DISSERTATION

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SUBMITTED BY;

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TITLE:

BACTERIAL VAGINOSIS: PREVALENCE AND VALUE OF DIFFERENT DIAGNOSTIC TESTS AMONG PRENATAL WOMEN AT KENYATTA NATIONAL HOSPITAL.

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TABLE OF CONTENTS

PICTORIAL PRESENTATIONS:

TABLES:

PIE CHARTS.....

DEFINITIONS

Bacterial Vaginosis: an imbalance in the normal vaginal flora with a reduced level of the usual predominant lactobacilli and the proliferation of various anaerobic bacteria.

Chorioamnionitis: infection of the chorion, amnion and amniotic fluid

Neo-natal death: death occurring before 28 days of age.

Pre-term labour: labour occurring between 20 and 37 weeks gestation

Pre-term premature rupture of membranes: rupture of membranes before 37 weeks and prior to onset of labour

Premature rupture of membranes: rupture of membranes prior to the onset of labour at any GA

LIST OF ABBREVIATIONS

ANC	Ante-Natal Clinic
BV	Bacterial Vaginosis
FFN	Fetal Fibronectin
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
LBW	Low Birth Weight
LMP	Last Menstrual Period
OR	Odds Ratio
PTB / L	Preterm Birth / Labour
PROM	Premature Rupture of Membranes
PPROM	Preterm Premature Rupture of Membranes
RCT	Randomized Controlled Trials
SPSS	Statistical Package for Social Scientists
STD / I	Sexually Transmitted Diseases / Infections
UON	University of Nairobi
WHO	World Health Organisation
NPV	Negative predictive value
PPV	Positive Predictive Value

DEDICATION

This book is dedicated to my loving Parents and my entire family whose love and support has brought me this far.

To my Fiancé for standing by me and encouraging me through the entire course.

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To my loving family, mum and Dad, your love and support during the programme has got me this far and my Fiancé David for always believing in me and supporting me.

To God Almighty I give thanks for everything.

DECLARATION.

This is to certify that this dissertation is my original work and no other similar study has been done in the same institution.

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ABSTRACT.

BACKGROUND

Bacterial Vaginosis (BV) is defined as an imbalance in the normal vaginal flora with a reduced level of the usual predominant lactobacilli and the proliferation of various anaerobic bacteria. [79] BV is associated with amplified risk of pregnancy losses, maternal and neonatal morbidity and mortality. Between 25% and 60% of preterm births are thought to be attributable to maternal infections, and are thus considered preventable. BV is fairly common, with a prevalence ranging from 10% to 30% in a typical obstetrical population to more than 50% in some high-risk groups.

OBJECTIVE: This was to determine the prevalence of BV and value of diagnostic tests for Bacterial Vaginosis in women attending Antenatal clinic at Kenyatta National Hospital.

STUDY P0PULATION AND AREA: A total of 190 women attending the Antenatal clinic at Kenyatta National Hospital between March and May 2011 were included in the study.

MAIN OUTCOME MEASURES: These included Prevalence of Bacterial Vaginosis and the Validity of diagnostic tests for BV (KOH Amine test, Vaginal PH, and clue cells) against the Gram stain method (the Gold standard test for diagnosis of BV).

DESIGN: This was a cross-sectional study

METHODOLOGY: The selected clients all underwent a sterile pelvic exam and were evaluated for clinical and microscopic presence of BV. The prevalence of Bacterial Vaginosis was calculated from the results. The clinical diagnosis criteria were validated against the Gram stain which is the gold standard.

DATA ANALYSIS: This was done using the Statistical Package for Social Scientists (SPSS) 17.0. Data was summarized and presented in tables, charts and graphs. Chi-square (χ^2) test and odds ratio (OR) were used to describe data.

RESULTS: Of the 190 study participants 26% were found to be positive for BV. Higher odds for BV were seen in older women, unmarried with lower education level and also in participants with prior history of STI treatment, prior miscarriage and HIV positive. Clinical criteria had high specificity of more than 95% when validated against gram stain and a low sensitivity of less than 10%. Individually Vaginal PH had the highest sensitivity against Gram stain of more than 95% while the other variables (KOH AMINE test, and Greyish Vaginal Discharge) individually had very high specificity of more than 95%.

RECOMMENDATIONS: High prevalence of BV in our population necessitates routine screening of High risk antenatal women. These include those with prior history of STI, Prior miscarriage, or positive for HIV.

Vagina PH has a very high sensitivity and can individually be used as a screening tool. Hence we should equip our antenatal clinics with PH strips which can be used for screening purposes for BV.

For diagnosis either Gram stain or Amsel clinical criteria can be used as the clinical criteria was found to have almost similar specificity as the Gram stain method of more than 95%.

INTRODUCTION

Much evidence indicates that infection is associated with preterm delivery. Most of the microorganisms isolated from the amniotic fluid and placenta in cases of preterm birth appear to come from the vagina among women with Bacterial Vaginosis.

Bacterial Vaginosis is defined as an imbalance in the normal vaginal flora with a reduced level of the usual predominant lactobacilli and the proliferation of various anaerobic bacteria. Current direction for research aimed at preventing PTL is to identify women with a subclinical infection as early as possible. Bacterial Vaginosis maybe an early infection marker as it is associated with PTL, PPROM, and Chorioamnionitis.

There are multiple areas of potential health gain for interventions for Bacterial Vaginosis. The personal health burden felt by women with BV is considerable and the long term health burden in economic, social and psychological terms is great. There are 1.2 million Neonatal deaths per year in Africa of which 23% are caused by prematurity and 27% by neonatal sepsis. Costs of treatment and management of complications associated with BV- [PTL and Neonatal sepsis] will be greatly reduced if patients are identified early and treated by screening in asymptomatic patients.

