years, respectively. No serious adverse events were detected. Among the participants, 55.3% (47/85) and 41.7% (25/60) had plasma TFV concentrations > 40 ng/mL at weeks 28 and 52, respectively. Residual pill counts and self-reported adherence were not correlated with plasma TFV levels. Participants with positive STI test results were significantly more likely to have plasma TFV concentrations > 40 ng/mL (adjusted odds ratio, 3.67; $P = 0.034$). The reported proportion of episodes of non-condom receptive anal intercourse decreased during the study.
Conclusion: Daily oral PrEP was safe and effective in MSM and not associated with increased sexual risk behavior. To our knowledge, this is the first analysis of risk compensation among PrEP users in East Asia.

Keywords: HIV Prevention; Pre-Exposure Prophylaxis; Retention; Adherence; Risk Compensation

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Disclosure

The authors have no potential conflicts of interest to disclose.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions

Conceptualization: Choi JY. Data curation: Kim JH, Ahn JY, Baek YJ, Lee SG, Choi JY. Formal analysis: Lee SG, Baek YJ. Project administration: Baek YJ, Lee Y, Lee JA, Ahn S, Seong J. Writing - original draft: Baek YJ. Writing - review & editing: Baek YJ, Lee Y, Lee JA, Ahn S, Han M, Seong J, Lee SG, Kim JH, Ahn JY, Choi JY.

INTRODUCTION

Pre-exposure prophylaxis (PrEP) is effective in preventing human immunodeficiency virus (HIV) infection and has been shown to reduce HIV transmission in individuals at risk of HIV infection in clinical trials.[1-3] The World Health Organization (WHO) recommends PrEP as an HIV preventive measure, along with HIV screening, early treatment, post-exposure prophylaxis, and condom use.[4] Promoting PrEP uptake among people who may have exposure to HIV is necessary for PrEP to be effective.[5] Men who have sex with men (MSM) have been identified as a key populations of HIV, particularly in high-income countries.[6]

As of 2020, The UNAIDS 95-95-95 goals had not been achieved in the Republic of Korea (Korea), regarding knowing their HIV status.[7] According to an annual report issued by the Korean Control and Prevention of Disease Agency, the number of individuals living with HIV in Korea exceeded 15,000 at the end of 2022.[8] Furthermore, approximately 1,000 new HIV infections have been reported annually over the past 10 years, and this figure has remained constant.[9] Thus, although anonymous HIV testing and earlier initiation of antiretroviral therapy have contributed to disease control, additional preventive strategies are required.

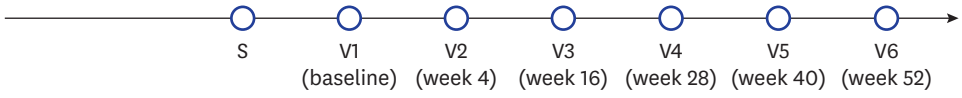
Guidelines for PrEP in Korea were published in 2017.[10] In June 2019, the Ministry of Health and Welfare granted reimbursement for tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) for HIV-negative individuals with potential sexual exposures to HIV-positive partners. However, the feasibility of PrEP in Korea has not yet been evaluated. Clinical trials have shown that the degree of HIV protection is strongly related to PrEP adherence.[2,11] Nonetheless, concerns have been expressed regarding the potential for sexual risk compensation among PrEP users, which could lead to an increase in sexual risk behaviors and a consequent increase in the incidence of sexually transmitted infections (STIs).[12]

In this context, this study aimed to assess the feasibility of providing MSM in Korea with open-label TDF-FTC for PrEP and identify factors affecting optimal plasma tenofovir diphosphate (TFV) concentration maintenance in study participants.

