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The Prevalence and Correlates of Sexually Transmitted Infections (STIs) among Heterosexual HIV-1 Sero-Discordant Couples Enrolled into HIV Prevention Clinical Trial in Western Kenya

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ABSTRACT

Sexually transmitted infections (STIs) are a major public health concern. Annually, over 300 million infections are reported worldwide, with 75-85% occurring in developing countries, with an estimated one million cases occurring daily. HIV-discordant couples remain at increased risk of transmission of HIV and STIs. Improved patient education is crucial in reducing the transmission of STIs, and to achieve this optimally, new strategies need to be developed. This study sought to determine the prevalence and risk factors associated with STIs in a cohort of heterosexual HIV-1 discordant couples in Western Kenya. A cross-sectional study of healthy heterosexual HIV-1discordant couples from Western Kenya enrolled into the Partners PrEP Study Eldoret site between September 2008 and October 2010. Socio-demographic data was obtained using specific case report forms. All participants were screened for the four classical STIs using Treponema Pallidum Hemagglutination Assay (TPHA) for Syphilis and nucleic acid amplification for Gonorrhea, Trichomonas, and Chlamydia. Descriptive statistics was used to determine frequencies, while the association between the STIs and the independent variables was evaluated using logistic regression. Data for 938 participants were available for analysis, of whom 469 (50%, 320 women, 149 men) were HIV-infected. The median was 26.97 years (IQR 23.52-31.93); (HIV-negative 35 years (IQR 29-40), and HIV-positive years (26-39). Prevalence was as follows: Chlamydia 11 (1.1%), Gonorrhea 7 (0.7%), Syphilis 14 (1.4%) and Trichomonas 55 (5.5%). There was no association between the presence of STIs and age, education, income, and gender. HIV-positive participants who reported alcohol intake were almost three times more likely to be diagnosed with an STI compared to those who did not take alcohol. [OR 2.841; 95% CI 1.16 – 6.95; p value 0.02] Those who were circumcised were one and a half times more likely to test negative for an STI compared to those who were uncircumcised, but this was not statistically significant [OR 1.556; 95% CI 0.980-2.472; p-value 0.061]. Focused counseling messages should be developed to target HIV-infected partners who (ab)use alcohol.

Keywords: STIs; HIV; Clinical trial; Discordant Couple

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INTRODUCTION

Sexually transmitted infections (STIs) are a major global public health concern. Annually, over 300 million infections are reported and 75-80% of these cases occur in developing countries [1, 2]. Globally, it accounts for almost 9% of disease burden in females and 1.5% in males aged between 15-54yrs. It is estimated that 1 million new cases occur each day worldwide and in sub-Saharan Africa alone, around 500,000 babies die each year due to congenital syphilis [1, 4] thus the need to reduce and also prevent these mortalities.

Failure to diagnose and treat STIs at an early-stage results in serious complications and sequelae. Apart from increasing the risk of HIV infectiousness through inflammatory processes [5, 6], STIs significantly increase morbidity in women (ectopic pregnancies, tubo-ovarian abscess, pelvic inflammatory diseases, infertilities, cervical neoplasia etc.). [7, 14] They also increase perinatal mortalities and morbidities (premature rupture of membranes, spontaneous abortions, preterm delivery, low birth weight infants, postpartum endometriosis etc) [7, 9], [15, 16] and have also been associated with neurological and cardiovascular disorders [17]. These sequelae place a heavy burden on the affected individuals as well as health care systems and therefore the need prevent these morbidities and sequelae.

According to CDC STI treatment guidelines 2010 [18], one of the five major strategies of prevention and control of STIs is through education and counseling persons at risk on measures to change sexual behavior using recommended preventive services. One of the three pillars of effective management of any infectious disease is prevention [19]. To effectively enhance this, improved patient education is crucial in reducing the transmission of STIs [20], and to optimally achieve this, new strategies and messaging need to be developed.