The objective of this study was to assess the prevalence of BV in our population and validate cheaper clinical diagnostic methods against the Gold standard Gram stain method. The Cochrane collaboration carried out systematic review to assess the effects of Antibiotic treatment of BV and significance on the incidence of adverse Neonatal outcomes.[1] The review studied RCTs comparing Antibiotic regimen for BV with placebo or no treatment as well as studies comparing two Antibiotic regimens among pregnant women of all ages at all stages of gestation. Three RCTs comparing women treated with oral metronidazole or placebo observed a significant decrease in the risk of PTL among the treated group.[7,8,9]

Bukusi et al (2006) in a local study of Risk Factors among Kenyan Women and Their Male partners found of the 219 women recruited and screened, 97% had BV. This population was from STD and Family planning clinics in Nairobi .The high prevalence among non-pregnant women necessitates the screening of pregnant patients in order to alleviate the adverse outcomes associated with BV in Pregnancy.[10b]

LITERATURE REVIEW

EPIDEMIOLOGY

Risk factors

Much information is known regarding the microbiology and identification of BV; however, limited information exists concerning the factors or behaviours that increase a woman's risk for BV during pregnancy. The current predictors of BV have been limited to race, sexual activity, socioeconomic status, and perhaps vaginal douching. Most of the epidemiologic studies conducted to date to determine risk factors for BV have concentrated on symptomatic cases and included results from women seeking care in sexually transmitted disease clinics or obstetric offices. Current literature is unclear since asymptomatic populations have not been examined fully and the current data represent only a subset of women of reproductive age.

Nonetheless, the reported prevalence of BV among pregnant women ranges from 10 percent to 35 percent, with higher rates occurring among African-American women, low-income women, or women with prior sexually transmitted diseases[12,] The Vaginal Infections and Prematurity Study, which measured BV among pregnant women between 13 and 36 weeks of gestation, found a 2.0 -2.5fold increased risk of BV among African-American compared with White pregnant women. [12]

Numerous studies have confirmed at least a twofold increased risk of BV among African-American women presumably due to Environmental/behavioral exposures or stressors [13,14]. Women of lower socioeconomic status and women self-reporting higher levels of psychosocial stress also have increased rates of BV. The reported prevalence of BV among obstetric populations ranged from a low of 10 percent among private patients to a high of 35 percent among women reporting low monthly incomes and low educational levels, although these studies did not adjust for race [15,16,]. Culhane et al. assessed the role of chronic maternal stress, as measured by the Cohen perceived stress scale, and found that independent of sociodemographic and behavioral factors, chronic maternal stress remained a significant predictor of BV among pregnant women [16.]

Epidemiologic studies have found early sexual activity, a high number of lifetime sexual partners, women with a new sexual partner, and women with a prior sexually transmitted disease are also at increased risk of BV [17–19].BV is more prevalent among women with a prior or current sexually transmitted disease. However, the occurrence of BV may be the direct consequence of exposure to the infectious pathogen, not the sexual behaviour. In fact, many pathogens have been shown to change vaginal flora by reducing the

concentration of *Lactobacillus* and promoting anaerobic bacteria proliferation and subsequent BV development.

Although sexually transmitted diseases and BV commonly coexist, particularly trichomoniasis and BV, BV is not considered a sexually transmitted disease. A study among school-age girls found similar rates of BV among virgin girls and non-virgin girls at 12 percent and 15 percent, respectively [20-23.]

Although the anaerobic organisms in excess in cases of BV have been cultured from the male sexual partners of women with BV, treatment of male sexual partners is not a reliable way to reduce the recurrence of BV in these women. However, a small study of monogamous lesbian women concluded that the likelihood of one partner having BV was 20 times greater if the other partner was BV positive (odds ratio = 19.7, 95% confidence interval: 2.1, 588.0), supporting the early finding by Gardner and Dukes that BV is transmissible through direct inoculation of vaginal secretions [24-26].

Some behaviours, such as vaginal douching, have been examined as potential risk factors for BV. Among non-pregnant woman, self-reported vaginal douching has been reported to increase the risk of BV. Holzman et al. found more than a two-fold increased risk of BV among non-pregnant women who self-reported vaginal douching in the prior 2 months [27,28].

No known studies have been published to date examining the role of douching and BV development among pregnant women. Vaginal douching may change the vaginal flora, reduce the amount of *Lactobacillus*, and create an environment promoting excessive anaerobic growth; on the other hand, the act of douching may be a consequence of the symptoms of BV (i.e., vaginal discharge and odour) or a current sexually transmitted disease [27,28].

Diagnosis and screening of Bacterial Vaginosis:

Two methods for diagnosing BV are the clinical criteria of Amsel et al. and Gram stain. In 1983, Amsel et al. proposed that clinical diagnostic criteria for BV be standardized to three of four of the following: vaginal discharge pH > 4.5, homogenous discharge adherent to the vaginal wall, amine 'fishy' odour immediately on mixture of discharge with 10% KOH solution, or clue cells.

The reliability of these clinical signs in community practice especially in obstetric practice is unknown. Measurement of pH in the vagina varies by whether the sample is taken from a vaginal wall, the vaginal fornix, or the cervical os, with the cervix having a higher pH than the vagina. The specificity of homogenous discharge in pregnancy has been questioned because many pregnant women experience increased vaginal discharge.[29,30] Clue cells are frequently used in clinical practice (at times as the sole criterion for treatment) because of their high predictive value, but they are subject to inter-observer

variation.[31] Clue cells are vaginal epithelial cells that have a stippled appearance due to adherent coccobacilli .The edges of the cells are obscured and appear fuzzy compared with the normally sharp edges of vaginal epithelial cells. To be significant for bacterial Vaginosis, more than 20 percent of the epithelial cells on the wet mount should be clue cells. Recently, test kits with simple indicators, such as plus signs for pH > 4.5 and presence of amines, have been marketed in attempts to improve reproducibility.