METHODS

Study design

This was an open-label, single-arm demonstration study, in which PrEP medication, laboratory tests, and clinic visit fees were provided at no cost to participants. The study was conducted at a tertiary hospital in Seoul, Korea. HIV-negative gay and bisexual men (GBM) aged ≥ 20 years living in Korea were recruited through a bulletin announcement in 2020. After enrollment, they were screened to confirm that they were MSM and seronegative for HIV. Individuals were excluded if they were seropositive for hepatitis B or C virus, had severe hepatitis, had an estimated creatinine clearance < 60 mL/min, or if microalbuminuria was detected using a urine test strip. Eligible participants had study visits scheduled after enrollment. The PrEP regimen consisted of a single daily tablet containing 300 mg of TDF and 200 mg of FTC (Truvada; Gilead Sciences, Foster City, CA, USA). At the first visit (baseline), participants were informed of potential adverse effects and were provided with 28 tablets. After the initiation of PrEP, the participants had a second study visit, 4 weeks later (week 4), and were counseled by a physician to confirm the safety and tolerability of the TDF-FTC regimen. Subsequently, all participants were asked to attend the clinic every 12 weeks for 52 weeks after PrEP initiation (visits 3–6). At



	S	V1	V2	V3	V4	V5	V6
Questionnaire	O	O	O	O	O	O	O
Residual pill count		O	O	O	O	O	O
Lab	O			O	O	O	O
U/A	O			O	O	O	O
STD PCR					O		O
Tenofovir drug level					O		O

Fig. 1. Scheme of the study.
S = screening, V = visit, U/A = urine assay, STD PCR = sexually transmitted diseases polymerase chain reaction.

every scheduled visit, the participants received a comprehensive package of prevention services. In addition, they were asked to complete questionnaires on their sexual behavior and adherence to PrEP. Participants reported their sexual behavior in the past 3 months. Information was obtained regarding the sex of the sexual partner, the type of anal intercourse, and the frequency of condom use. Residual pills were collected and counted by an assistant nurse. Blood and urine samples were collected at each visit. At visits 4 and 6, participants were screened for STIs using multiplex real-time polymerase chain reaction, and the TFV concentrations were measured in plasma and urine samples. A schematic of the study design is shown in **Fig. 1**.

Laboratory testing

Blood tests included testing for HIV (HIV antigen/anti-HIV antibody combination test), hepatitis B virus (hepatitis B surface [HBs] antigen and anti-HBs antibody), anti-hepatitis C virus antibody, serum blood urea nitrogen (BUN), creatinine, aspartate transaminase, and alanine transaminase. Spot urine samples were tested using urine test strips, at each visit. Urine samples were tested for STIs using a multiplex real-time polymerase chain reaction assay (GC Biopharma, Yongin, Korea). The test detected *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma hominis*, *Mycoplasma genitalium*, *Trichomonas vaginalis*, and *Ureaplasma urealyticum*. TFV concentrations in plasma and urine samples were measured using ultra-performance liquid chromatography-mass spectrometry.

Outcomes

The primary outcome was to assess the retention in PrEP care at 52 weeks. The secondary outcomes were the safety of daily PrEP, adherence rates, drug concentrations, and risk compensation behavior. The objective marker of adherence was the measurement of plasma and urine TFV concentrations, whereas subjective adherence was estimated using self-reported adherence and residual pill counts. In this study, the optimal concentration of TFV was defined as a plasma TFV level ≥ 40 ng/mL, based on the findings of previous studies.[5,13-16] Changes in sexual behaviors and the prevalence of STIs were also measured.

Statistical analysis

The incidence rate of HIV and other STIs per patient-year was calculated as the number of new cases divided by the follow-up time. Continuous variables are reported as medians and interquartile ranges (IQRs), whereas categorical variables are reported as frequencies and percentages. The laboratory test results obtained at study visits were analyzed using a linear mixed model. Spearman's rank correlation coefficient was used to assess the correlation

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between non-normally distributed continuous variables and Pearson's correlation coefficient was used to assess the association of between normally distributed continuous variables. The significance of associations between variables was assessed using Pearson's χ^2 test or Fisher's exact test for categorical data, and the Mann–Whitney *U* test for continuous data. Univariate analysis was performed to identify factors associated with an optimal plasma concentration of TFV. Additionally, multivariable logistic regression was used to calculate adjusted odds ratios (ORs) and 95% confidence intervals (CIs). Statistical significance was set at a two-tailed *P* value < 0.05. Statistical analyses were performed using R Studio version 4.2.1.