HIV discordant couples remain at increased risk of STIs and HIV partly because the available STIs and HIV prevention tools have not fully mitigated the risk and partly because most couples in Sub-Saharan countries desire to have children of their own. A deeper understanding of the risk factors associated with STIs in this population will ensure the development of targeted counseling messages that can be used widely in primary care for risk reduction. Counseling messages relating to STIs and HIV for this group are scarce and research focusing on this topic is sparse. This study sought to bridge the knowledge gap by documenting the prevalence and the correlates of STIs in this risk population within Eldoret. It also sought to find out if the association differs with the HIV serostatus. With this expanded knowledge base, the challenges of STI counseling in HIV sero-discordant couples may be reduced.

METHODOLOGY

Study Design and Sample Size

Study participants consisted of healthy individuals within HIV-1 sero-discordant relationships in Western Kenya enrolled into Partners PrEP Study Eldoret site. The participants were aged between 18 and 65 years, were sexually active and were intending to remain as partners for the duration of the study. They were enrolled into the study from September 2008 - December 2010 and followed up for 3 years. The Partners PrEP study was a multi-site phase III randomized, double blind placebo controlled clinical trial of parallel comparison of tenofovir and emitricitabine/tenofovir pre-exposure prophylaxis to prevent HIV-1 acquisition within HIV-1 discordant couples. The study enrolled 4758 couples, of whom the Eldoret site contributed 488 couples. It is from these 488 couples that the data were derived. The overall results of the Partners PrEP study have been reported [21] and the overall characteristics of the couples involved in the study have also been documented [22].

Study Procedures

At enrollment and as part of study procedures, all female participants had vaginal swabs collected for *Naisseria gonorrhea* (GC), *Trichomonas Vaginalis* (TV) and *Chlamydia trachomatis* (CT) analysis. Males had urine analyzed for the same pathogens. A venous blood sample was collected from all participants for syphilis testing.

Laboratory Methods and Analysis

Syphilis was analyzed using the Rapid Plasma Reagin method (Immutrep RPR, Omega Diagnostic) at the Ampath Reference Laboratory in Eldoret Kenya [23]; all positive sera were confirmed using Treponema Pallidum Haemagglutination Assay (Immutrep TPHA, Omega Diagnostics). GC, CT and TV were detected using nucleic acid amplification testing (Hologic/Gen-Probe APTIMA Combo-2 and TV ASR) at the University of Washington-University of Nairobi STI Laboratory in Mombasa, Kenya [24].

Data Collection and analysis

We Analysed socio-demographic data and STI results obtained at the time of participants' enrollment in the study. Socio-demographic data were obtained from the enrollment social demographic case report forms (ESI) and included data on participant's age, gender, education level, income, circumcision status, HIV sero-status, presence of other sexual partners and years in marriage. STIs data were obtained from enrollment sexually transmitted infections case report forms (ESTI). All participants were screened for the four classical STIs, namely GC, TV, CT and syphilis.

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Descriptive statistics were used to present the frequencies of each STI while the association between the presence of an STI (individuals who tested positive for any of the STIs studied) and the independent variables (age, gender, income, alcohol intake, education level, years in marriage, HIV status etc) were evaluated using unadjusted and adjusted logistic regression model. Association based on sero-status was evaluated using SPSS 16.0 software and P-values <0.05 were considered to be statistically significant.

Ethical Considerations

The Partners PrEP study was approved by the ethics Committees of the following universities: (1) University of Washington (UW-HSD); (2) Indiana University (IUPUI-IRB); and (3) Moi University Teaching and Referral hospital (MU IREC)-ClinicalTrials.gov number, NCT00557245. All participants provided written consent before participating in the study and also consented to the use of their data for subsequent analyses. Formal approval from the Site Principal Investigator was sought before commencement of this data sub-analysis.

