"CLINICAL AND PATHOLOGICAL CHARACTERISTICS OF HIV DISCORDANT COUPLES AT KENYATTA NATIONAL HOSPITAL"

A dissertation presented in part fulfillment of the requirement for the degree of masters of medicine in Internal Medicine by:

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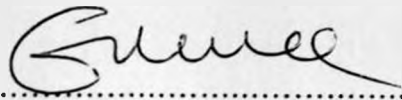
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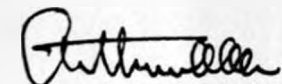
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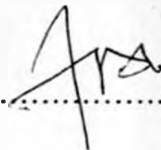
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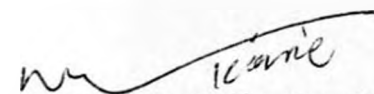DEPARTMENT OF MEDICINE AND CLINICAL THERAPEUTICS
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DEDICATION:

This study is dedicated to all couples living in HIV discordant relationships.

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ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

AIDS	-	Acquired immunodeficiency syndrome
CD4	-	CD4+ T lymphocytes
ELISA	-	Enzyme-linked-immunosorbent assay
EU	-	Exposed uninfected
HAART	-	Highly active antiretroviral therapy
HIV	-	Human immunodeficiency virus
HVS	-	High vaginal swab
KNH	-	Kenyatta National Hospital
PSC	-	Patient support center
RANTES	-	Regulated upon activation,normal T expressed and secreted.
SDF-1	-	Stromal cell derived factor-1
STI	-	Sexually transmitted illness
Tho	-	T suppressor lymphocytes
Th1	-	T regulator lymphocytes
Th2	-	T cytotoxic lymphocytes
UON	-	University of Nairobi
VCT	-	Voluntary counseling testing center
WHO	-	World Health Organisation

ABSTRACT

Background: HIV discordance is common in African couples .Despite knowledge on the population dynamics,epidemiology and transmission of HIV in stable couples ,we do not have data on their clinical, pathological and sexual characteristics in discordant couples.

Objectives: To determine the clinical , pathological and sexual characteristics of HIV-1 discordant couples and compare factors that influence HIV -1 transmission in male and female discordant couples attending PSC at the Kenyatta national hospital.

Design: Cross-sectional descriptive study.

Setting: PATIENT SUPPORT CENTER (PSC) at KNH

Study population: Adults (over18 years) HIV-1 sero-discordant couples.

Methodology: 96 discordant couples referred to the Patient Support Center were recruited in the study. HIV test by rapid test method for couples more than a week since referral date to the PSC and for those without copies of HIV-1 results. Only those who gave a written consent and fulfilled the inclusion criteria were recruited. History and physical examination was undertaken on each participating partner .The WHO clinical stage of HIV disease was established in the positive partner. Urine specimens, pus swabs from bases of ulcerative and exudative genital ulcers in both partners ; urethral discharge specimen in male and a high vaginal smear in female cases were collected for microbiology analysis. Seven milliliter sample of venous blood was drawn aseptically from antecubital vein for CD4 lymphocyte count and HIV-1 VIRAL LOAD of the sero-positive partner in the HIV-1discordant relationship.

Data Analysis: Data was analyzed using SPSS/PC + VERSION 12 programme.

Descriptive statistics for continuous and categorical data were done from which measures of central tendency and proportion were derived. Using univariate logistic model with each partner discordance status as the dependent variable and CD4,VIRAL LOAD, frequency of sexual intercourse, duration of marriage and STI as independant variables ,comparison were made on variables that alter HIV-1 transmission dynamics in a discordant relationship in male and female positive partners.

Results:96 couples were analyzed in the study. Of this, 69 female(72%) and 27 male(28%) were HIV positive giving a female to male ratio of 2.6:1.The median age of the all male participants was 34 years while for the female partners was 26 years.Eighty nine percent of positive partners were in early WHO clinical stages 1 and 2. The mean viral load in the positive partners was 11447 copies per ml with a median of 4505 copies per milliliter. The mean CD4 cell count was 446 cell per microlitre in the positive partners..Most couples engaged in protected marital sex post notification of their HIV status. The male positive partners had advanced disease based on a higher mean viral loads(20074 versus 9045 viral copies) and lower mean CD4 cell counts(407 versus 455 CD4 cells) than the female positive partners .

Conclusion: There are more female positive partners in HIV discordant couples attending PSC clinic at the Kenyatta national hospital .Most partners present in early WHO clinical stage of disease with a low mean viral load and favourable CD4 count.The couples have a low STI prevalence.Other than duration of marriage and frequency of sexual intercourse, there are no gender differences in the transmission factors in male and female positive partners in discordant couples. Molecular characterization of these negative partners is required to assess further the factors preventing transmission of the virus.

LITERATURE REVIEW

PROBLEM STATEMENT

HIV-1 discordance is common in African couples ranging from 3%to 20% in the general population[1,2]and 30%-51% within couples in which one seeks HIV care services.[3,4].

In Africa, over 85% of adult HIV infections are due to heterosexual transmission.[5] Although HIV-seronegative partners in HIV-discordant (one partner HIV positive and one partner HIV negative) couples are at a 10% annual risk of acquiring HIV infection[6] and a large proportion of new HIV infections in Africa occur in stable partnerships, most HIV prevention programs in Africa focus on reducing the number of casual sexual partners, using condoms during casual sex, and increasing fidelity among married partners. However, for persons in an HIV-discordant relationship, encouraging monogamy without safer sexual behavior will not decrease the risk of HIV transmission. HIV discordance among couples is an increasingly important issue in HIV prevention programmes.[7].Improving our understanding of behavioral and biologic correlates of HIV transmission in couples should help couples cope with discordant results and improve counseling and medical care strategies for HIV-discordant couples. In addition to behavioral factors, biologic differences in transmissibility of HIV-1 may play a role in explaining the spread and patterns of HIV discordance among couples.

Most studies on HIV discordance among couples in Africa have focused on the effects of couples counselling on the subsequent rates of HIV-1 acquisition [8,9], on the effects of serodiscordance on coping strategies within relationships [10], or on the effect of HIV therapies on sexual behaviour among serodiscordant couples [11]. Two African studies investigated the

relative risk of infection among men and their regular female partners[12,13]. Another study [14] compared risk factors for HIV-infection among HIV-negative concordant couples and HIV discordant couples, concluding that, in most cases, husbands acquired HIV infection first and then transmitted it to their wives. A study in Uganda [15] examined HIV-1 infection among couples who were either HIV-discordant or HIV-negatively concordant, and measured the incidence of HIV-1 over 1 year in these couples. Among discordant couples, the male was HIV-positive in 57% of the cases, the female in the remaining 43% of cases. The sample was stratified according to place of residence; in trading and intermediate centres, women were as likely as men to be the source of new infections in the couple. However, in the rural villages, men were the predominant source of new infections .

Several correlates influence transmission of HIV disease.An interplay of host and viral factors contribute to the spread of HIV disease.Viral factors include the clade and viral load.The presence of genital lesions and STDs in the host,use of HAART ,advanced stage of HIVdisease all contribute to the ability to transmit the virus.

None of the above African studies set out to look at the clinical correlates and laboratory characteristics in a discordant relationship and such correlates are not well described in our setting.

By understanding such correlates of transmission and characterizing discordant couples in a heterosexual relationship,we shall be exposing further preventive measures to curb the spread of HIV-1.

PATHOGENESIS AND TRANSMISSIBILITY OF HIV — HIV-1 most often enters

the host through the genital mucosa. The viral envelope protein, glycoprotein (GP)-120, binds to the CD4 molecule on dendritic cell lineages; interstitial dendritic cells are found in cervico-vaginal epithelium but also in tonsillar and adenoidal tissue which may serve as initial target cells in infection transmitted via genital/oral sex [16,17,18].

Macrophage (rather than T lymphocyte) tropic viruses are preferentially transmitted in humans . In order to enter cells, an important co-receptor for GP-120 has been elucidated which for macrophages is a surface chemokine receptor, CCR5 [19,20].

Macrophage tropic viruses are designated as R5 in comparison to T cell tropic viruses called X4 for the CXCR4 co-receptor on these cells [21].