Ethics statement

The study was approved by the Institutional Review Board of the Severance Hospital (4-2018-0671) and conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all study participants on enrollment.

RESULTS

Study population

Of the 104 screened individuals, 100 were enrolled between June 12, 2020, and January 13, 2023 and included in the analysis. The baseline characteristics of the study participants are shown in **Table 1**.

Table 1. Baseline characteristics of the study participants

Characteristics	Participants (N = 100)
Age group, yr	
20–29	49
30–39	43
≥ 40	8
Final education level	
High school	22
Undergraduate tertiary education	68
Graduate degree	10
Employment level	
Full-time, ≥ 30 hr per wk	62
Part-time, < 30 hr per wk	9
Student	15
Unemployed or freelancer	14
Partner type	
Steady and living together	3
Steady and not living together	39
Casual relationships	58
Sexual orientation	
Homosexual	88
Bisexual	12
Circumcision	
Yes	59
No	38
Unknown	3
Self-reported high-risk factors at baseline	
Condomless anal intercourse with 2 or more partners in the past 12 wk	80
Receptive anal intercourse with 2 or more partners in the past 12 wk	55
History of gonorrhea in the past 12 mon	1
History of chlamydia in the past 12 mon	9
History of syphilis in the past 12 mon	9
History of condyloma in the past 12 mon	5
Drug use	7

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The median age of the participants was 30 years (IQR, 26–33.5 years), with 92% of the participants being under the age of 40. Of the 100 participants, 62 worked full-time, 39 were in a steady relationship with a non-co-habiting partner, and 58 were in casual relationships. At baseline, 80 participants reported engaging in condomless anal intercourse, and 55 reported experiencing two or more episodes of receptive anal intercourse during the past 3 months.

Retention in PrEP care

Among the 100 participants, the median follow-up time was 392 days (IQR, 366.8–433.8 days). Of the 100 participants, 77 completed the study (77% retention-in-care). Fourteen participants withdrew from the study and eight were lost to follow-up. One participant was withdrawn after visit 3 because of seroconversion to HIV positive.

Allowing a grace period of 1 week between each visit, the number of participants coming later than their scheduled appointment gradually increased: 19 at visit 3; 23 at visit 4; 27 at visit 5; and 28 at visit 6. The dropout rates were 1% at visit 2, 3% at visit 3, 7.3% at visit 4, 6.7% at visit 5, and 7.2% at visit 6.

Safety and laboratory test results

None of the participants developed serious adverse events associated with PrEP. Blood tests revealed no significant changes in creatinine, BUN, or liver enzyme levels during the 52-week follow-up period (**Supplementary Table 1**).

Reasons for taking PrEP and adherence

The primary reason for participating in the study at baseline was to reduce the risk of HIV infection via PrEP (32.9%). This was followed by the need to receive regular counseling from the physician to reduce the risk of HIV infection (20.9%), a willingness to contribute to the progress of science (17.0%), and a desire to support the gay community (14.8%).

The average self-reported compliance scale scores were comparable across all study visits. According to the questionnaire answered by participants who reported forgetting taking pills every time or frequently, the reasons for poor compliance were not carrying PrEP medication (5.3%), not having sex recently (3.9%), or forgetting to take the pills (2.3%). Five participants reported poor compliance owing to side effects, with the main symptoms being diarrhea and nausea. The proportion of participants submitting 12 or fewer pills remained consistent across visits from visit 3 to visit 6 (visit 3, 85.3%; visit 4, 82.1%; visit 5, 86.3%; and visit 6, 84.2%). The criterion for residual pill count was set at 12 or fewer pills remaining, based on a 12-week follow-up period with the assumption of missing one pill per week.

Of the participants, 49.7% had an optimal plasma TFV concentration. The proportion of participants with a plasma TFV concentration > 40 ng/mL was 54.0% (48/87) at visit 4, and 41.7% (25/60) at visit 6. The proportion of participants with a urine TFV concentration > 1,500 ng/mL was 88.8% (72/88) at visit 4, and 66.7% (50/75) at visit 6. The TFV concentration in the urine was strongly correlated with the plasma TFV concentration ($r = 0.68$; $P < 0.001$; **Supplementary Fig. 1**).