Gram stain of vaginal discharge is a more reliable means of diagnosing BV and offers the added ability of quantifying and classifying bacterial load.[32 , 33] Gram stain has moderate sensitivity(62%) and positive predictive value(76%), but excellent specificity (95%) and negative predictive value (92%) . For these reasons, Gram stain has been the primary means used to diagnose BV in epidemiologic and treatment studies.

The economical advantage of any medical screening and treatment is always a consideration. Is there economical benefit of screening and treating women with bacterial Vaginosis? A clinical study was conducted in Germany (Muller et al, 1999) to estimate the economical impact of screening and treatment in comparison to no screening for, and no treatment of, Bacterial Vaginosis during early pregnancy. In three different gynaecologic practices in Berlin, 300 consecutive pregnancies were studied. Patients were screened for BV identifying clue cells on a wet mount. The presence of clue cells is the single most reliable predictor of BV (Sobel, 1997). Practice A treated the 63 (21%) positive cases of BV with clindamycin 2% vaginal cream. Practice B treated the 62 (20.7%) positive cases with a lactobacillus preparation. Practice C did no screening. Total cost of delivery: Practice A-$493,159, Practice B-$497,619, and Practice C-$534,926. The net savings per delivery for Practice A, as compared to Practice C was $168. Costs applied to the clinical outcomes were determined from standard German references and the charges from university clinics. Factors that influenced the cost associated with BV included the cost of preterm labor, preterm birth, low birth weight and other perinatal complications.

Previous literature reviews clearly support the fact that bacterial vaginosis is a most significant cause of prematurity. Efforts to find the right test, the most accurate and affordable test, and a test that can be easily implemented by clinicians to identify genital tract infections in order to reduce the number of premature infants continue. In this study we validated each of the Amsel criteria components against the gold standard gram stain to see which would be most appropriate screening tool.

Adverse Pregnancy Outcomes

BV is very prevalent among reproductive-age women, but, for a common condition, the subsequent risk of adverse pregnancy outcomes is marginal [34].

The finding of a relatively low risk for a variety of events may in fact be due to the imprecise definition of exposure. BV is a syndrome with degrees of positivity. The current literature has examined the relation between BV positivity and health outcome, but no known studies have examined the organism-specific risks for disease. In addition, it is unclear whether BV is the risk factor for disease or whether exposure to BV or the various microorganisms causes inflammatory changes that are the necessary event predicting adverse outcomes.

It is known that BV diagnosed from the lower genital tract has been related to

- An increased potential for other vaginal pathogens to gain access to the upper genital tract.
- The presence of enzymes that reduce the ability of leukocytes to reduce infection..An increased level of endotoxins stimulating cytokine and prostaglandin production[35-40].

Imseis et al. reported higher vaginal levels of interleukin-1 beta, an inflammatory cytokine, among pregnant women with BV, and Spandorfer et al. found higher levels of both cervical interleukin-1 beta and interleukin-8 cytokine levels among non-pregnant women with BV[41'42].

More research is required to define BV exposure and to outline the inflammatory consequences of BV exposure and risk of adverse pregnancy outcomes. The vast majority of epidemiologic research designed to examine the role of BV and adverse pregnancy outcomes has focused on the risk of preterm delivery. These studies have consistently shown a twofold increased risk of preterm delivery among women diagnosed with BV, particularly BV diagnosed in the early second trimester [41,42].

A meta-analysis reviewing studies examining the role of BV and the risk of preterm delivery reported a summary odds ratio of 1.6, indicating a 60 percent increased risk of preterm delivery among pregnant women with BV. A smaller number of studies have assessed the relation between BV and the outcomes of premature labour, low birth weight, and premature rupture of the membranes. One study examining several pregnancy outcomes related to BV diagnosed during the first trimester of pregnancy reported a 2.6-fold increased risk of preterm labor (95 percent confidence interval: 1.3, 4.9), a 6.9-fold increased risk

of preterm delivery (95 percent confidence interval: 2.5, 18.8), and a 7.3-fold increased risk of preterm, premature rupture of the membranes (95 percent confidence interval: 1.8, 29.4) . Another study found that BV diagnosed in the second trimester was associated with an increased risk of preterm delivery and premature rupture of the membranes and that BV accounted for 83 percent of the attributable risk for preterm birth [43]

A growing body of literature has begun to suggest an increased risk of spontaneous abortion among pregnant women with BV [44,,45.] Studies have reported a three to fivefold increased risk of spontaneous abortion amongst pregnant women with BV in the first trimester, although these studies were hampered by small sample size [45].

Two additional studies among high-risk pregnant women also reported an increase in spontaneous abortion among women diagnosed with BV [46,47,] . A study enrolling women undergoing infertility treatment found more than a twofold increased risk of spontaneous abortion among women with BV after adjustment for maternal age, prior live birth, and self-reported cigarette smoking (relative risk = 2.67, 95 percent confidence interval: 1.26, 5.63) [46].

