SEXUAL BEHAVIOUR AND HIV RISK AMONG YOUNG WOMEN USING PrEP IN KENYA.

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ABSTRACT

Introduction Adolescent girls and young women (AGYW) in sub-Saharan Africa are disproportionately affected by HIV. In 2020, UNAIDS estimated that AGYW contributed 30% of all new HIV infections in sub-Saharan Africa and were 2.5 times more likely to acquire HIV than young men of the same age[1]. PrEP is an effective HIV prevention tool available to them. However, multiple studies report that PrEP use in this age group is not sustained after initiation. If AGYW maintain sexual activity and multiple partners after discontinuing PrEP, they return to having potential risk for acquiring HIV. Questions remain about whether AGYW maintain a consistent level of sexual activity and HIV risk if this risk can be assessed using validated scoring tools, including the VOICE risk score.

Method: Between 2016 and 2018, 350 young women aged 18-24 years with high risk of HIV were enrolled into the monitoring PrEP among young adult women (MPYA) study in Kisumu and Thika, Kenya and followed for up-to 24 months. Participants were offered PrEP, provided adherence support through reminder short message service (SMS), and monitored for PrEP adherence via electronic pill boxes. Data on adherence, sexual risk behavior and risk perceptions were collected during quarterly study visits. We used generalized estimating equations to estimate whether the number of sexual partnerships, condomless sex acts, and self-assessed risk perception were associated with the level of HIV risk score.

Results: At baseline, the median age was 21 years, majority reported high school. Completion, 55% were single but had a stable partner, majority being students (38.9%). When comparing those who had a high (≥6) versus a moderate risk score(4,5), The likelihood of having a high risk score was greater among AGYW with more partners (odds ratio [OR] 2.2,95% CI 1.6, 3.1) and those who reported ≥1 casual partners (OR 2.2, 95% CI: 1.6, 3.1) but neither were statistically significant different after adjustment for confounding factors. The likelihood of reporting any condomless sex was similar in both groups with an OR of 1.0 (95% CI 0.7, 1.4). When adjusted for confounding, the difference was statistically significant with an adjusted OR of 1.3 (95% CI: 1.1, 2.5). There was a reduction in self-assessed perception of being at risk of HIV, from 52% at enrolment to 12% at month 24 feeling at risk. There was no association between the score and self-assessed risk perception.

Conclusion: In our study we found that sexual risk behavior was similar among those with moderate or high risk on the VOICE scoring tool. We need to identify risk scoring tools that capture HIV sexual

risk and the varying levels of risk to support appropriate, client-tailored counseling about HIV and HIV prevention options for AGYW.

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Introduction

Despite global progress in reducing new HIV infections, adolescent girls and young women (AGYW) in sub-Saharan Africa (SSA) are disproportionately affected by HIV. In 2020, UNAIDS estimated that AGYW aged 15 to 24 years contributed 30% of all new HIV infections in SSA and were 2.5 times more likely to acquire HIV than young men of the same age[1]. Appropriate, acceptable, and accessible HIV prevention tools are required to prevent future HIV infections. Daily oral pre-exposure prophylaxis (PrEP), a person-centered, antiretroviral-based HIV prevention medication, is over 90% efficacious, when used with good adherence.[2] This could contribute towards filling this gap, if it is delivered widely with high uptake and adherence.

While PrEP is available at no cost in public facilities in Kenya and uptake among AGYW has been high, long term retention in the program and daily adherence to the medication is often low[3]. For example, in the Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) project, AGYW initiating PrEP had a median use of 56 days and only 37% received a refill after initiating PrEP[4]. The rapid reduction in PrEP use may align with reductions in sexual behavior and partners but programmatic data are often unable to assess this alignment.[5,6,7]

The VOICE risk score was developed to provide efficient and effective identification of AGYW at risk of HIV[9]. However, the risk score was validated with data from South African women who may have important risk differences from women East Africa. Use of the score to predict high risk behavior to identify those likely to need further support requires further evaluation.