The residual pill counts and plasma TFV concentrations showed a negative association; however, this was not statistically significant ($P = 0.164$). Self-reported adherence was inversely associated with the TFV concentration ($P = 0.038$) and was not associated with residual pill counts ($P = 0.183$) (**Fig. 2**). Among the participants who reported that they had

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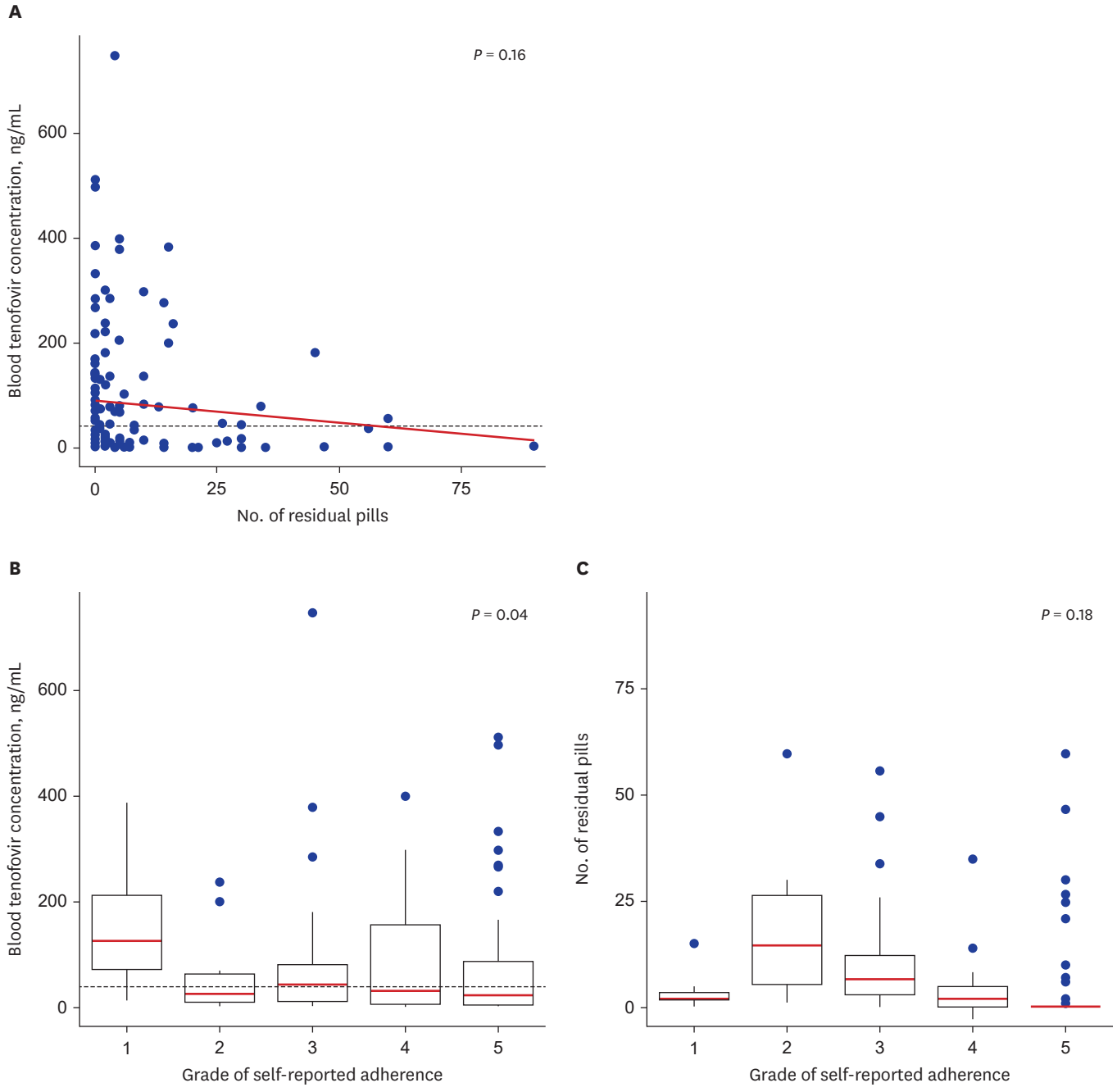