CD4 is the primary HIV receptor allowing for entry of the virus to the cell.However the two coreceptor CCR5 and CXCR4 are required for fusion and entry into the macrophage and CD4 T cells predominantly.These belong to the G-protein family of receptors and bind other ligands such as chemokines RANTES and MIP-1.[22]

Patients homozygous for a deletion in CCR5 are relatively resistant to R5 infection although cases of X4 infection have rarely been reported in these individuals [19].Heterozygous CCR5 delta 32 deletions,CCR2-641 mutations which dimerizes with CXCR4 thus downregulating the receptor and RANTES 28-G mutations delay infection and progression of HIV-1.Also homozygous SDF-1-3'A mutation confers delayed infection by up-regulating SDF-1 gene thus enabling which is a natural ligand to CXCR4 to compete for the binding site with the T tropic virus. HLA A,B,C B35,C04 accelerate disease progression.[23]

HIV infected cells fuse with CD4+ lymphocytes leading to spread of the virus; virus is detectable in regional lymph nodes within two days of mucosal exposure and in plasma within another three days [17,23]. Once virus enters the blood, widespread dissemination to organs such as the brain, spleen, and lymph nodes occurs.

At the time of initial infection with HIV, patients have a large number of susceptible CD4+ cells and no HIV-specific immune response. Viral replication is therefore rapid; plasma HIV RNA levels may climb to more than 10(7) copies/mL and p24 antigen levels may exceed 100 pg/mL.

Neutralizing HIV-1 antibodies and polyclonal CD8 CTL response slows disease progression.Immunological set-point is determined by the degree of CTL response.Levels of enhancing and inhibiting cytokines determine the replication.

Virus clade/subtypes determine the level of replication and course of disease.Certain subtypes e.g clade A,C,D which predominate in sub-Saharan Africa are more pathogenic than B found in Europe and North America.[24]

Some people repeatedly exposed to the human immunodeficiency virus (HIV), such as commercial sex workers, intravenous drug users, or partners of HIV-infected individuals, remain free of any detectable sign of infection and seem to be protected against HIV infection (exposed uninfected individuals [EUs];as reviewed by Kulkarni et al (25).

Past studies associated resistance to HIV-1 infection to genetic factors, such as the CCR5-[DELTA]32 mutation in white populations, or particular HLA haplotypes(26).Humoral and/or cellular immune responses were also suggested to contribute to protection in EU populations (27,28). Indeed, both HIV-1-specific antibodies and/or antibodies directed to HIV-1 cellular

receptors(IgA Anti-GP41 and IgG Antigp120) have been detected in vaginal secretions and/or sera of EU people. Anti-HIV-1 cytotoxic T CD8$^+$ lymphocyte (CTL) responses have also been reported in a significant number of EU people. Suggestions that innate mechanisms of restriction of viral infection, such as HIV inhibitory secreted factors, natural killer cell-enhanced activity, or decreased susceptibility of T lymphocyte CD4$^+$ cells to infection, may also explain resistance in EU populations have been forwarded(29).

RISK FACTORS FOR TRANSMISSION

Many risk factors for transmission have been described(7,12,30).yet fewer studies have dealt with the understanding of the risk factors and transmission dynamics of the epidemic in Kenya. Transmisssion risks have been approximated as follows(5):

Sexual intercourse   -1:1000

Needle stick   -1:333

Untreated mother to child   -1:5

Perinatal on AZT   -1:12.5

Blood transfusion   -95:100

Certain factors may alter this risk remarkably; Studies of AIDS pathogenesis have established or proposed, a number of genes encoding molecules as logical candidates for pathogenetic roles in HIV/AIDS: co-receptors and their ligands, cytokines and their receptors, transcription factors, antigen-presenting proteins, and other HIV-1-mediating immune destruction factors .

Mutations in chemokine receptors ,for example ,the CCR5 delta 32 mutations confer resistance to infection.Other mutations CCR2 – 641 mutations ,RANTES 28-G mutation slow disease progression.(19,20,31)

Genital tract abrasions and cervical ectopy especially in the young age group enhances transmission of HIV virus across the cervico-vaginal barrier.[32]

Inflammatory lesions increase chances of infection by upregulating cells with receptors for HIV attachment. Such lesions are seen in syphilis,HSV-2 virus and chancroid[33]

WHO clinical Stage of HIV disease,concurrent illnesses,immune activation by vaccination may also alter the rate of transmission. Early modeling published data suggested that subjects with acute HIV infection might be particularly important to the spread of HIV given their high viral load. This hypothesis received powerful support from further interpretation of the study by Quinn in the Rakai District of Uganda that showed higher seroconversion rate in couples whose partners had a higher viral loads and presence of STI[34]. In a retrospective analysis of discordant couples assembled from research records, Quinn et al. found that 43.2% of all transmission events in this cohort could be ascribed to index (infected) subjects with acute and early infection. In addition, subjects with advanced disease were also more likely to transmit HIV, consistent with increased viral burdens during these windows of time[34].

Use of HAART reduces viral load hence risk of transmission.High viral load has been positively identified in trials as a major risk factor for seroconversion in a discordant relation[34,36]

Presence of sexual transmitted illness increases chances of transmission of HIV and studies have shown that treatment of STI in a stable population is associated with reduction in the incidence of HIV in the population [37].Opportunistic infection like Tuberculosis which lower the immunity , increase the chances of transmission.

HIV DISCORDANCE

Major studies on serodiscordance have been published in literature and clinical practice but no scientific evidence has been tabled to explain its occurrence in a heterosexual setting other than a number of variables which on analysis have shown an increased chance of transmission and hence seroconversion.

The Ugandan study at Rakai on HIV transmission probability per coital act in discordant couples in a monogamous heterosexual relation found that 415 couples among the 8898 couples screened (4.7%)were HIV serodiscordant and analysed socio-demographic data that influenced the sero-conversion. Transmission probabilities were highest in younger individual and increased strikingly with high viral loads greater than 38500 copies/ml compared to less than 1700copies/ml. Other than genital ulcerations,serological evidence of syphilis,HSV-2 and labaratory diagnosis for current gonorrhoea,Chlamydia,bacteria vaginosis or trichomonas infection or among those reporting dysuria or discharge did not significantly affect transmission.[34]]

Host, viral and local factors manifesting in genetics,virus subtype/clade ,male circumcision(38,39) and genital abrasion and cervical ectopy are some of the factors thought to influence the transmissibility of HIV possibly explaining seroconversion.

Biomedical factors apart, key socio-demographic factors alter transmission:living together, migration[40,41],sexual behavioral factors ,non- hormonal contraceptive use like condoms(40,42) ,education status,age ,HIV awareness and poverty affect the transmission.

Data remarkably show a causal effect .For instance, the regular use of male condoms reduces the risk of acquiring or transmitting HIV. In the most definitive example,a multicenter study, the European study on heterosexual transmission of HIV in discordant couples, carried out in nine

European countries, found that individuals who reported consistent condom use had no seroconversion despite a total of about 15000 episodes of intercourse. In this study the male to female transmission was 1.9 more effective than female to male after adjusting for confounders like stage of disease,sex during menses and age (43).Another study by Saracco et al (44) approximated the annual rate of HIV-1 transmission in a stable relation from male to female at 7.2 per 100 person years who did not use or never used condoms and 1.1 among those who always used them(44).In couples not always using condoms and where the man had a low CD4+ cell count ,the joint presence of blood viral antigens and AIDS symptoms conditioned a five fold increased risk of seroconversion of the woman.

Ryder et al found a seroconversion-incidence in women of 3.7/100 person years follow-up and 8.6 /100 person year follow up for pregnant women with positive male index in their trial in DRC on 178 discordant couples;positive women index had a seroconversion-incidence of 6.8/100 person year follow up(PYFU) in both cases: yet factors affecting the sero-conversion were not clearly elucidated even for those who went on to have children.The study raised important issues on safe sex in discordant couples willing to have children and psychological effects of sero-status notification on the marriage.[45]

Further review of published literature on HIV incidence among discordant couples suggests that the incidence of HIV infection among the heterosexual partners of infected persons in India(46) is much lower (1.22/100person years) than what has been previously reported from african countries including Tanzania(10),Uganda (34) and Zambia(63) (11.8, 5-10, 8.5/100 person-years respectively.