To respond to this gap in knowledge about sexual behavior among young women in a PrEP program, we conducted a secondary analysis of longitudinal sexual behavior and HIV risk among young women enrolled in a PrEP adherence study that utilized real time PrEP adherence monitoring tools (Wisepill pill boxes) and short message service (SMS) to support adherence in Kenya (Haberer, et al., 2021)(MPYA study: NCT0291536714)[8]. Initial analysis of the study reported that all randomized participants initiated PrEP and adherence levels were 38.5% over 6 months and 26.8% over 24 months of follow-up. The study also reported 4 seroconversions from among the 348 who were randomized[8]. This low PrEP persistence and low HIV incidence in this cohort led us to assess sexual risk behavior and appropriateness of the risk scoring tool in identifying their levels of risk. In this paper, we describe

patterns of sexual behavior, HIV risk, and assess the association of sexual behavior and HIV risk with an empirically derived risk scoring tool[9]

Methods

Study Overview and Setting

Data from the 'Next generation real-time monitoring for PrEP adherence in young Kenya women' (MPYA) project were used in this study (NCT02915367)[8]. Between 2016 and 2020, the MPYA trial enrolled young women at high risk of HIV infection who were interested in taking PrEP. Women were seen at two clinical research sites in Kenya: Thika, a town 40km northeast of Nairobi with HIV prevalence estimated at 4%, and Kisumu, a city in western Kenya with an HIV prevalence estimated at 16%[5]. The primary objective of the MPYA project was to evaluate the acceptability and feasibility of a wireless device for tracking PrEP adherence.

Eligibility and recruitment.

All participants in the MPYA trial were included in the sample population for this review. This study enrolled young adult African women who met the following requirements: Aged 18-24 years, willing and able to provide informed consent, HIV uninfected (confirmed via HIV rapid test), at high risk of HIV acquisition as measured by the HIV risk score >4 on the VOICE risk scoring tool, willing to use PrEP for at least 6 months, sexually active and owned a personal mobile phone (enabling receipt of SMS reminders and surveys). The study recruitment team mobilized potential participants from the local community, colleges, and health facilities that offered HIV counselling and testing. The recruitment messages focused on broad information about HIV prevention and PrEP for young women. Potentially eligible women were referred to a qualified counselor for eligibility screening.

Procedures

Study visits were conducted at the Thika and Kisumu study clinical sites. Following enrollment, study visits were scheduled 1 month later and then quarterly thereafter up to 24 months. HIV testing and risk reduction counseling was conducted at every visit as per national protocol[9], after which co-formulated emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)[11] was prescribed as PrEP according to Kenyan guidelines to HIV negative participants as part of comprehensive HIV prevention services. PrEP dispensing and additional adherence counseling were provided by the pharmacist at each visit. Data

on demographics, sexual behavior, and self-reported PrEP use were collected via interviewer-administered questionnaires in the participant's preferred language (English, Kiswahili or Dholuo) throughout the study.

Statistical analysis

Descriptive methods were used to summarize sexual risk behavior over the 24 month follow up period. Sexual behavior included details on the number of casual and main partners and the frequency of sex acts, including those with and without condom use. Logistic regression models with a generalized estimating equation (GEE) extension were used to estimate the association between sexual behavior and the VOICE risk score, which was dichotomized into high (≥6) and moderate (4,5) categories. We examined the influence demographic variables as a potential confounder on the primary exposure of interest. Variables that changed the risk estimate by 10% were maintained in the final model. Separate logistic regression models with a generalized estimating equation (GEE) extension were used to analyze the association between risk perception (Yes, No and do not know) and the VOICE risk score. We examined adjustments for covariates including age, number of years of education, living arrangements, marital status and income earning status and included variables in the model that substantially changed the point estimate by >10%. R version 4.1.0 statistical package was used for analysis (R Core team, 2021)[12].

Ethical Approval

The parent study was approved by the Kenya Medical Research Institute (KEMRI) Ethics Review Committee and institutional review boards at the Massachusetts General Hospital and the University of Washington. All participants provided written informed consent.

Results

Participant Characteristics

A total of 348 women were enrolled in the study. At baseline, the median age was 21 years (IQR: 19-22), the majority had completed at least 12 years of school, and approximately half (55.5%) reported that they were single but had a stable partner. Most of the young women reported living with their parents (60%). Fewer than one-third of the enrolled women (30.2%) reported earning any form of salary

with majority being students (38.9%). Belief of the effectiveness of PrEP to prevent HIV acquisition was high where 68% reported believing that “PrEP made sex completely safe”. When asked to assess themselves for HIV risk, 42.1% reported that they were “not at risk,” and 4.9% were “unsure” of their HIV risk (Table 1). The frequency of condomless sex was primarily stable during the 24-month follow up period, including with main and casual sexual partners (Figure 1). At enrollment, 66% reported condomless sex with their main partner and 50% reported condomless sex with casual partners. This frequency rose to 90% 1 month later and remained constant throughout follow up. 35% reported that they had more than 1 partner, and 66% reported that they had condomless sex in the month prior to enrolment.