Associated outcomes

Many studies have identified association of BV and anaerobic vaginal flora with adverse obstetrical outcomes: premature rupture of membranes, intrauterine infection, spontaneous abortion, and PTL.[44, 45.]BV is further associated with ascending genital tract infection as evidenced by its association with preterm premature rupture of membranes (PPROM), low birth weight (LBW), chorioamnionitis, and postpartum endometritis.[44], [45], [46] and [47] Despite the identification of such associations, the mechanisms leading to the pathology associated with BV infection have yet to be elucidated. Multiple regression analysis has demonstrated that the diagnosis of BV in the first 16 weeks of gestation is associated with a 5-fold increased risk for both late miscarriage and preterm birth; this association was found to be independent of potential confounders: smoking, African-American race, and history of PTB.[69]

Previous observational studies demonstrate associated risk of PTL (i.e. onset of labor prior to 37 weeks' gestation) with vaginitis and suggest that such risk may be prevented. Notably, the Prematurity Prediction Study (n = 3000 women in the USA) showed a strong relationship between BV and subsequent preterm delivery. Recent data demonstrated a 25% incidence of BV in women with

preterm delivery versus an 11% incidence of BV in women delivering at term; this significant difference (P = 0.024) along with an odds ratio (OR) of 2.63 for

PTB with BV ,clearly suggests both causation and need for further investigation regarding the pathogenesis and need for effective interventions.[73]

BV infections present before 16 weeks' gestation pose the greatest risk for PTL (OR: 7.55), which may be indicative of a critical period during which BV can gain access to the upper genital tract, setting the stage for subsequent PTL.

Infection is universally accepted as a risk factor for both PTL and LBW. Evidence of infection from microscopic evidence, microbial cultures, or inflammatory markers (e.g. cytokines in the amniotic fluid or membranes) is often associated or occurs concurrently with onset of PTL and PPROM; this association has an inverse relationship with gestational age.

Because the microbes from the vagina have the most direct access to the amniotic fluid, Bacterial Vaginosis poses a threat for the development of chorioamnionitis. Both failure of tocolytic drug therapy and preterm delivery are strongly correlated with the diagnosis of chorioamnionitis. Hence, the onset of PTL associated with BV is thought to arise from its ability to trigger inflammation of the amnion and decidua and, thus, activate pathways of labor.[74] and [75]

High concentrations of lactobacilli demonstrate an inverse relationship with not only growth of BV-associated organisms but also with BV-associated adverse obstetrical outcomes. Substances produced by BV-related organisms are thought to play a role in tissue damage and stimulation of pro-inflammatory cytokine release leading to PTL/PPROM; these substances include sialidase, collagenase, elastase, mucinase, phospholipase, and protease.[75]

Evidence of such claims has been supported by the increased expression of interleukin (IL)-1, IL-6, IL-8, tumor necrosis factor (TNF)-α, prostaglandin (PG) E_2, and $PGF_{2\alpha}$ observed in the amniotic fluid of BV-positive women having PTL.[71] BV infections and the resulting inflammatory response triggered is not only an obstetrical and gynaecological problem that manifests as PTL, chorioamnionitis, postpartum endometritis, and vaginal pruritus, rather, BV infections also present paediatric concerns.

The inflammatory cytokines (e.g. IL-1, IL-6, IL-8, TNF-α, PGE_2 and $PGF_{2\alpha}$) associated with BV diagnosis demonstrate clear roles in both inflammation and infection. Elevated expression of inflammatory cytokines measured in amniotic fluid correlates with common morbidities of PTL – cerebral palsy, periventricular leukomalacia, and bronchopulmonary dysplasia. Preterm neonates born to mothers with BV have higher rates of both inflammatory cytokines and the aforementioned morbidities of PTL.[77], [78], [79] and [80]

Conceptual framework:

Theoretical;

BV represents a polymicrobial infection characterised by an overgrowth of bacteria normally found in the vagina. Lactobacilli, the dominant vaginal bacteria are replaced with anaerobic bacteria. It is the most prevalent form of vaginal infections of reproductive age women. Although it is an infectious disease, as many as 40% of women will be asymptomatic (ACOG 48th clinical meeting 2000). Incidence varies in different patient populations being highest in patients visiting STD clinics (32-64%), 12-25% in other clinic populations and 10-26% in obstetric populations (Association of professors of Gynaecology and Obstetrics APGO, 1996)

BV has been associated with PTL and delivery and other adverse pregnancy outcomes and perinatal complications. Awareness of risks related to BV during pregnancy has led to numerous studies on screening and treatment of pregnant women for BV as a method to reduce the adverse outcomes.

A good screening test has two requirements to be considered effective;