In a South-african study cohort on migrants and non migrant couples(47) and their rural partners, aimed at understanding the transmission dynamics and risk factors of the epidemic in South –

Africa, migrant couples were 3 times more likely to be discordant than non-migrant couples.Sixty –one percent of male were HIV positive compared to thirty nine percent of female in the discordant couples . The prevalence of discordance in the two groups was 26.7% versus 11.5% in the migrant compared to non-migrant couples .

One western data reported higher male to female transmission compared to female to male though these study enrolled fewer female HIV positive index cases(50).Data from Rakai study and elsewhere in Africa (51,52,53) too seems to show significant male to female transmission.The biological justification lies in the higher surface area of the female genitalia that predisposes them to acquire the virus from an infected male partner.

JUSTIFICATION OF THE STUDY

1. Data on the baseline clinical and labaratory characteristics of the discordant couples is lacking in our set-up.This would help us understand the transmission dynamics altering HIV-1 acquisation in a discordant heterosexual relationship.

2. With the absence of effective HIV-1 vaccine, most focus in the preventive strategies had in the past focused on high risk groups like commercial sex workers and track drivers. The stable heterosexual relationship in married couples is increasingly becoming an important target group to curb the spread of HIV-AIDS. Data on the discordant couples will thus help form a basis for couple centred clinical intervention strategies.

3. Results of this study may in future guide in formulating policies aimed at preventing HIV-1 spread in a stable heterosexual relationship. This will augment primary preventive strategies by further targeting such risk groups.

4. The study would help in giving more data on the biomedical risk factor and socio-demographics associated with discordance and form a basis for future research in that field.

OBJECTIVES:

Broad Objective:

To describe the clinical, pathological and sexual characteristics of discordant couples and compare factors that influence transmission in male and female partners in HIV-1 discordant couples attending PATIENT SUPPORT CENTER at Kenyatta National Hospital.

Specific Objectives:

1. To describe the clinical characteristic and WHO clinical stage of the positive partner in HIV discordant couples .

2. To determine CD4 and Viral load counts in the positive partner in HIV-1 discordant couples.

3. To determine the sexual behavior and frequency of sexually transmitted illnesses in discordant couples.

4. To compare risk factors for transmission between male and female positive partners in a HIV discordant relationship.

METHODOLOGY

STUDY DESIGN:

This was a cross-sectional survey

SAMPLE SIZE ESTIMATION:

The sample size was calculated using formula below:

$$N = \frac{Z^2pq}{d^2}$$

Z   =standard deviation for a 2 tailed at 95% CI

N   = Minimum sample size

$\propto$ = Level of significance = 5%

P   = Proportion estimated to have a particular characteristic.

Literature review did not find any study which has assessed the individuals   clinical and laboratory characteristics therefore 50% was used which is the acceptable figure in statistics.

d   = Degree of precision ± 10%

Z = 1.96 (from tables of two tailed

HENCE, $N = \frac{1.96^2 \times 0.5 \times 0.5}{0.1^2}$

=96.

The minimum sample size required will be ninety-six HIV-1 discordant couples.

STUDY AREA

This was a hospital-based study conducted at **Patient Support Center** of KNH, a tertiary referral hospital.Discordant couples are routinely diagnosed at different VCT centers and antenatal facilities in Nairobi and referred here.

STUDY POPULATION

Discordant couples aged over 18 years who had given an informed and written consent.

CASE DEFINITIONS:

SERO-DISCORDANCE was defined as a positive HIV-1 rapid test in one partner in the heterosexual couples involved in sexual activity for at least 6 months prior to enrollment.

HIV INFECTION was defined as a positive HIV-1 reactive rapid test. (appendix III)

COUPLE was defined as heterosexual partners who admitted to be in a sexual relationship for a period of at least 6 months prior to enrollment.

GENITAL ULCER DISEASE was defined as physical examination findings of penile, vulvar, or cervical ulcerations with or without vesicles.

SEXUAL TRANSMITTED INFECTION-Defined as the presence of active disease diagnosed based on present history of discharge or genital ulceration with confirmed laboratory diagnosis tests or reported treatment for an STI 6 months prior to entry in to the study .This included gonorrhoea,trichomoniasis,and bacterial vaginosis(appendixIII).

URINARY TRACT INFECTION –was defined as the presence of dysuria frequency or urgency in last 6 months with/out isolation of organisms on microsopy and culture or presence of more than 5 pus cell per high power field on microscopy.

PATIENT SELECTION

INCLUSION CRITERIA

1. Adults couples over 18 years of age.

2. HIV infection in at least one partner in the couple.

3. Informed and written consent.

4. Sexually active for at least 6 months prior to recruitment.

EXCLUSION CRITERIA

1. language barrier in the couples interviewed

2. declined consent

SAMPLING PROCEDURE

Eligible couples were consecutively recruited into the study until the sample size of ninety six was achieved. Couples were interviewed and recruited from Monday to Friday every week by the principal investigator with help of a medical officer research assistant.

CLINICAL PROCEDURE

The principal investigator interviewed couples in the PSC. A rapid diagnostic kit was used for HIV test in partners whose result were unknown or those who come with a referral of discordance after a week or those without copies of the HIV results.Those who satisfied the inclusion criteria were recruited. Recruited sero-discordant couples were interviewed based on the study pro-forma .Each partner was interviewed and examined separately . Data on their socio-demographic, clinical and laboratory characteristics was obtained.

A thorough history and physical examination for clinical staging purposes was undertaken. HIV positive partners had a CD4 lymphocyte count and HIV-1 viral load done from seven milliliter of venous blood sample drawn from the ante cubital vein.

Mid stream urine samples in a sterile bottle and urethral swabs in male with discharge were taken for microbiological analysis of Neisseria gonorrhea and bacterial vaginosis.In the female a HVS was taken for microbiological analysis with help of a qualified nurse. Pus swabs were taken from the base of ulcers for microscopic examination and culture.

All samples reached the laboratory in one hour and where necessary were stored appropriately under desirable conditions to preserve them prior to transport to the laboratory for analysis.

Patients were fully counseled for any procedure. Blood samples were transported in EDTA bottles to the laboratory.

Analysis in designated laboratories was carried out by qualified technicians in microbiology for the microbiology samples and by technician immunologist for the viral load and CD4 counts.

CLINICAL METHODS:

For each of the recruited couples, history with details of the following was undertaken. Each partner was interviewed and physically examined separately once the couple were recruited as per the study inclusion criteria. Data obtained information such as:

- Demographics (Age, Gender, Marital Status, age at marriage, area of residence, formal education, Migration status, Occupational history).

  Alcohol and other psychotropic drugs taken.

  Duration of sexual activity in marriage: Past marital history e.g divorce or separation.

- History of sexual behaviour was elicited by inquiring separately from the partners the following:

  The average frequency of sex they usually had in a week was obtained; nature/route of the sexual intercourse; barrier methods used during sexual intercourse and consistency in use of such preventive methods both pre and post notification of their sero-status; intercourse during menstruation; History of extra-marital sex and condom use in such instances;

  The number of children the couples had pre and post notification of their sero-status was obtained.

- Whether on HAART or any form of secondary prophylaxis against opportunistic infections if already HIV state is known.

- History of sexually transmitted illness in last 6 months was obtained in keeping with the study's case definition for STI(page 26) .

- We obtained history of blood transfusion in last 2 years; Intravenous drug use and sexual risk behaviors.

- We inquired into any past History of persistent chronic cough or TB ,jaundice, loss of appetite, chronic diarrhoea, weight loss body rash, oral lesions,

Physical Examination was carried out individually on each couple in confidentiality.It entailed:

- General Examination

- Weight measurement in Kilograms using standard weighing scale.

- Examination of the genitalia for any ulcerations; significant medial inguinal node enlargement, discharges: circumcision status of the male patient was noted at that point

- Systemic examination of the patient was done thereafter.(Appendix I)

LABORATORY METHODS

Seven milliliters sample of blood was taken from the ante-cubital vein for analysis using a ten milliliters syringes and a gauge 21 needles.The sample was used to determine the viral load and CD4+ cell counts.