RESULTS

Baseline Characteristics

Data for 938 participants were available for analysis, of whom 469 (50%, 320 women, 149 men) were HIV-infected. The median age of the study group was 26.9 years (IQR 23.5-31.9); among those who were HIV-negative, the median (IQR) age was 35 years (29-40) while for those who were HIV-positive it was 33 years (26-39). Majority (42.6%) of the participants were aged between 26-35 years. Almost half (46.3%) of the participants were educated to the upper primary level only, with 36.4% having attained post primary education. More than half (61.3%) of participants had no income, majority (85.7%) reported no alcohol intake, 95% had no other sexual partner and over three quarters of males (88.9 %) were circumcised. Social demographic characteristics of the study participants are presented in Table 1.

Table 1: Socio-demographic Characteristics of the Study Participants

Variable	N=938	Percentage
Age (years)		
< 25	160	17.1
26-35	400	42.6
36-45	264	28.1
> 45	114	12.2
Gender		
Male	462	49.3
Female	476	50.7
Education level		
Lower primary	163	17.4
Upper primary	434	46.3
Post primary	341	36.4
Income		
No income	575	61.3
With income	363	38.7
Male Circumcised		
No	104	11.1
Yes	834	88.9
Alcohol intake		
No	804	85.7
Yes	134	14.3
HIV Status		
Negative	469	50.0
Positive	469	50.0
Other sexual partner(s)		
No	897	95.6
Yes	41	4.4
Years in marriage		
0-5	317	33.8
6-10	250	26.7
Above 10	371	39.6

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Prevalence of STIs
Overall, 78 (8.1%) participants tested positive for at least one STIs. TV was the most common STI at 5.2% (n=49), and GC was the least common at 0.7% (n=7). Prevalence is presented in Table 2.

Correlates of STIs
In unadjusted analyses (Table 3), couples who were aged between 26-35 yrs were likely to be diagnosed with HIV compared to those above married for <25 yrs [OR 0.44; 95% CI 0.24-0.81; p-value=<0.01], this finding was not statistically? Those who reported being married for over 21 years were almost three times as likely to be diagnosed with an STI compared to those married for 11-15 yrs [OR 2.72; 95% CI 1.07- 6.95; p-value=0.04]. Participants who were circumcised were one and half times as likely to test positive for an STI compared to those who were uncircumcised, but this association was not statistically significant (OR 1.56; 95% CI 0.98-2.47; p-value=0.06). There was no association between STI status and participant gender, level of education, income, alcohol intake, HIV status, or other sexual partners.

Among the HIV-negative participants (Table 5), those aged between 26 and 35 yrs were almost three times more likely to be diagnosed with an STI compared to those below 25 yrs. [OR 0.28; 95% CI 0.11-0.74; p-value=<0.01], almost the same significance was seen in the adjusted analysis. HIV-negative participants who reported 0-4 yrs in school were almost three times more likely to be diagnosed with an STI compared to those reported > 9 yrs in school [OR 2.77; 95% CI 0.09-0.84; p-value= 0.05]. There was no correlation with the participant's gender, income, male circumcision status, alcohol intake, and years of marriage.

Table 2: The Prevalence of STIs in the Cohort, N=938

STI	N	Percentage	95% CI
Trichomonas Vaginalis	49	5.2	3.78-6.62
Naisseriae Gonorrhoea	7	0.7	0.17-1.23
Syphilis	12	1.3	0.58-2.02
Chlamydia Trichomonas	12	1.3	0.58-2.02
Overall	78*	8.1	6.35-9.84

*Some participants had co-infections

Table 3: Logistic Regression Models of Associations between Socio-Demographic Factors and the Prevalence of an STI (N=938).