Fig. 2. Association between plasma concentration of tenofovir diphosphate and the grade of drug adherence measured by (**A**) the number of residual pills, (**B**) self-reported adherence, (**C**) the association between number of residual pills and the grade of self-answered adherence.
Grade 1 = forget every time, 2 = forget frequently, 3 = forget sometimes, 4 = rarely forget, 5 = never forget to take pills.

not forgotten to take their pills, 57.5% (50/87) had a plasma TFV concentration < 40 ng/mL. The blood tenofovir concentration and residual pill counts classified by self-reported adherence were described in **Supplementary Table 2**.

Sexual behaviors, STIs, and risk compensation

The proportion of non-condom receptive anal intercourse (ncRAI) decreased progressively from 68.4% (65/95) at the screening visit to 49.3% (31/77) at visit 6, a significant decreasing

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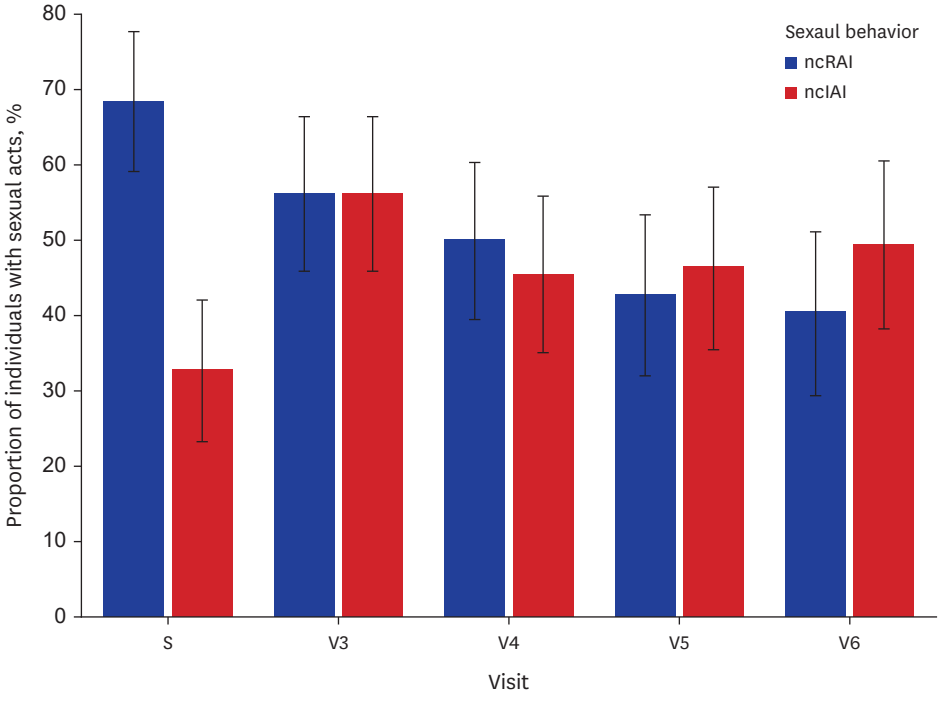

Fig. 3. Proportion of self-reported condomless sexual behavior in the past 3 months during the follow-up period.
S = screening, V = visit, ncRAI = condomless receptive anal intercourse, ncIAI = condomless insertive anal intercourse.

linear trend ($P < 0.01$). The proportion of non-condom insertive anal intercourse (ncIAI) did not change significantly over the study period. It was 32.6% (31/95) at baseline and initially increased between the screening visit and visit 3, and then decreased between visit 3 and visit 6 (**Fig. 3**). The pattern of other sexual behaviors is shown in **Supplementary Table 3**. During the study period, the main sexual activity among participants was anal sex, with a high rate of ncRAI and ncIAI.