CD4+ CELL COUNT

Blood was transported to the laboratory in EDTA bottles and reach there within five hour of collection. CD4+ count was determined by the automated flow cytometry analyzer (appendix III). All subjects will be categorized by their immune status according to the CDC 1993-revised classification of system for HIV infection by CD4-+T cell categories. (Appendix IV)

URINE/URETHRAL DISCHARGE ANALYSIS-Patients collected a mid stream urine sample in a sterile bottle after proper instructions on the technique .Swabs specimens from genital discharges were collected.

Microscopy was done on a centrifuged urine sample and /or urethral discharge:

White Cell Count analysis on the sample was done. Samples were reported suggestive of UTI with the finding of more than 5 pus cell/high power field on microscopy and isolation of organism on culture.

Gram Stain of the centrifuged urine sample was done to look for causative organisms for STI (appendixIII)

PUS SWAB ANALYSIS

A Swab was obtained from bases of ulcerative lesions and exudative genital lesions using standard technique avoiding contamination:

In male partners ,a urethral swab was taken if discharge was present.

Female partners had a high vaginal swab taken by help of a female chaperon nurse using a speculum. Delivery of samples stored under ambient conditions to laboratory for microbiological assay was done within 1 hour.(Appendix III)

HIV-1 VIRAL LOAD

This was carried out in the immunology lab at KNH and KEMRI laboratory by use of RT-PCR kit , amplicor HIV-1 monitor test V1.5 manufactured by Roche.

The RT-PCR method is based on five major processes to establish viral load in a sample of blood: Specimen preparation, Reverse transcription of target RNA to generate complimentary DNA(cDNA), PCR amplification of target cDNA ,Hybridization of the amplified product to oligonucleotide probes and Detection by colometric determination .It has a limit of detection of 400-750000 copies of HIV-1RNA per milliliter.   (Appendix III)

STUDY OUTCOME CLINICAL VARIABLES

WHO HIV STAGE, CD4+ CELL COUNT, VIRAL LOAD.

DEMOGRAPHICS (age, occupation, gender)

DURATION OF MARRIAGE

BARRIER METHODS LAST 6 MONTHS like use of Condoms

MALE CIRCUMCISION

SEXUAL BEHAVIOUR NATURE/FREQUENCY/HIGH RISK(appendix I)

SEXUAL TRANSMITTED ILLNESS (appendix III).

DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data was coded (open ended questions) and entered into a computer using SPSS /PC + Version 12 programme. Data cleaning and validation was done before analysis. Analysis involved descriptive statistics such as means, medians and standard deviations for continuous variables and proportions and frequency distributions for categorical variables. Study population was described in terms of age, gender, residence,migration, level of education, occupation, WHO clinical stage, CD4 count and viral load as the dependent variable. To determine association between categorical data, Chi-square was be used. Student t test was used to compare means between two dependent variables like gender, age, and duration of marriage.Mann Whitney U was used to compare differences in medians and ANOVA was used to compare viral loads and CD4+ in couples at different durations in time of marriages. Using a univariate model with partner discordance as dependent variable and CD4+,VIRAL LOAD,sexual frequency ,STI, contraception and duration of marriage as independent variables , variables that influence HIV-1 transmission dynamics in male and female discordant couples were described. Associations were measured and considered statistically at significance level set at alpha=0.05 . Results were presented in form of tables, pie charts and graphs.

ETHICAL CONSIDERATIONS

The study was undertaken after approval by the Department of Internal Medicine, University of Nairobi and the Kenyatta National Hospital Ethics Review Committee. (Appendix V)

Couples eligible to participate in the study were included after going through the consent process as outlined below:

1. The couples were informed that the project involves research.

2. They were told the purpose of the research.

3. The procedures of the study were explained clearly with full details of all the tests done.

4. They were assured that participation was voluntary. No medical attention or advice was denied to those who declined to participate.

5. The couples were informed of the medical benefits and also physical and any psychological harms to their satisfaction prior to being included in this study.

6. The couples were assured of full and free access to their results and therapeutic interventions were recommended where the need arose, according to accepted standards of practice.

7. Confidentiality was strictly maintained and all data was securely stored and only revealed upon a need-to-know basis. Following the full explanation and acceptance by the couples of the above, the partners signed a consent form on request

RESULTS:

DEMOGRAPHIC CHARACTERISTICS

Between January and April 2007 ,111 HIV -1 discordant couples were screened at the patient support center.15 couples were excluded for various reasons.4 couples were unaccompanied by their partners while the remaining 11 couples were either below the study's entry criteria age of 18 years or had been married for less than 6 months.

Couples recruited in the study were referred from ANC clinics and VCT clinics around Nairobi. Data for the recruited 96 couples was analysed.

The sex distribution for the positive partners in this study comprised of 69 female (72%) and 27 male (28%) giving a female to male ratio of 2.6:1.(table1).Amongst the negative partners ,there were 69 male and 27 female partners.

The mean age for the male positive participants was 34.33 years with a median of 34 years while the mean age for the female positive participants was 27.13 years with a median of 26 years. The mean age for the male negative participants was 34.2 years with a median of 32 years while the female negative participants had a mean age of 29.60 years with a median of 27 years. The mean age for all HIV positive participants was 29.16 years+/-7.02(95%CI27.73-30.58) with a median of 28.0 years while for the HIV negative participants was 29.60years+/-6.454(95%CI 28.30-30.91) with a median of 29 years.

DEMOGRAPHIC CHARACTERISTICS OF PARTNERS RECRUITED IN THE STUDY.(Table 1)

CHARACTERISTIC	MALE POSITIVE	FEMALE POSITIVE	MALE NEGATIVE	FEMALE NEGATIVE
NUMBER	27	69	69	27
AGE (years)				
Mean	34.33	27.13	34.20	29.60
Median	34	26	32	27
Range	30	23	29	26
Education				
No educated	6	13	18	7
Educated(primary/secondary/college)	21	56	51	20
Occupation				
Yes	11	37	33	10
No	16	32	36	17

77 HIV positive partners (80.2%) had attained at least primary education while only 71(74%) negative partners had attained above secondary education.

48(50%) positive partners were in formal employment while only 43(41%) of the negative partners were in formal employment.(table 1 above)

66 couples resided within Nairobi province while 30 were from the outskirts of the city.Majority of this couples came from the catchment area of PSC in Kenyatta National Hospital where the study was carried out.

Among the 96 couples, 15(16%) had been in previous marriages with outcomes of divorce(1%), separation(13.5%) or being widowed(1%)..In our study, all 96 couples were in a heterosexual relationship.In the study population,97%(93 couples) were in a monogamous relationship.

6 couples had children after the notification of the HIV sero-status of the positive partner.In this couples, 4 female were HIV positive.

The mean duration of marriage for the 96 couples was 5 years with a range of 15 years and median of 4 years.(table 2).Comparison of mean duration of marriage between the male and female positive participants was statistically significant,p=0.007.

Table2 ;duration of marriage in years for the study's couples.

Duration of marriage in years	Minimum	Maximum	Median (years)
	1	16	4

Eighty six couples had children in their current relationship. The mean number of children per household was 2.42 with a median of two, minimum of zero and a maximum of seven children.

Six couples had children after the notification of their sero-status. These couples were pregnant at the time of the diagnosis of the HIV state.

50 couples (52.1%)stayed together for most of the time under one roof.33 (34%) were staying away from home for more than a week but less than a month while the remaining 13 (14%)stayed away from their partner for more than a month in the month preceding the recruitment into the study.