	Diagnosed with an STI		Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age (years)						
<25	21(13.1%)	139(86.9%)	*R		*R	
26-35	25(6.2%)	375(93.8%)	**0.44(0.24-0.81)**	**<0.01**	0.51(0.26-1.02)	0.06
36-45	18(6.8%)	246(93.2%)	**0.48(0.25-0.94)**	**0.03**	0.63(0.27-1.45)	0.28
Above 45	12(10.5%)	102(89.5%)	0.78(0.37-1.66)	0.52	1.19(0.45-3.12)	0.74
Gender						
Female	43(9.3%)	419(90.7%)	*R		*R	
Male	33(6.9%)	443(93.1%)	0.73(0.45-1.17)	0.38	0.65(0.36-1.18)	0.16
Years in School						
0-4	19(11.7%)	144(88.3%)	1.74(0.93-3.28)	0.09	1.89(0.97-3.68	0.06
5-8	33(7.6%)	401(92.4%)	1.09(0.63-1.88)	0.77	1.19(0.68-2.08	0.54
Above 9	24(7.0%)	317(93.0%)	*R		*R	
Income						
No income	45(7.8%)	530(92.2%)	*R		*R	
With income	31(8.5%)	332(91.5%)	1.10(0.68-1.77)	0.69	1.36(0.82-2.28)	0.24

Male circumcised						
No	10(9.6%)	94(90.4%)	*R		*R	
Yes	66(7.9%)	768(92.1%)	0.81(0.40-1.63)	0.18	0.91(0.44-1.86)	0.79
Alcohol intake						
No	63(7.8%)	741(92.2%)	*R		*R	
Yes	13(9.7%)	121(90.3%)	1.26(0.68-2.37)	0.47	1.60(0.80-3.15)	0.19
Other sexual partners						
No	40	427	*R		39	415 *R
Yes	02	014	1.525(0.335- 6.949)	0.586	0.000 (0.000-0.000)	0.998
Years in marriage						
<5 yrs.	28(8.8%)	289(91.2%)	*R		*R	
6-10 yrs.	22(8.8%)	228(91.2%)	0.99(0.56-1.79)	0.99	1.58(0.80-3.12)	0.19 0
>10 yrs.	26(7.0%)	345(93.0%)	0.78(0.45-1.36)	0.38	1.31(0.61-2.80)	0.50

*R-----Reference point

Table 4: Logistic Regression Models of Associations in/among HIV Positive Participants and the Prevalence of an STI (N=469).

	Diagnosed with an STI		Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age (years)						
<25	12(12.2%)	86(87.8%)	*R		*R	
26-35	16(7.9%)	186(92.1%)	0.62(0.28-1.36)	0.23	0.44(0.16-1.17)	0.10
36-45	10(8.3%)	111(91.7%)	0.65(0.27-1.57)	0.33	1.30(0.42-4.01)	0.65
Above 45	4(08.3%)	44((91.7%)	0.65(0.20-2.14)	0.48	**3.74(1.33-10.52)**	**0.01**
Gender						
Female	32(10.0%)	288(90.0%)	*R		*R	
Male	10(6.7%)	139(93.3%)	0.65(0.31-1.36)	0.25	0.44(0.17-1.16)	0.10
Years in School						
0-4	10(11.4%)	78(88.6%)	1.37(0.58-3.23)	0.47	1.44(0.58-3.59)	0.44
5-8	18(8.3%)	199(91.7%)	0.97(0.47-2.01)	0.93	1.04(0.49-2.21)	0.92
> 8	14(8.5%)	150(91.5%)	*R		*R	
Income						
No income	28(8.9%)	287(92.2%)	*R		*R	
With income	14(9.1%)	140(90.9%)	1.03(0.52-2.01)	0.94	1.12(0.53-2.36)	0.77
Male Circumcised						
No	4(7.7%)	48(92.3%)	*R		*R	
Yes	38(9.1%)	379(90.9%)	1.20(0.41-3.52)	0.73	1.35(0.44-4.15)	0.60
Alcohol intake						
No	35(8.2%)	393(91.8%)	*R		*R	
Yes	7(17.1%)	34(82.9%)	2.31(0.95-5.60)	0.06	3.87(1.37-10.95)	0.01
Other sexual partners.						
No	40	427	*R		39	415 *R
Yes	02	014	1.525(0.335- 6.949)	0.586	00	0 30 0.000 (0.000-0.000) 0.998
Years Married						
< 5	16(10.1%)	142(89.9%)	*R		*R	