One participant was diagnosed with HIV infection after visit 3. Because he was excluded from the study before visit 4, his TDF level was not measured according to the protocol. He reported that he had not forgotten to take the pills, but the residual pill counts were 10 and 20 at visits 2 (week 4) and 3 (week 16), respectively. He reported engaging in ncRAI, and that he had not taken some pills owing to side effects of headache, dyspepsia, and nausea. No other participants developed HIV infection during the study period. Therefore, the overall HIV incidence rate during the study period was 0.98 per 100 person-years (95% CI, 0.95–1.01).

Fourteen participants were diagnosed with one or more STIs other than HIV during the follow-up period (incidence rate of 13.67 per 100 person-years). The prevalence of STIs at visit 4 and visit 6 was 10.47 and 14.29 per 100 person-years, respectively, a non-significant difference ($P = 0.483$).

Factors associated with an effective plasma TFV concentration

A total of 158 samples were collected and analyzed to evaluate plasma TFV concentration and self-answered adherence at visits 4 and 6. In the unadjusted analysis, the risk factors associated with optimal plasma TFV concentration were STIs other than HIV and later visits (visit 6). In the multivariable analysis, STIs were the only significant factor associated with optimal plasma TFV concentration. Participants with an STI were more likely to have an optimal plasma TFV concentration (adjusted OR, 3.67; 95% CI, 1.19–13.89; $P = 0.034$) (**Table 2**).

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Table 2. Factors associated with having an optimal plasma tenofovir diphosphate concentration

Variables	Unadjusted analysis		Multivariable analysis	
	OR (95% CI)	*P* value	Adjusted OR (95% CI)	*P* value
Demographics				
Age	1.03 (0.98–1.08)	0.311	1.02 (0.97–1.09)	0.471
Level of education	1.19 (0.84–1.69)	0.198	1.02 (0.68–1.55)	0.912
Employment[a]	0.66 (0.47–1.92)	0.901	0.89 (0.42–1.89)	0.771
Other STIs	3.64 (1.21–13.34)	0.032	3.67 (1.19–13.89)	0.034
Late visit	0.63 (0.33–1.21)	0.166	0.60 (0.30–1.16)	0.129

OR = odds ratio, CI = confidence interval, STI = sexually transmitted infection.
[a]Employment refers to any form of working status, including full-time and part-time.

DISCUSSION

This study was a demonstration of the use of PrEP. It was conducted to prospectively follow a cohort of GBM over a one-year period and identify the demographic factors and sexual behaviors of participating GBM using PrEP. No significant changes were observed in laboratory test results or serious adverse effects associated with taking daily TDF-FTC. The retention in PrEP after 52 weeks of follow-up was 77% in our study, which was like that in a similar demonstration project implemented in Australia (81%).[17] The the overall HIV incidence rate during the study period was 0.98 per 100 person-years (95% CI, 0.95–1.01), which is similar to rates reported in other studies: 0.9 in China and 0.82 in France.[18,19]

PrEP adherence was strongly correlated with PrEP effectiveness as indicated by steady-state TFV concentrations in the blood or urine.[14] We defined optimal plasma TFV concentration as a plasma TFV level ≥ 40 ng/mL, which was achieved in 49.7% of participants. Because plasma TFV detects dosing of PrEP in the previous 24–48 hours, it is a short-term measure of adherence.[16] However, the unreliable estimates of TFV in the blood could be attributable to a short-term increase in adherence, referred to as "white coat adherence."[20] A urine TFV concentration > 1,500 ng/mL was associated with taking 300 mg TDF within the past 24 hours.[21] Urine TFV testing is more sensitive than plasma TFV testing for detecting adherence in the past 7 days, but should be validated because of individual variability in TFV metabolism.[22] Self-reported adherence was not a reliable measure of adherence as participants who reported high adherence were more likely to have lower plasma TFV concentration. A similar mismatch has been reported in previous studies,[23-25] and can be attributed to recall bias, over-reporting, and social desirability bias.[26] The pill counts were not significantly associated with TFV concentrations. Even though pill counting is inexpensive, patients must remember to bring their pill bottles to the clinic and the leftover pill count may not be an accurate indicator of PrEP use because of the possibility of discarding unused medication or distributing it to others.[16]