WHO CLINICAL STAGE OF HIV DISEASE IN THE POSITIVE

PARTICIPANTS:

Overall ,88.6% of HIV positive partners were in WHO stages 1 and 2 .Of these

21(22%) were male and 64(78%) were female partners.Only 11% of positive

partners had advanced clinical stage of disease(stage 3,4). (figure1).
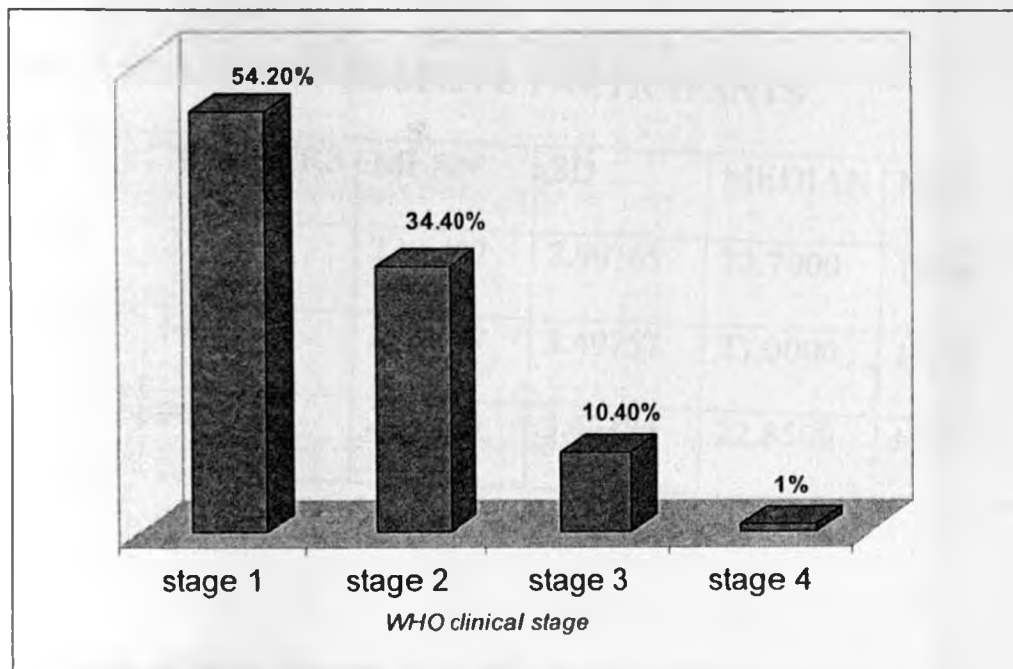
Figure 1 WHO clinical stage distribution for the couples

The mean BMI for the male positive partners was 22.64 compared to 22.61 for the

female positive partner.(table 3).Both current and past illnesses identified in the

partners and which are included in the WHO clinical staging Aids defining

illnesses(ADI) were used to classify study subjects into the various WHO clinical

stages.The most common Aids defining illness in the HIV positive partners were

lymphadenopathy 28.1%, mucocutaneous lesions 19.7%,old herpes zoster scar

14.6% recurrent URTI 12.5% and past history of pulmonary TB in the year preceding recruitment into the study. 12% had recorded weight loss of more than 10%.(table 4).

Table 3 BMI OF HIV POSITIVE PARTICIPANTS

SEX	NUMBERS	MEAN	SD	MEDIAN	MIN	MAX
MALE	27	22.6407	3.99165	22.7000	15.60	28.9
FEMALE	69	22.6109	3.49757	23.0000	17.20	29.00
ALL	96	22.6193	3.62176	22.8500	15.6	29.0

Table 4 Aids defining illnesses in the HIV positive study subjects.

Wasting	12%	Mucocutaneous lesions	19.7%
Fever	4.2%	Recurrent URTI	12.5%
Oral thrush	5.2%	Jaundice	0%
Lymphadenopathy	28.1%	Chronic diarrhoea	2%
Herpes zoster scar (old)	14.6%	Kaposi sarcoma	0%
Pulmonary tuberculosis.(past) 7.2%		PJP	0%

Male circumcision status was present in 77 (80.2%) out of the 96 male participants in the study. Of these 22 were HIV positive while 55 were HIV negative.

CD4+ CELL COUNT AND VIRAL LOAD IN THE POSITIVE PARTICIPANTS:

The mean CD4+ cell count in the positive partners in the study was 446.08.(95% CI 405-489).The minimum cell count was 107 with a maximum of 978 cells per microlitre of blood. Mean CD4+cell count was 407 cell per microlitre in male positive against 445 cells per microlitre.in the female positive participants.Partners with multiple sexual partners tended to have a lower CD4+ cell count compared to their counterparts without history of multiple sexual partners in the preceding year(table5).The CD4+cell count depicted a trend towards worsening with progressing age of the patient comparing the youngest age bracket between18 and 25 years and over 41 (table 6).The difference in CD4+ cell count between male and female was not statistically significant.(p=0.973)(table 7)

Table 5 .COMPARISON OF CD4+CELL COUNT IN THOSE WITH/WITHOUT EXTRA-MARITAL AFFAIRS .

MULTIPLE SEX PARTNERS	MEAN	STD DEVIATION	MINIMUM	MAXIMUM	MEDIAN
YES	405.74	168.27	107	744	361
NO	461.86	211.60	112	978	417

Table 6. CD4+ CELL COUNT IN DIFFERENT AGE GROUPS.

AGE GROUP	MEAN	STD DEVIATION	MINIMUM	MAXIMUM	MEDIAN
18-25	466.3824	200.8607	173	817	474
26-33	423.7778	186.923	114	744	378.5
34-40	476.2105	231.322	112	978	497
41+	380.4286	202.187	107	685	361

Table 7 .CD4+CELL COUNT IN MALE AND FEMALE PARTICIPANTS.

SEX	MEAN	STD DEVIATION	MINIMUM	MAXIMUM	MEDIAN
MALE	407.1852	184.35147	107	744	478
FEMALE	455.6522	208.58168	112	978	400

P VALUE=0.973) t-0.033

The mean viral load was 11447.19 copies per ml.Minimum   level was unrecordable   meaning less than 400 viral copies   per mililtre present were undetected by the assay method used.In view of the fact that the RT-PCR machine used had a minimum detection level of 400 copies per milliliter, a value of 399 was used in analysis of those samples with undetectable viral load..The maximum viral load was 115560 copies per ml.of blood The range was 115161   with an interquartile range of 10927.50.The median viral load for the whole positive group was 4505 copies per mililtre.Higher viral load for the male positive partners and individuals with multiple sexual partners was noted with no statistical significant differences,p=0.359,p=0.475 respectively (table 8,9).

Table 8.VIRAL LOAD IN MALE AND FEMALE POSITIVE PARTNERS

SEX	MEAN	STD DEV	MIN	MAX	MEDIAN
MALE	20074.81	10721.69	510	115560	5360
FEMALE	9045	7616.07	399	37500	3980
ALL POSITIVE	11447.19	17168.19	399	115560	4505.00

(P VALUE=0.359 t =0.921)

The difference in viral loads of male and female partners was not   statistically significant (p=0.359).

Table 9.VIRAL LOAD IN PARTNERS WITH MULTIPLE SEXUAL PARTNERS

MULTIPLE SEX PARTNERS	MEAN	STD DEV	MIN	MAX	MEDIAN
YES	8741.4815	9553.1596	399	36900	4590
NO	7413.6232	8555.7814	600	115560	3980

(P=0.475 t= 0.717)

The difference in viral loads for positive partners with extra marital sex was not statistically significant with a p=0.475.

Table 10.mean viral load at different age groups

AGE GROUP	MEAN	STD DEV	MIN	MAX	MEDIAN
18-25	6230	5773.24	600	26680	4635
26-33	7382.5	8556.13	510	31400	3580
34-40	9277.89	11049.77	900	37500	3400
41+	13384	13993.91	1200	115560	7600

There was an increase in mean viral load with advancing age .The mean viral load in the 18-25 years age bracket was 6230 copies per millilitre compared to a mean of 13384 copies per millilitre with age bracket 41 years and above.(table10)

Table 11.viral load in copies per ml at different duration of marriage

Marriage duration (years)	Mean	Number of subjects	Minimum	Maximum	Median
1-4	6861	56	399	31400	4040
5-8	8332	26	1000	37500	4020
>9	10477	14	980	115560	3950

The mean viral load was higher in positive partners who had been married for a longer duration .There was a trend towards increase in mean viral load with longer durations of marriage(table 11).

Only 5.8 % of the eligible patients (11.4%) as per WHO clinical stage were on anti-retroviral therapy for HIV infection .

SEXUAL BEHAVIOUR CHARACTERISTICS

Twenty-seven of ninety-six (28%) positive partners had multiple extramarital sexual partners in the preceding year before enrollment in the study compared to eleven of ninety-six (11%) negative partners.