6-10	12(9.5%)	114(90.5%)	0.93(0.43-2.05)	0.87	1.55(0.60-4.00)	0.37
> 10	14(7.6%)	171(92.4%)	0.73(0.34-1.54)	0.41	1.33(0.46-3.90)	0.60

*R-----Reference point

Table 5: Logistic Regression Models of Associations in/among HIV Negative Participants and the Prevalence of an STI (N=469)

	Diagnosed with an STI		Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age(years)						
<25	9(14.5%)	53(85.5)	*R		*R	
26-35	9(4.5%)	189(95.5%)	**0.28(0.11-0.74)**	**0.01**	**0.27(0.09-0.84)**	**0.02**
36-45	8(5.6%)	135(94.4%)	**0.35(0.1.3-0.95)**	**0.04**	0.36(0.09-1.34)	0.13
Above 45	8(12.1%)	58(87.9%)	0.81(0.29-2.260)	0.69	0.93(0.22-3.89)	0.92
Gender						
Female	11(7.7%)	131(92.3%)	*R		*R	
Male	23(7.0%)	304(93.0%)	0.90(0.43-1.90)	0.79	0.96(0.40-2.28)	0.92
Years in School						
0-4	9(12.0%)	66(88.0%)	2.28(0.89-5.86)	0.09	**2.77(1.00-7.72)**	**0.05**
5-8	15(6.9%)	202(93.1%)	1.24(0.54-2.83)	0.61	1.51(0.64-3.55)	0.34
> 9	10(5.9%)	167(94.4%)	*R		*R	
Income						
No income	17(6.5%)	243(93.5%)	*R		*R	
With income	17(8.1%)	192(91.1%)	1.27(0.63-2.55)	0.51	1.54(0.74-3.24)	0.26
Male circumcised						
No	6(11%)	46(88.5%)	*R		*R	
Yes	28(6.7%)	389(93.3%)	0.55(0.22-1.40)	0.21	0.56(0.21-1.52)	0.26
Alcohol intake						
No	28(7.4%)	348(92.6%)	*R		*R	
Yes	6(6.5%)	87(93.5%)	1.26(0.68-2.37)	0.47	0.92(0.35-2.41)	0.86
Other sexual partners.						
No	40	427	*R		*R	
Yes	02	014	1.525(0.335- 6.949)	0.586	0.000 (0.000-0.000)	0.998
Years in marriage						
< 5 yrs.	12(7.5%)	147(92.5%)	*R		*R	
6-10 yrs.	10(8.1%)	114(91.9%)	1.08(0.45-2.58)	0.87	1.77(0.64-4.93)	0.27
>10 yrs.	12(6.5%)	174(93.5%)	0.85(0.37-1.94)	0.69	1.48(0.45-4.88)	0.58

*R-----Reference point

DISCUSSION

The purpose of this study was to determine the prevalence and the correlates of STIs in HIV-1 discordant couples within Eldoret. Findings in the study revealed a low prevalence of STIs in this population with no difference according to HIV serostatus or gender. Factors associated with a higher risk of STIs were different for HIV-infected and uninfected participants. Based on these results, the prevalence of STIs in this region is generally low, and this is comparable to the findings of the main study [21] and other findings within the region [7, 25, 26]. The low prevalence in this study is also comparable to studies outside this region, mainly those that face similar economic challenges [2, 11, 27]. Among the four classical STIs evaluated, TV was the most common prevalent STI; this is comparable to

findings from the Tanzania study [28] which was conducted in a general population setting. Thus, attempts should be made to reduce this comparatively high prevalence through prevention and prompt treatment of STIs.