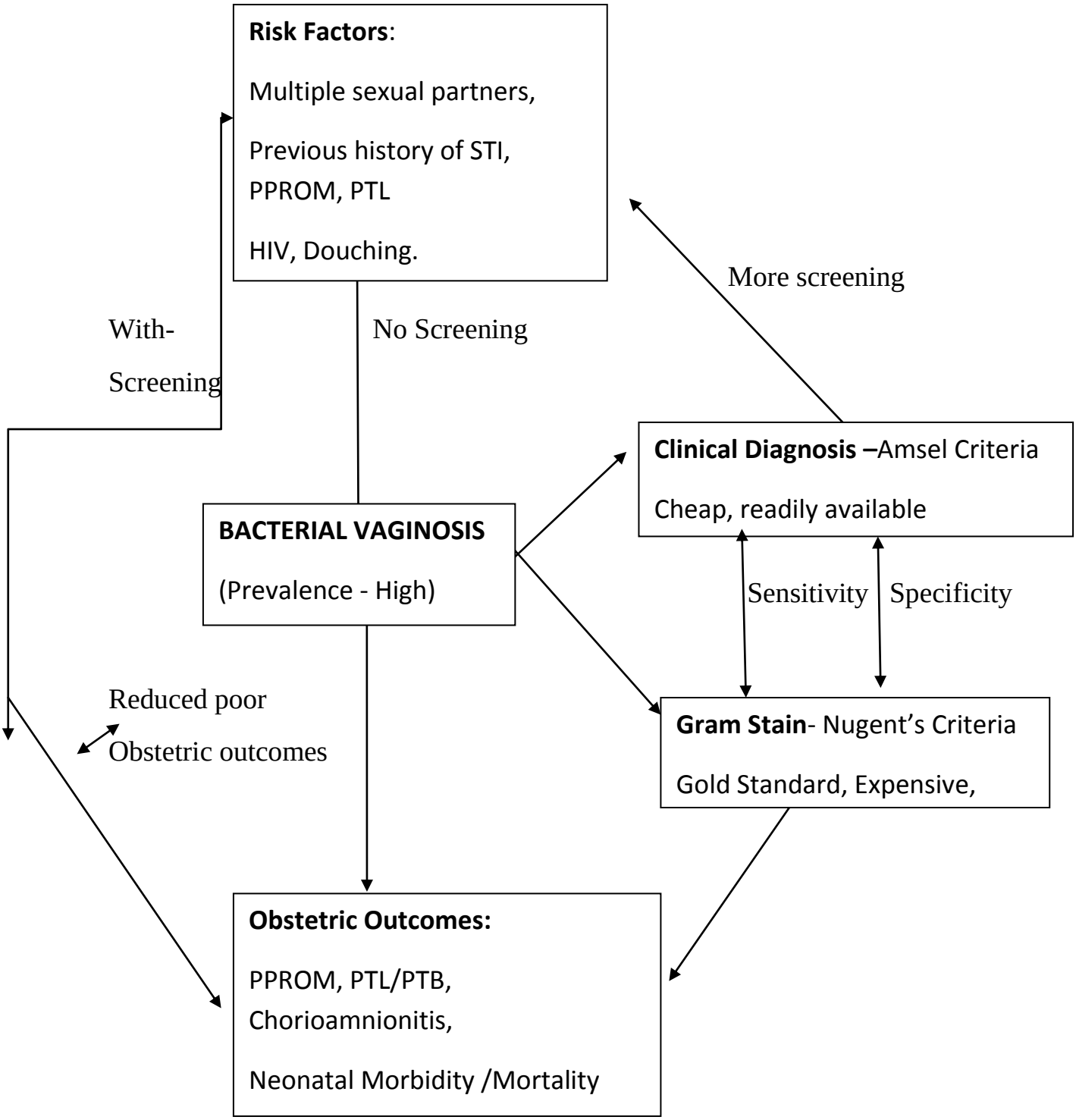
Accuracy of screening test

Effectiveness of early detection

This study focuses on Prevalence and accuracy of screening and diagnostic tests for BV using Gram stain as the gold standard. Accuracy is measured in two indices; Sensitivity –Proportion of persons with the condition who test positive when screened. Specificity - Proportion of persons without the condition who correctly test negative when screened.

The purpose of this study was to determine how well the diagnosis of BV using Amsel clinical criteria compares to Gram stain the gold standard and ascertain the prevalence of BV in women attending ANC at KNH.

Routine screening of BV is directly proportional to pregnancy outcome. The more screening that is done the more positive the pregnancy outcomes. It is assumed here that if screening is positive for BV, then appropriate treatment is initiated which should decrease the adverse pregnancy outcomes which in turn decreases the cost factors, morbidity and mortality rates for both mother and neonate.


Risk Factors:
Multiple sexual partners,
Previous history of STI, PPROM, PTL
HIV, Douching.
More screening
With-
Screening
No Screening
Clinical Diagnosis –Amsel Criteria
Cheap, readily available
BACTERIAL VAGINOSIS
(Prevalence - High)
Sensitivity
Specificity
Reduced poor
Obstetric outcomes
Gram Stain- Nugent's Criteria
Gold Standard, Expensive,
Obstetric Outcomes:
PPROM, PTL/PTB,
Chorioamnionitis,
Neonatal Morbidity /Mortality

STUDY JUSTIFICATION

The role of the obstetrician is to help predict and prevent maternal/fetal infection/inflammation related to neonatal mortality and morbidity. Current antenatal care has not achieved primary prevention of PTL.

Most studies have focused solely on diagnosis, associated risk factors, treatment in and out of pregnancy, and outcomes of symptomatic BV. Recently reported data addressed characteristics of subclinical or asymptomatic BV. Of women diagnosed with BV during pregnancy (n = 754 of 1916 total screened), 67% were asymptomatic. These asymptomatic carriers were more likely to have a history of sexually transmitted diseases [relative risk (RR): 1.03; 95% confidence interval (CI): 1.01–1.07], greater quantity of *Mobiluncus* spp. (1.04; 95% CI 1.01–1.07), and have lower reported stress scores (0.78; 95% CI 0.67–0.89) than symptomatic BV carriers. No increased risk of adverse pregnancy outcomes were found to be related to symptomatology,

BV also significantly increased the risk of late miscarriages and maternal infections in asymptomatic patients [50] High incidence of BV (52%) was reported in developing countries [51] and European studies of asymptomatic pregnant women show BV range of 4.9% [52] to 21.9% [53].Indian studies show a wide variation ranging 11.53% to 38% [54]

Govender et al found 46%of total cases had poor pregnancy outcome with BV - Late abortions, Preterm labor, PROM are the most adverse sequelae of BV. Asymptomatic BV was shown to be equally important in risk for PTL Bacterial Vaginosis more than doubled the risk of preterm delivery in asymptomatic patients.

RESEARCH QUESTION

What is the prevalence of BV and diagnostic value of different tests for Bacterial Vaginosis in Antenatal women attending ANC at Kenyatta National Hospital Antenatal clinic?

OBJECTIVES

Broad Objective

To determine the prevalence of BV and diagnostic value of different tests for Bacterial Vaginosis in Antenatal women attending ANC at Kenyatta National Hospital.

Specific Objectives

1. To determine the prevalence of BV in women attending ANC in KNH.
2. To determine the social economic, obstetric and sexual behavioural characteristics of pregnant women attending ANC in KNH with BV.
3. To validate the value of clinical macroscopy, KOH Amine test, clue cell and vaginal PH against Gram stain in the diagnosis of BV in pregnancy.