Sexual behavior

At enrolment, sex acts with main and casual partners were similar in frequency with a median sex acts of 2 (IQR 1-4) with casual partners and 2 (IQR1-4) with main partners in the past month (Figure 2). The frequency of sex acts with main partners was consistent through 24 months and fluctuated for casual partners, including higher medians at month 6 and 21. There was some variance in the number of sex acts reported with 14 women reporting >100 sex acts per month.

Twenty seven percent of AGYW assessed to have a high HIV risk score reported ≥ 2 sex partners, and 12% ≤ 1 sex partner. This translates to a two-fold likelihood of having a high risk score ≥ 6 among AGYW with ≥2 partners (odds ratio [OR]= 2.2, 95% CI 1.6-3.1). After adjustment for living arrangements and marital status, however, this difference was not statistically significant (adjusted OR =1.12, 95% CI 0.74-1.73). Among AGYW with a high risk score, 35% percent reported condomless sex and 31% did not with an OR 1.0 (0.7, 1.4) (p=0.9). When adjusted for living arrangements, marital status, and work status, the aOR was 1.3 (95% CI: 1.1-2.5) translating to a 0.3 difference in condomless sex (P=0.013). Casual partnerships were more frequently reported by those with a high risk score compared to those with moderate risk score (43% versus 19%). This translates to a two-fold increase in the likelihood of having a high risk score among those who reported 1 or more casual partners (OR=2.2, 95% CI:1.6-3.1). However, when adjusted for living arrangements, marriage, and age, the aOR was 1.1(0.8,1.6) and not statistically significant P=0. 56.

Association between self-reported risk perception and risk score

We compared self-reported HIV risk perception at enrolment, Month 12, and Month 24 with the baseline risk score. There was an overall decline in perception of being at high risk from 52% at enrolment not 19% at Month 12 and 12% at month 24. At enrolment, (52%) of those with a high risk score reported feeling at risk of HIV while (57%) of those with moderate risk score reported being at risk. At Month 12, (19%) of AGYW reporting feeling at risk with concurrent high risk score was and (20%) of those with moderate HIV risk score reporting feeling at risk of HIV. At month 24, (13%) of those who had a high risk score reported feeling at risk of HIV, while (14%) of those with moderate risk score felt that they were at risk of HIV. Overall, the frequency of having a high-risk score was similar for those who reported feeling at risk and not at risk with an unadjusted adjusted OR=0.75, (95% CI: 0.4,1.2).

Discussion

In this cohort of young Kenyan women using PrEP, initial sexual risk behavior and condomless sex levels were modest but increased after enrolment and remained stable over the two years of follow-up. These levels of sexual risk behavior are consistent with those seen in other studies[14,16]. In addition, reports of condomless sex were more frequent among those who scored ≥6 on the VOICE risk score, demonstrating an alignment of sexual risk and the VOICE HIV risk score[9]. Sexual risk behavior among those who had a high risk score and a moderate risk score was similar throughout the study.

This study found low incident HIV infections, indicating that even with the continued sexual activity, women remained HIV-negative, potentially due to the protective benefits of PrEP. The similarity between the moderate and high risk groups in behavior highlighted the need for a more comprehensive screening tool to identify risk among AGYW initiating PrEP. In addition to a quantitative risk scoring tool, a combination of qualitative and quantitative risk assessment may provide an option for capturing individual specific risk[17,18].

This study had several limitations and strengths. The study had a high retention rate up to 24 months and was conducted in research clinics experienced in creating a youth friendly environment. Limitations include all participants had a risk score of 4 and above thus we had a small distribution of risk (moderate to high) and did not have a comparison group with no/low risk. HIV risk behavior is a dynamic multifaceted issue that could be affected by ongoing HIV prevention counseling that each participant received. Finally, the VOICE HIV risk score was created using data from South African women who

participated in clinical trials more than five years ago[19]. Therefore, the score may not necessarily be generalized across different environments or perform well over time. The score also omits some key factors associated with HIV risk including age of partners, HIV status, and power dynamics[9]

In conclusion, with sexual risk behavior appearing consistent throughout the study, we need to identify risk scoring tools that capture additional aspects of risk as it is a complex issue to determine. Additionally, being able to efficiently identify varying levels of risk with contextual considerations may assist health providers tailor support for each group. Other risk factors also need to be identified and captured appropriately[15].