The generally low prevalence observed may have further been influenced by the fact that most of the HIV Infected participants in our study were enrolled in the HIV comprehensive care clinics (CCC), and in these clinics, STI screening and treatment are part of the standard care given. The partners of those infected with STIs may have benefitted from the STI management principle of contact tracing and treatment. Proper and consistent use of condoms has been advocated for use by HIV-discordant couples as part of risk reduction management; this may have had an impact on the prevention of transmission of STIs within their relationships, thus contributing further to the low prevalence seen in our study. The same reason explains why HIV status in this study did not correlate with STIs; the proportions were almost the same irrespective of the HIV status, i.e., 39/445 and 42/441 for HIV uninfected and infected, respectively.

Multiple sexual partners in a relationship are a risk factor for STIs [26, 29, 32]. However, in this study, multiple partners did not show any significant association with STIs in unadjusted or adjusted analyses. This finding is explained by the fact that the number of participants who reported having other sexual partners was low (4.8%, n=46), thus lowering the power of our analyses to determine an association. A low number of other sexual partners is a pointer to monogamous relationships in this study, and therefore, the risk of exposure to STIs by either gender was comparable; this explains why there were no associations of STIs with gender.

Although income has been associated with STIs [27], this study had no association in bivariate or multivariate analysis. This is because most of the participants in this study had no income, which may have further influenced our findings. Furthermore, most of our participants were between 26 and 45 years old; this age group is burdened with many family demands. The demands vary from having children in school and feeding the family to providing family basic needs, which are demanding, especially in resource-limited setups and, therefore, no surplus to spend on other activities.

In this study, being HIV-negative at an advanced age (above 55) was a risk factor for STIs; this finding is comparable to the Midland study [33]. This finding may have further been influenced by the low numbers of those who were of this age bracket and the fact there were no HIV-positive participants with an STI. Occupation was not associated with STIs in this study, and this finding is similar to the Nigeria study [27]. This may have been further influenced by most of our participants being self-employed. Being self-employed entailed being a hawker, subsistence farmer, selling second-hand clothes, Jua-kali artisan, selling groceries, motorcycle (*boda-boda*) riders, etc. Being self-employed in a resource-limited region is not only involving but also demanding, thus draining one's time and energy; this leaves little or no time and room for other activities.

Strengths and Limitations

This study is among the first to examine STI in HIV serodiscordant relationships in this region and so makes significant contributions to informing public health messaging and practices. The data presented herein show an in-depth analysis of the risk factors for STIs in HIV serodiscordant relationships. These findings are original and will contribute significantly to future STI/HIV research in this population. The study had several limitations: the sample, sampling procedure, and sample size were predetermined. So, this may not reflect the entire HIV serodiscordant population, and since the participants were from one geographical region, the results may not be generalisable.

CONCLUSION

In conclusion, therefore, HIV-infected participants who (ab) use alcohol, young HIV-uninfected individuals, and those couples who are newly married were found to be at risk of STIs in this study. Focused health education and STI counseling messages should be developed to target them. This will go a long way in mitigating the challenges posed by STIs in this at-risk population.

ABBREVIATIONS

STIs– Sexually Transmitted Infections
HIV– Human Immunodeficiency Virus
TPHA – Treponema Pallidum Haemagglutination Assay
CDC– Centre for Disease Control
GC- Neisseria Gonorrhea
TV - Trichomonas Vaginalis
CT- Chlamydia trachomatis

FUNDING

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CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

ETHICAL APPROVAL

Ethical approval obtained from (1) University of Washington (UW-HSD); (2) Indiana University (IUPUI-IRB); and (3) Moi University Teaching and

Referral hospital (MU IREC)-ClinicalTrials.gov number, NCT00557245.

AUTHORS' CONTRIBUTION

JK conceptualized the paper. JK, EW designed and prepared the paper. DO, AK, GK and JS participated in data collection and management. EK performed data analysis. EW, PA and JB reviewed this manuscript.

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