METHODOLOGY

Study Design

This was a hospital based cross-sectional study in which the prevalence of Bacterial Vaginosis in 190 women attending ANC at Kenyatta National hospital and validity of different diagnostic tests for BV was determined.

Study Area

The study area was Kenyatta National Hospital. The hospital is a national referral and teaching hospital. It is situated in Nairobi, 4 kilometers west of the central business district. It is also the main teaching hospital for the College of Health Sciences, University of Nairobi. The hospital caters to patients from Nairobi and its environs as well as referrals from other hospitals in the country and the greater Eastern Africa region.

KNH has one Labour ward, three antenatal/postnatal wards (GFA, GFB and 1A) as well as an NBU. Patients in pregnancy above 20 weeks gestation and those who are in immediate pueperium are admitted in the antenatal/postnatal wards. Patients in labour or with conditions requiring close monitoring, such as preterm labour, are admitted in labour ward. It also has a maternity theatre for caesarean sections and other obstetric procedure.

Study duration

March 2011 – May 2011.

Study population

Antenatal women attending ANC at Kenyatta National Hospital.

Inclusion Criteria

ANC Women:

a. 14- 37 weeks gestation (confirmed by LMP-with 12 normal menstrual cycles prior to current pregnancy or a first trimester ultrasound scan).
b. Consent to undergo a pelvic examination.
c. Older than 18 years.

Exclusion criteria

ANC women with:

a. Antibiotic use in the past 2 weeks.
b. Ante partum haemorrhage,
c. Advanced pre-term labor (> 4cm dilation)/PROM.
d. Cervical cerclage.

SAMPLE SIZE:

The Fischer's formula was used to calculate the valid sample size, n: n =deff* $(z^2 * p * q) / d^2$ (1)

Where,

n – Required Sample size
Deff=design effect (set at 2)
z - Standard normal deviate at the 95% confidence level (1.96)
p – Estimated proportion of patients with bacterial Vaginosis in Nairobi (44%, =0.44)
d – Estimated margin of error / level of significance (1%.0.1)
q – (1 – p)

Substituting the values in (1) above we have,

n=189.33
=190 study participants.

Sampling procedure

A convenient sample of all women attending the ANC clinic during the study period was recruited to the desired sample size (190). Participants were consecutively conveniently picked from the clinic attendees by the investigator. The files of the participants were coded with numbers 1 to 190 and their hospital registration numbers included until the desired sample size to avoid double recruitment.

Informed consent was obtained from the women meeting the inclusion criteria above and the participants were subjected to a standardized interview conducted by the investigator and the responses coded in a structured questionnaire.

Sample collection

All participants underwent a standard speculum examination. This was a sterile procedure done by the investigator. A Cusco's speculum was used with no lubricant added except for plain water. Macroscopic evaluation of the vaginal walls for colour, amount and consistency of the discharge was noted. Thin grey homogenous discharge is characteristic for BV. A PH stick was applied on the lateral vaginal wall and the vaginal PH noted. Cervical mucus was avoided as it can cause a higher PH. A sterile cotton swab was used to obtain the discharge from the posterior fornix and placed in a sterile bacterial culture container to maintain moisture and labelled with the patient's name, for transport to the laboratory. The speculum was removed and two drops of 10% KOH added on the lower blade of the speculum for amine or "fishy "odour ("whiff test")

A clinical evaluation sheet noting the patient's name, medical record number and patients' code number, date of exam, and gestational age was filled out. A checklist of clinical findings according to the clinical criteria was filled out with the patients' details and kept in a separate folder which was kept safe by the investigator. The evaluation sheet together with the vaginal swabs were sent to the microbiology laboratory for Gram stain and evaluation. Three types of bacteria were evaluated by gram stain- Lactobacillus, Bacteroides/Gardnerella and Mobiluncus and the results graded using Nugent's criteria for diagnosis of BV. A saline wet smear was also done in the laboratory for clue cells. Clue cells are vaginal epithelial cells that have a stippled appearance due to adherent coccobacilli. The edges of the cells are obscured and appear fuzzy compared with the normally sharp edges of vaginal epithelial cells. To be significant for bacterial Vaginosis, more than 20 percent of the epithelial cells on the wet mount should be clue cells

Diagnosis: Microscopy

In the lab, the frosted edge of a glass slide was labeled with patients name and file number. A cotton swab was used to make a thin smear on the glass slide and allowed to air dry. After the smear was dried, heat-fixed, and cooled off, it proceeded as follows:

1. The slide was placed on a staining rack and specimen covered with crystal violet and Left to stand for 1 minute.

2. It was washed briefly in tap water shaking off the excess.

3. The specimen was covered with iodine solution and let stand for 1 minute.

4. It was washed with water and shaking off the excess.

5. The slide was tilted at 45° angle and decolorized with the acetone-alcohol solution until the purple colour stopped running then washed immediately with water shaking off excess.

6. The specimen was covered with neutral red and let to stand for 30 seconds to 1 minute.

7. It was washed with water, shaking off excess, and gently blotted dry. The smear was ready to be read. (Using oil immersion lens.)

Principle of Gram's Stain

The crystal violet stain is the primary stain, which stains everything in the smear blue. The Gram's iodine acts as a mordant that causes the crystal violet to penetrate and adhere to the gram-positive organisms. The acetone-alcohol mixture acts as the decolourizer that washes the stain away from everything in the smear except the gram-positive organisms. The neutral red is the counter-stain that stains everything in the smear that has been decolorized: pus cells, mucus, gram-negative organisms. The gram-negative organisms will stain a much deeper pink than the pus cells, and mucus will stain even lighter pink than the pus cells.