Most of the partners practised safe sex with use of condoms in their extra-marital affairs(81.5% and 72.7% condom use)in the positive partners and negative partners respectively.

28.1% of partners (24 female ,3 male)had active genital discharge on examination while 6.3%(6 female) had genital ulcer disease.

TABLE12.CHARACTERISTICS OF POSITIVE PARTNER BASED ON CONDOM USE POST NOTIFICATION OF SERO-STATUS.

CHARACTERISTICS	CONDOM USE POST NOTIFICATION	NO CONDOM USE POST NOTIFICATION
NUMBER	71	25
MEAN CD4+ CELL STD DEVIATION	400.63 191.44	473 203.37
MEAN VIRAL LOAD COPIES	11883.5	10720.4
WHO CLINICAL STAGE(%) 1 2 3 4	45.1%(32) 42.3%(30) 9.8%(7) 2.8%(2)	60%(15) 32%(8) 8%(2) 0

Condom use amongst the married couples as a preventive measure in their relationship increased to 74%(71 couples) after the sero-notification of the status(table12). This was high from the initial 16.7%(16 couples) who had reported history of occasional use of condoms as means of barrier contraception prior to knowing the partners HIV -1 status.

Past history suggestive of sexually transmitted illnesses ,dysuria or genital ulcers in the preceding 6 months prior to entry in the study was32.3% in the positive partners(24 female,7 male) as opposed to 10.4% in the negative partners (6 female ,4 male)(table 13).

(Table13) frequency of past STI,dysuria and genital ulceration in the couples.

	POSITIVE PARTNER FREQUENCY	PERCENT	NEGATIVE PARTNER FREQUENCY	PERCENT
YES	31	32.3	10	10.4
NO	65	67.7	86	89.6

The yield of urine specimens for organisms on microscopic evaluation showed a mixed flora of gram positive and negative bacteria with no growth isolated for Neisseria and gardenella. Culture of urine specimen did not grow any organisms known to be transmitted sexually like gonorrhea and gardenella species.

Table 16. MICROSCOPIC ANALYSIS OF HVS SWAB

Observed organism	Frequency
Gram negative bacteria	33
Trichomonas vaginalis	11
Gram positive bacteria	19

COMPARISON OF RISK FACTORS FOR TRANSMISSION BETWEEN

MALE AND FEMALE POSITIVE PARTNERS

Table 17 risk factors for intra-couple infection in male and female positive couples.

Variable	Male positive (n=27)	Female positive(n=69)	Statistical test of difference in variables between male and female positive partners
Number of sexual partners			χ2=2.747: 2df p>0.05
<2	18.5%	15.9%	(0.253) no significant
2-4	29.6%	47.8%	difference
>4	51.9%	36.2%	
Duration of marriage (yrs)			**χ2=9.926: 2df P<0.05**
1-4	33.3%	68.1%	**(0.007) significant**
5-9	40.7%	21.7%	**difference**
>9	25.9%	10.1%	
History of male circumcision			χ2=0.038: 2df p>0.05
Yes	81.5%	79.7%	(0.845) no significant
No	18.5%	20.3%	difference
History of STI			χ2=0.019: 2df p>0.05
Yes	33.3%	31.9%	(0.891) no significant
No	66.7%	68.1%	difference
WHO clinical staging			χ2=4.296: 2df p>0.05
Stage 1	48.1%	56.5%	(0.117) no significant
Stage 2	26.9%	36.2%	difference
Stage 3 & 4	**22.2%**	7.2%	

The following variables were used for comparison of risk factors for intra-couple transmission of HIV between male and female: viral loads ,CD4+ count and WHO clinical stage of disease.Cofactors for HIV transmission like STI ,duration of marriage ,high risk behaviour like having multiple sexual partners and factors related to the sexual act like frequency of sexual contact and use of condoms were also analysed.(table17)

Female positive partners tended to have better mean CD4+ cell count(table7) and a mean viral load lower than their male positive partners(table8). This however was not statistically significant P=0.973,P=0.359 respectively.

Mean duration of marriage at entry into the study was 4.3 years in couples where the female was HIV positive . The proportion of female positive with discordant partners dropped from 68.1% in the first 4 years to 10.1% in the duration of marriage exceeding 9 years.This was statistically significant (p=0.007).This trend was static in the male positive partners 33.3% in the first 4 years to 25.9% after 9 years duration of marriage.(table17)

TABLE 18 FREQUENCY OF SEX BETWEEN MALE AND FEMALE POSITIVE PARTNERS AND THEIR NEGATIVE SPOUSES.

EX	MEAN	MEDIAN	SIGNIFICANCE P VALUE (Mann Whitney U test)
ALE	2.11	2.00	0.038
EMALE	1.77	2.00	
LL	1.86	2.00	

The median frequency of sex was twice in a week in both couples where male and female were positive with HIV disease.

Female positive partners had a mean weekly frequency of sexual intercourse of 1.77.(79.7 %) with their negative husbands.This was lower than the male mean frequency of 2.11. The difference between these two groups was statistical significant(p=0.038).The frequency of sex in a week was lower in positive partners with advanced WHO clinical stage and lower CD4 cell count.

The proportion of circumcised men in the study was high in both male positive(81.5%) and negative partners(79.7%). Circumcision as a protective factor against transmission to male partners did not differ significantly

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between the two groups where male and female were positive partners (p=0.845) .

Majority of positive partners were in stages 1 and 2 WHO clinical stage. Only 7.2% of female positive participants were in advanced stages 3 and 4 compared with 22.2% in the male positive participants.There was no significant difference in the two groups despite a three times higher proportion of male positive in advanced stage than female(22.2% versus 7.2%,p=0.117)

Condom use in extra-marital sex for the positive partners was high in both male and female partners with no significant difference. There was no significant difference in STI rate in these 2 groups (p=0.891).

DISCUSSION:

HIV discordance is common in a heterosexual relationship and this places the negative partner in such discordant relationships are at 10% annual risk of acquiring HIV infection.(45)

Several studies in Africa which have looked at HIV-1 transmission dynamics in this population of married couples have analyzed factors that affect intra-couple transmission of HIV like viral load , presence of STI,duration of marriage,use of condoms , frequency of sexual intercourse and migration.(12,34,49).

In this cross-sectional study, we aimed to determine the clinical and pathological characteristics of the discordant couples at presentation and to compare factors known to influence transmission of HIV between the male and female positive partners. Such factors may suggest gender differences in transmission and help explain why the negative partner fails to acquire the disease.

The female to male ratio of partners who were positive was 2.6:1.This is in contrast to findings in other African studies. Quinn and Gray in two different community based studies in Rakai in Uganda found female to male ratio of 0.8:1 in their studies (34,39).Pablo Barreiro in Spain looked at natural pregnancy in discordant couples on HAART and found a female to male ratio of 0.6:1 (68).The difference in gender ratio found in this study may have been due to selection bias in our study as most of the study participants were referred from ANC and VCT clinics around Nairobi whereas the

other studies were community based.This finding is further confounded by the fact that whereas most women get to know there HIV status during child birth and antenatal care, most male clients attending VCT centers are asymptomatic.Similarly,the seroprevalence of HIV in the general population is higher in female.HIV virus is also easily transmitted from male to female .

Our study participants were in their reproductive age with a median age of 34 years and 28 years in male and female respectively.This is the expected age bracket of majority of the VCT and ANC clinic attendees. Our age distribution is comparable to other couples studies on discordant couples in African which had the same age distribution consisting of ages 25 -39 years bracket (34,45,70).

The overall reported sexually transmitted illness incidence in this cross sectional study was low and probably is protective against HIV transmission in the negative partner .This compares with the findings in the Rakai study by Quinn and colleagues (34) which failed to show an STI cofactor in transmission of HIV .In that study, other than genital ulceration, presence of STI, which had a low incidence, did not affect HIV transmission in discordant couples.