In our study, the main reasons for poor compliance were not carrying PrEP medication (5.3%) and not having sex recently (3.9%). Another study performed in the USA suggested that the main obstacles to PrEP uptake among young MSM were the burden of daily dosing, the sense of feeling that the risk was not high, the stigma of being a PrEP user, and preference for other prevention strategies.[27] A recent qualitative analysis of Korean MSM described the difficulties of PrEP accessibility due to high costs and limited availability of providers.[28] Pill burden, behavioral changes, and structural barriers related to cost and accessibility might have disrupted the PrEP uptake and retention-in-care in our study.

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The proportion of self-reported ncRAI and ncIAI decreased during the PrEP period, consistent with the results of the open-label extension study, which showed a trend toward decreases in the total number of sexual partners, ncRAI, and ncIAI, with a comparable syphilis incidence.[11] A Dutch study found that the number of acts of condomless anal intercourse with casual partners decreased in a group receiving daily PrEP; however, the number of partners remained stable.[29] This finding contrasts with several studies showing the trend of an increase in condomless sex among PrEP users, without a change of the proportion of men engaging in any condomless sex from a meta-analysis.[30] Notably, participants with STIs were more likely to have a plasma TFV concentration in the optimal range, implying that a reduction in risk behaviors could have reduced the motivation of participants to use PrEP. Some participants reported poor adherence to daily PrEP due to a perceived lack of high-risk sexual behaviors. It appears that participants assessed their risk of HIV infection based on their knowledge and/or regular counseling. Because the need for PrEP could change over time with changes in sexual risk behavior, the concept of prevention-effective adherence paradigm including multiple prevention strategies should be considered.[31]

PrEP implementation has many challenges. According to a survey on the acceptability of PrEP conducted in Korea in 2017, the reasons MSM did not take PrEP were non-reimbursement (32%), concerns about adverse effects (13.2%), and fear of exposing their PrEP user status (18%).[32] Even after introducing reimbursement for PrEP, limited access, poor knowledge, and high costs are barriers to PrEP implementation.[33] Targeted counseling, combined with feedback on objective markers, motivates individuals to attend clinic visits and facilitates the allocation of resources to those in greatest need.[34,35]

This study had some limitations. First, alternative HIV prevention regimens were not addressed in this study. For example, event-driven PrEP, which is endorsed by both the WHO[36] was not included in the recommendations of this study. Additionally, although WHO has recommended injectable cabotegravir as a preventive measure,[37] it has not yet been introduced in Korea. Second, participants were not tested for syphilis and herpes simplex. Because syphilis is one of the most common STIs among Korean MSM,[38] the incidence of syphilis might more accurately reflect sexual behavior patterns. In addition, STI testing was not performed at baseline, and symptomatic STIs were treated, limiting our ability to calculate STI incidence. This study was conducted during the coronavirus disease 2019 pandemic, so this might have affected the usual sexual activities and demand for PrEP by study participants. Finally, even though different methods were used to measure adherence, the measures of drug adherence might not have been accurate. Exploring appropriate approaches to sustaining adherence is critical. In this study, the participant who was diagnosed with HIV infection reported nonadherence owing to adverse effects, suggesting that self-reported nonadherence correlates well with nonadherence. Asking the right questions combined with other measures is crucial for promoting adherence and preventing HIV infection.

In conclusion, this study demonstrated the safety and efficacy of PrEP in Korea. Daily PrEP is safe, and participants at a higher risk of HIV infection showed 77% retention-in-care and 49.7% adherence. Risk compensation was not observed, confirming that concerns over risk compensation should not limit the promotion of PrEP interventions.

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SUPPLEMENTARY MATERIALS

Supplementary Table 1
Laboratory test results by study visit

Supplementary Table 2
Blood tenofovir concentration and residual pill counts stratified by self-reported adherence

Supplementary Table 3
Sexual patterns of participants during the study period

Supplementary Fig. 1
Correlation between tenofovir diphosphate concentrations in the plasma and urine.

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