Reading and Reporting the Smears

A drop of oil was placed on the slide and, using the oil immersion objective of the microscope, the smear was read. The smear was then evaluated for the following morphotypes under oil immersion (1000× magnification): large Gram-positive rods (lactobacillus morphotypes), small Gram-variable rods

(G vaginalis morphotypes), small Gram-negative rods (Bacteroides species morphotypes), curved Gram-variable rods (Mobiluncus species morphotypes) and Gram-positive cocci. The results were graded using Nugent's criteria for diagnosis of BV. They were each graded on a scale of 1-4 (1+ is <1 cell per field, 2+ is 1-5 cells per field, 3+ is 6-30 cells per field, and 4+ is >30 cells per field). In this system, *Lactobacillus* and *Bacteroides/Gardnerella* are given scores between 0-4 but *Mobiluncuss* is only graded from 0-2. Total scores are then calculated and used as follows: 0-3 (Normal), 4-6 (intermediate bacterial count), and 7-10 (bacterial Vaginosis).

Proficiency and quality assurance

The laboratory diagnosis of BV is mainly achieved by microscopy. Quality assurance therefore ensured good practice in preparing and reading Gram stains, competency of the microscopists, and corrects maintenance and set up of the microscopes. The laboratory had ongoing communication with the clinician to ensure that the smear being submitted is vaginal and not cervical. This was indicated on the specimen requisition. A negative result for BV on a cervical smear could lead to inappropriate patient management. Good practice requires that the report on the Gram smear should mention the presence or absence of yeast cells which was done in the reporting.

IV. STANDARD LABORATORY QUALITY CONTROL

A. Check appearance of reagents daily

a. If crystal violet has precipitate or crystal sediment, refilter before use even when purchased commercially. **NOTE**: Some stains, especially basic fuchsin and safranin, can become contaminated. When suspected, either culture or start with fresh material in a clean bottle.
b. Evaporation may alter reagent effectiveness; working solutions should be changed regularly if not depleted with normal use.

B. Daily and when a new lot is used, prepare a smear of *Escherichia coli* (ATCC 25922) and *Staphylococcus epidermidis* (ATCC 12228) or *Staphylococcus aureus* (ATCC 25923). Fix and stain as described. Expected results

a. Gram-negative bacilli, pink
b. Gram-positive cocci, deep violet **NOTE**: An alternative QC source is material scraped from between teeth with a wooden applicator stick; both gram-positive and –negative organisms will be present.

C. The following are some common causes of poor Gram stain results

a. Use of glass slides that have not been precleaned or degreased. NOTE: Storing slides in a jar with 95% ethanol will ensure clean slides. Drain excess alcohol or flame slide before use.
b. Smear preparations that are too thick
c. Overheating of smears when heat fixation is used
d. Excessive rinsing during the staining procedure

D. To ensure accuracy of interpretation, set up a system for reviewing Gram stain reports.

a. Daily review of selected Gram stains by supervisory personnel may help determine competency/retraining needs and will help in correlating relevant clinical information.
b. Compare final culture results with Gram stain reports. NOTE: Not all organisms seen on a smear can be cultured.
c. A set of reference slides should be available for training and comparison

Data Management

The data was collected using a structured questionnaire. The questionnaires were coded to make the data entry easy. The filled questionnaires were kept in a safe place ready for the data entry and for the confidentiality of the patient's details.

After cross checking the questionnaires for any missing entries a data base was designed in MS Access which allowed the researcher to set controls and validation of the variables. On completion of the data entry exercise the data was exported on the Statistical Package (SPSS – Version 17.0) for analysis.

The data was presented in tables and figures where applicable. Non- Parametric tests (Mann Whitney U test) was used to examine whether there is any significant association between the continuous variables e.g. age, while chi-square was used to establish the significant associations between the categorical variables.

Odds Ratios (OR) and associated 95%Confidence interval (CI) were calculated to identify the factors that are more likely to be associated with Bacterial Vaginosis. P-value of less than 5% ($P<0.05$) was considered statistically significant.

ETHICAL CONSIDERATIONS

During the study the following ethical issues were considered

1. The nature of the study was explained to the personnel at ANC clinic at KNH.
2. Informed consent was sought from mothers before being included in the study. No names of participants were written, study subjects were coded with numbers. No woman was victimised for declining to participate in the study.
3. The study protocol was presented at the department of Obstetrics/ Gynaecology as well as the KNH Ethical committee who approved it.
4. Participants who were diseased were treated with Clindamycin gel for a week.

STUDY LIMITATIONS

: Maternal-fetal outcomes in the index pregnancy were not assessed however previous obstetric outcomes were correlated with the index pregnancy.

: Cultures and Sensitivities to identify the specific micro-organisms in causation of Bacterial Vaginosis were not done due to cost limitation. This however did not affect the result interpretation as its been observed that Obtaining routine vaginal cultures in patients with BV has no utility because this is a polymicrobial infection. BV is considered a condition with a spectrum of positivity. A case of BV is classified as either positive or negative without an organism-specific definition or an assessment of organism-specific risk for disease. However, obtaining cultures to exclude other infectious etiologies (eg, *Trichomonas* species, *C trachomatis, N gonorrhoea*) is appropriate.