The mean number of children was 2.42 with a median of two. This compares to other studies with mean number of children ranging from 1.7-2.1(14,45).Six couples who had

children after notification of their HIV status may have been pregnant at the time of sero-notification during routine ANC follow-up of the female partner. Discordant couples have also been known to have children without seroconversion especially if the transmission factors are low.(45)

Most of the couples were in their first marriage and resided with their partners. Long term migration (>1 month) was reported in only 14% of the couples. In a South-African study (47), migrating couples were 3 times more likely to be in a discordant relationship. Male were predominantly long term migrants in our study due to employment away from home.However,migration as a factor did not affect discordance significantly in our study.

HIV positive patients with early stage disease (Stage 1,2) have a better immunity and a lower viral load count than those with advanced disease.A lower viral load decreases the probability of viral transmission during sexual intercourse(34). 88.6% of our positive partners were in WHO class I and II. In those with advanced disease (stages III and IV),22.2% were men compared to 7.2% female suggesting that the women are the reservoir of disease. By the time women have advanced stage of disease(stage 3 and 4), majority would have passed on the disease to their husbands,hence the low number (7.2%)of female seropositive in discordant couples at that stage. Physical examination findings classifying positive partners into different WHO clinical stage of HIV disease did not differ from those of Mehendale et al in Pune ,India(46) who found the same

presentation but at a higher proportion when they looked at discordant couples in that population

Mean CD4+ lymphocyte cell count was 446 cells per milliliter cubed with a mean HIV -1 viral load of 11,447 copies per milliliter. There was no statistical difference in the CD4 and viral loads based on gender, presence of multiple sexual partners and age. Male positive partners tended to present late with advanced disease explaining their high viral load compared to female positive obtained in this study.Randomised control trials done in Uganda(34) looking at the role of viral load in transmission of HIV expectedly showed that a lower plasma viral load in a partner protected the negative partner in a couple from HIV acquisition. This may have been due to a lower virus load in genital secretions in the female and semen in male.There were no transmissions at 1500 or less viral copies. In that study,done in the pre –HAART era,male had a higher mean viral load than women.(59,591 compared with 36,875 copies per ml).The mean viral load was higher than that in this study and would probably explain the lack of HIV transmission to the negative partner in our population sample.

Male circumcision was high in this couple study group. Circumcision has been extensively studied as one of the factors that confer protection against the transmission of HIV to the male partner.The inner mucosal surface of the human foreskin ,exposed upon erection ,has nine times higher density of HIV target cells(langerhans,CD4+ cell and macrophages) (39,70).This could partly explain the protection conferred to the

negative male partner.There was no statistical differences in the circumcision status of the male positive and male negative (81.5% versus 79.5%).

Reported genital ulcer disease was lower with a prevalence of 6.3% in this study. Epidemiological studies have associated the presence of genital ulcers with high transmission of HIV virus between partners(33,34).Such patient tend to have an increased number of cell with receptors that aid in attachment and entry of the virus in the body. Other studies have found higher prevalence(14.3%) of GUD in couples who are discordant.(46)Increasing use of antibiotic especially over the counter in urban set-ups has led to an overall decline of this disease and this may explain the figures obtained in this study.

Use of preventive measures increased after notification of HIV sero-status from 16.7% to 74%.Male condoms were the main preventive technique used.ANC and VCT studies have shown increased condom use in partners after notification of the status.(15,57,66).Twenty five percentage of couples did not use protective devices despite counseling on the risk posed to the negative partner.These couples ,who did not report condom use,had better mean CD4+ cell count(473 cells) compared to the partners who embraced condom use(400 CD4+cells).92% had early stage HIV disease based on the WHO classification as opposed to 87% in their counterparts on condom use. There was no significant differences in the mean viral loads of the two groups(11883.5 copies in those with condom use versus 10720.4 viral copies).

STI prior to enrollment(reported) was low in the negative partners than in the positive partners(10.4% versus 32.3%).Laboratory analysis of specimens for causative organisms of STI were low in yield signifying a lack of a significant STI cofactor in this couples. Many confounders like antibiotic use, recall bias of the patient may have contributed to this low results.

The average frequency of sex (2.11per week in male positive and 1.71per week in female positive) in the couples did not differ from that found in other African studies(mean 8.9 per month) (12).The mean sexual frequency showed a tendency towards a decline with age and increasing viral load of the positive partners and WHO clinical stage.This could suggest that probably the positive partners get too ill with advanced disease to perform any sexual act. This further correlates with the finding of more male positive partners (22%)in advanced stage of HIV disease in the study.

This study brings out important characteristics among both male and female positive partners that seem to explain the low level of transmissibility of the HIV -1 virus to their negative partners partner,findings which have been reproduced in other studies(34,70).

Male negative partner seems to be protected by the fact that their partners had a low viral load (mean 7045.94 copies/ml),low frequency of weekly sexually contact(1.77/week) significant condom use post notification in marital and extra -marital affairs may also aid in protection.Their positive partners had a mean CD4 cell count of

445 cell per microlitre and a better WHO clinical stage of disease putting them at a lower transmission rate for HIV .

Female negative partner seems to be protected by the low frequency of sexual intercourse (2.11/week),their lower rate of current STI, and post notification condom use.Their partners had a mean viral load 20074.81copies/ml with 22% having advanced disease based on WHO clinical staging . This findings are comparable to Malamba et al study in VCT setting in Uganda.(70)

STUDY LIMITATIONS

- This was a hospital-based study with a biased sample and its findings may not be representative of the characteristics of all discordant couples seen nationally .

- This study was not investigating causes of discordance in the partners hence associations established may not have causal effect with HIV discordance.

- Only one blood sample was taken to rule out HIV in the negative partner by a rapid test. This may have resulted in recruitment of some negative partners in the window period of HIV disease without a confirmatory test.

- Some data especially sexual history data and past history given by the couples for analysis may have been under/overestimated due to recall bias.

- Viral clades and co-receptor polymorphism studies were not done.

CONCLUSIONS:

1.Most positive partners in the couples were in early WHO clinical stage of disease.

2.Women predominate men as the positive partners in the couple.Couples are mostly in the reproductive age.

3.Most of the female positive partners had a low viral load and a favorable CD4 cell count than male positive partners.

4.There was a low incidence of sexually transmitted illnesses in the couples despite high risk sexual practices in both male and female partners.

RECOMMENDATIONS:

1.Further studies to confirm findings at a wider scale and delineate viral and host factors that determine discordance in couples are needed and more so to look at molecular factors at the cellular level that protect the negative partner from acquiring the disease. .

2.Enhance counselling and awareness programmes on condom use and high - risk behaviour change by the couples after sero-notification of HIV status.

3.Close follow–up of discordant partners for timely initiation of HAART which augments protection of negative partner.

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QUESTIONNAIRE FOR DISCORDANT COUPLES STUDY

DATE OF INTERVIEW

OUT/INPATIENT NUMBER

STUDY NUMBER

1. NAMES... AGE.............

2. SEX OF DISCORDANT NEGATIVE PARTNER

3. RESIDENCE 1) Rural 2) Urban

4 MARITAL STATUS a) monogamous

b) Polygamous

5. LEVEL OF EDUCATION 1) primary 2) secondary 3) college

6. OCCUPATION STATUS YES FORMAL/INFORMAL. NO

7 HISTORY OF ALCOHOL INTAKE YES/NO

8 MIGRATION/MOBILITY STATUS

a)None (both partners stays at home together most of the time)

b)short time mobile (less than 1 month away from home)

c)long time mobile(more than 1month away from home)

9. DURATION OF MARRIAGE (YEARS)............

10 PAST MARITAL HISTORY. A)separated B)widowed C)divorced

11 NUMBER OF CHILDREN...............LAST BORN.........

12. SEXUAL FREQUENCY IN A WEEK.............................

13.HISTORY   TICK   Yes OR   No

Contraception(includingcondoms, vaginal creams) ☐

STI in last 6 months/symptoms ☐

(rash ,itch,pain,ulcers,discharge,dysuria) ☐

Multiple sex partners(past year)

Extra marital sex contraceptive use

Blood transfusion(last 2 year) ☐

PTB treatment (last 1 year) ☐

14 Preventive strategies used:

a)condom b)abstinence c)separation in bed ☐

d)cessation of relation e)contractual agreement for outside partner

15   PHYSICAL EXAMINATION

Wasting ☐

Fever ☐

Oral thrush ☐

Lymphadenopathy ☐

Jaundice

Chronic diarrhea

Recurrent URTI

Kaposi sarcoma

Mucocutaneous lesions

Circumcision

Herpes zoster scar

Genital ulcers/ vesicles

Genital discharge

Weight................