Table 1

Characteristics	No/Median (%)IQR
Age, years	21 (19–22)
18–21	159 (45.4%)
22-24	191 (54.6%)
Education, years	12 (10–13·0)
HIV risk score*	7(6,7)
Partnership factors	
Number of sex acts in previous month	2 (1,5)
>1 current sexual partner	121 (34.9%)
Any condomless sex in past month	228 (66%)
Marital status	
Single, no steady partner	128 (36.8%)
single steady partner	193 (55.5%)
Married (monogamous)	20 (5.8%)
Married (polygamous)	3 (0.9%)
widowed	1 (0.9%)
Living Arrangement	
With Parents	123 (34.4%)
Spouse	21 (6.1%)
Sexual partner	5 (1.4%)
Alone	80 (23.1%)
With other family	89 (25.6%)
With Friends	25 (7.2%)
Job /Occupation	
Student	135 (38.9%)
Employed steady salary	11 (3.2%)
Employed no stable salary	87 (25.1%)
Parent (own child)	2 (0.5%)
Household help (Nanny)	6 (1.7%)
Farmer	1 (0.2%)
Unemployed	98(28.2%)
Beliefs about PrEP/HIV	
PrEP makes sex completely safe	236 (68%)
Did not feel at risk of HIV	144 (42.1%)
Unsure of HIV risk	18 (4.9%)

Table 2: Association of sexual behavior and HIV risk score

Variable	n/N (%) with risk score ≥6	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	P value
No of partners					
≥2	496/1820 (27%)	2.2 (1.6, 3.1)	<0.001	1.12(0.74, 1.73)	0.58*
0-1	30 / 242 (12%)				
Condomless sex					
Reported	925 / 2629 (35%)	1.0 (0.7, 1.4)	0.972	1.3(1.1, 2.5)	0.013**
None reported	93 / 309 (31%)				
Casual Partners					
≥1	699 / 1617 (43%)	2.2 (1.6, 3.1)	<0.001	1.1(0.8,1.6)	0.56***
0	44 / 228 (19%)				