Height.................

BMI...................

Other specific examination findings:

....

....

....

....

16 URINE characteristics

                    MICROSCOPY

                    a)Gram negative intracellular diplococci

                    b)Trichomonas vaginalis(wet mount/gram stain)

                    c)Gram positive bacteria/coccobacilli

                    CULTURE OF URINE SPECIMEN on CLED MEDIA

17. PUS/URETHRAL SWAB/HVS Characteristics

Microscopy:

a)gram positive rods/cocci b)gram negative rods c)trichomonas vaginalis

Culture for BACTERIA ON BLOOD AGAR eg Neisseria gonorrhoea....

18.CD4 COUNT......................

19 HIV-1 VIRAL LOAD....................

20   A . WHO Clinical stage of HIV

          B. HAART use   ☐

          1) Yes   2) No   If   Initial CD4   Current CD4   (If yes)

          C. CDC staging   ☐

APPENDIX II

WHO staging system for HIV infection and disease in adults and adolescents

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Clinical stage I

Asymptomatic

Primary HIV infection

Persistent generalized lymphadenopathy

Performance scale 1: asymptomatic, normal activity

Clinical stage II

Weight loss, <10% of body weight

Minor mucocutaneous manifestations (seborrheic dermatitis, papular pruritic eruption,

fungal nail infections, recurrent oral ulcerations, angular cheilitis)

Herpes zoster within the last five years(uncomplicated)

Recurrent upper respiratory tract infections (i.e. bacterial sinusitis, otitis media) in past 12 months

Thrombocytopenia not responsive to steroids

And/or performance scale 2: symptomatic, normal activity

Clinical stage III

Weight loss, >10% of body weight and/or BMI <18.5, unexplained.

Unexplained chronic diarrhoea, >1 month

Unexplained prolonged fever (intermittent or consant), >1 month

Oral candidiasis (thrush)

Oral hairy leukoplakia

Pulmonary tuberculosis within the past year

Severe bacterial infections (i.e. pneumonia, pyomyositis,bacterial meningitis, bacteraemia)

Bacillary angiomatosis

Herpes zoster: complicated(recurrent, disseminated, multidermatomal)

And/or performance scale 3: bedridden <50% of the day during the last month

Clinical stage IV

HIV wasting syndrome, as defined by the Centers for Disease Control and Prevention[a]

Pneumocystis carinii pneumonia

Toxoplasmosis of the brain

Cryptosporidiosis, Isosporiasis, Microsporidiosis with diarrhoea >1 month

Cryptococcosis, extrapulmonary

Cytomegalovirus disease of an organ other than liver, spleen or lymph nodes

Herpes simplex virus infection, mucocutaneous >1 month, or visceral any duration

Progressive multifocal leukoencephalopathy

Any disseminated endemic mycosis (i.e. histoplasmosis, coccidioidomycosis, Penicilliosis)

Candidiasis of the oesophagus, trachea, bronchi or lungs

Non-tuberculuos mycobacteriosis, disseminated

Non-typhoid *Salmonella* septicaemia

Extrapulmonary tuberculosis

Lymphoma

Kaposi's sarcoma

HIV encephalopathy, as defined by the Centers for Disease Control and Prevention.[b]

Invasive cervical carcinoma

American trypanosomiasis-reactivation

Major aphthous ulceration: ulcers of GI tract >5mm and for >1 month

Nephropathy

Cardiomyopathy, unexplained

Visceral leishmaniasis

Strongyloides hyperinfection syndrome

And/or performance scale 4: bedridden >50% of the day during the last month

Note: both definitive and presumptive diagnoses are acceptable.

a. HIV wasting syndrome: weight loss of >10% of body weight, plus either unexplained chronic diarrhoea

(>1 month) or chronic weakness and unexplained prolonged fever (>1 month).

b. HIV encephalopathy: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection which could explain the findings.

Fascount Machine for CD4 Count (Benedict Dick USA)

Procedure

1. Blood was taken in an EDTA K₃ sterile bottle

2. It was mixed   to avoid clotting

3. 50mcl of the blood was taken in to an already made reagents (monoclonal

   Antibodies) for CD4 and CD8 counts.

5. It was incubated for 1-2 hours to allow staining to take place

6. Fixing of the already stained samples with fixative was done.

7. Read the machine within 30min.

VIRAL LOAD ANALYSIS

Procedure

4cc of blood was collected in a EDTA bottle and sent to the lab for analysis using the RT-PCR kit manufactured by ROCHE. The RT-PCR method combines a material that gives off light with the sample after processing. This material connects with HIV particles .The amount of light is measured and converted into viral load its lowest limit of detection is 400 viral copies per millilitre of blood.

NEISSERRIA GONORRHOEA(MICROSCOPY/CULTURE).

A Gram stain for the presumptive diagnosis of *N. gonorrhoeae* infection was performed on thin smears of urethral exudate from men and was presumptively positive if the smear contained typical Gram-negative diplococci within polymorphonuclear (PMN) leukocytes. Culture isolation on blood Agar followed by oxidase testing . Gram-negative extracellular diplococci without any intracellular diplococci observed in smears from men with early symptomatic infections was taken as positive.

URINE MICROBIOLOGY

procedure

10 ml of Urine was collected in a sterile bottle and taken to the labaratory.

Specimen was centrifuged and the supernatant analysed both by light microscopy for microbiology and culture by a trained microbiologist using standard procedures carried out in the labaratory .Culture of the specimen was carried on CLED media for 24-48 hours.

PUS SWAB/URETHRAL SWAB/HVS SAMPLES

Procedure

Wet specimens were collected under aseptic methods from the bases of the ulcer or genital secretions and smeared on a slide and stained by gram stain technique then viewed microscopically for identification of bacteria ,trichomonas and fungus.

Bacterial culture of the specimens on appropriate media like blood agar for aerobic and anaerobic organisms was done for 48 hours and the organism grown identified.

HIV-1 RAPID TEST

Using an Abbott laboratory determine test kit ,whole blood or serum was impregnated on a sample pad for the detection of antibodies to HIV1/2.This test is a visualized qualitative immunoassay for detection of antibodies.It contains 10 HIV1/2 recombinant antigen and synthetic peptide coated test in the kit used.

50 microlitres sample is impregnated and the test read after 15 minutes

DIAGNOSIS OF BACTERIAL VAGINOSIS

The causative agent are small gram negative rods(Gardenella vaginalis).Presumptive diagnosis was made in a female partner with a whitish malodorous (fishy)smelly discharge, vaginal pH more than 4.5,clue cells on microscopy in the background of small gram negative bacterial rods and few or no lactobacilli.(AMSTEL CRITERIA)

CONSENT EXPLANATION

Introduction

My name is Dr. Bwire Vitalis. I am a postgraduate student pursuing a master's degree in Internal Medicine at the University of Nairobi. I am in the part II of the study. The curriculum requires that I write a thesis, which entails research collecting and analyzing data on various aspects of diseases. My research is on the baseline clinical and laboratory characteristics of HIV discordant couples. To do this I will require a thorough history and physical examination from each participant. A urine sample, swabs and venous blood samples will be required. Decency will be maintained at all stages of history taking and physical examination. The extent of discomfort (minor) during venepuncture will be explained and fears allayed.

Benefits

This study is intended to establish the patterns of presentation both clinically and pathologically in HIV-1 discordance. This will help in planning the care of couples with HIV infection in the community that utilize KNH. Furthemore it will open new avenues for research in this field. The investigation done will also help in the management of the patient

Risks

History taking, physical examination and specimen collection have no risks. Taking venous blood for analysis has some level of minor discomfort. Use of sterilized needles, and syringes with proper aseptic techniques during blood sampling will ensure no risk to the participants.

Participation

Participation in this study is purely voluntary. All information collected will be confidential. A written consent will be required. Participants have a right to withdrawal from the study at any stage. They also have a right to know results of all tests done.

Current treatment

This study will not in any way jeopardize standard treatment participants are on during the study.