* Adjusted for living arrangements and marital status

** Adjusted for Living arrangements, Marital status, and work status

*** Adjusted for living arrangements, marriage, and age

Figure 1: Proportion of condomless sex with main and casual partners

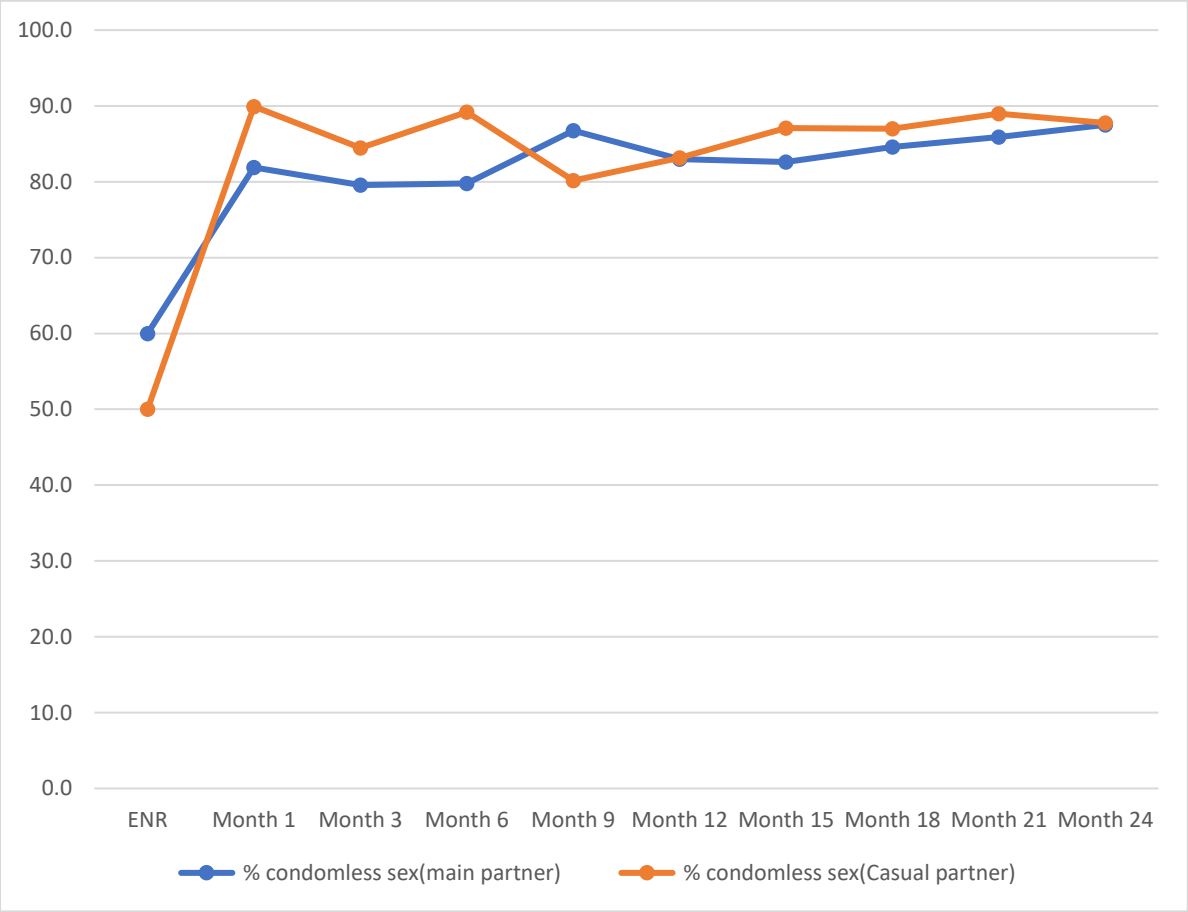
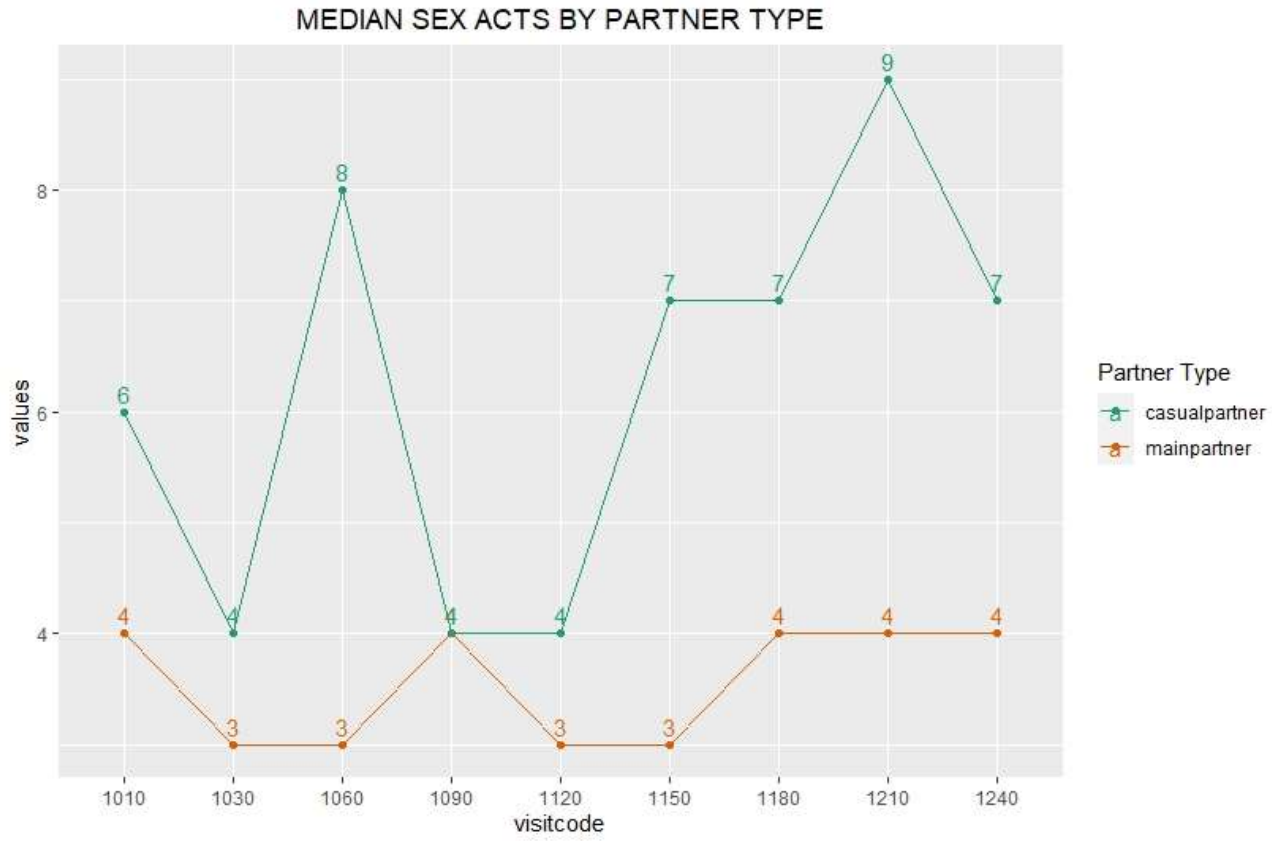


Figure 2: Median sex acts by partner type



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