RESULTS

Table 4.1: Bio-Data of the Study Subjects (n=190)

Characteristic	Factor Level	Frequency, n (%)	95% CI proportion
Age (in years)	< 20	4 (2.1)	0.04 – 4.2
	20 – 24	37 (19.5)	13.8 – 25.2
	25 – 29	82 (43.2)	36.1-50.3
	30 – 34	41 (21.6)	15.7-27.5
	35+	26 (13.7)	8.8 – 18.6
Marital Status	Single	17 (8.9)	4.9-13.0
	Married	172 (9.5)	86.3-94.7
	Separated/Divorced	1 (0.5)	-0.5-1.5
	Widowed	-	-
	Other	-	-
Highest Level of Education	Informal	-	-
	Primary	14 (7.4)	3.6-11.1
	Secondary	79 (41.6)	34.5-48.7
	College	86 (45.3)	38.1-52.4
	University	11 (5.8)	2.4-9.1
Occupation	Employed	123 (64.7)	57.9-71.6
	Unemployed	67 (35.3)	28.4-42.1
Residence	Rental	156 (82.1)	76.6-87.6
	Owned	34 (17.9)	12.3 -23.4

As shown in Table 4.1, the mean age of the study participants was 28.3 (27.6-29.0). Most patients were married, educated and employed living in rental homes mostly middle social economic status.

Table 4.2: a) Sexual and Reproductive History (n=190)

Characteristic	n (%)	Mean	std	95% CI mean
Gestational Age (weeks)		28.0	1.2	25.6-30.4
• < 18 • 18 – 27 • 28 - 36 • 37+	30 (15.8) 35 (18.4) 75 (39.5) 50 (26.3)			
Parity		1	0.1	0.7 – 0.9
Primigravida • 1 • 2 • 3	29(15.3) 85 (44.7) 67 (35.3) 9 (4.7)			

4.2:b)

Characteristic	Factor Level	Frequency, n (%)	95% CI proportion
Previous miscarriage	Yes No	67 (35.3) 123 (64.7)	28.4-42.1 57.9-71.6
Gestation of Miscarriage (n=)	< 16 weeks 16 – 28 weeks > 28 weeks	43 (22.6) 13 (6.8) 15 (7.9)	16.6-28.6 3.2-10.5 4.0-11.8
Age first intercourse (years)	< 18 18-25 25-35 > 35	27 (14.2) 151 (79.5) 12 (6.3) -	9.2-19.2 73.6-85.3 2.8-9.8 -
Number of Sexual partners Last 6 months	0-1 2-3	188 (98.9) 2 (1.1)	97.5-1.00 -0.4-2.5
Number of Sexual partners Lifetime	1-2 3-4 > 4	136 (71.6) 43 (22.6) 11 (5.8)	65.1-78.1 16.6-28.6 2.4-9.1
Previous STI	Yes No	31(16.3) 159 (83.7)	11.0-21.7 78.4-88.9
HIV Status	Positive Negative Unknown	17 (8.9) 171 (90.0) 2 (1.1)	
Douching	No Yes	148 (77.9) 42 (22.1)	

In Table 4.2a and b, Prior miscarriages were reported in 67/190(35.3%) with majority being early pregnancy losses (less than 16 weeks) 43/67(64.2%). Sexual debut was between the age of 18 and 25 years in 79.5% with 71.6%(136) having less than 2 sexual partners in their lifetime .Of the participants 16.3% had been treated previously for a sexually transmitted infection and 8.9%(17) were HIV Positive .

Table 4.3: Vaginal Discharge Characteristics

Characteristic	Factor Level	Frequency, n (%)
Discharge n=190	Present	162 (85.3)
	No discharge	28 (14.7)
Discharge colour n=162	Clear	42 (25.9)
	White	111 (68.5)
	Greyish	9 (5.6)
Odour N=162	Present	3 (1.9)
	No Odour	159 (98.1)
Consistency N=162	Thick	35 (21.6)
	Curd-like	35 (21.6)
	Watery	69 (42.6)
	Other	23 (14.2)

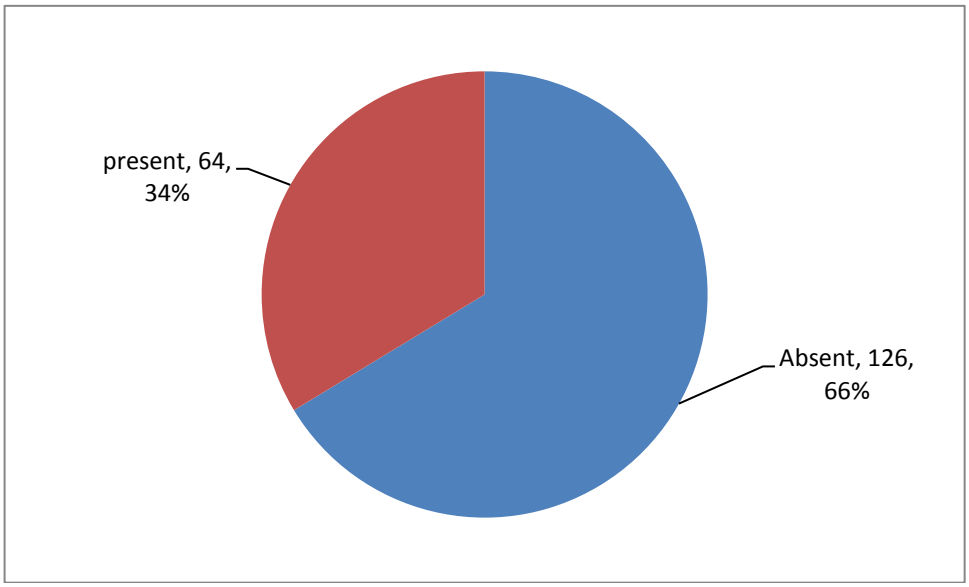
As shown in table 4.3, majority of participants on examination were found to have vaginal discharge (85.3%) which was mostly white and odourless.

Table 4.4: Distribution of Prior Obstetric events.

Characteristic	Factor Level	Frequency, n (%)
Pre-term Labour	Yes	5 (2.6)
	No	185 (97.4)
PR0M	Yes	0
	No	190 (100.0)

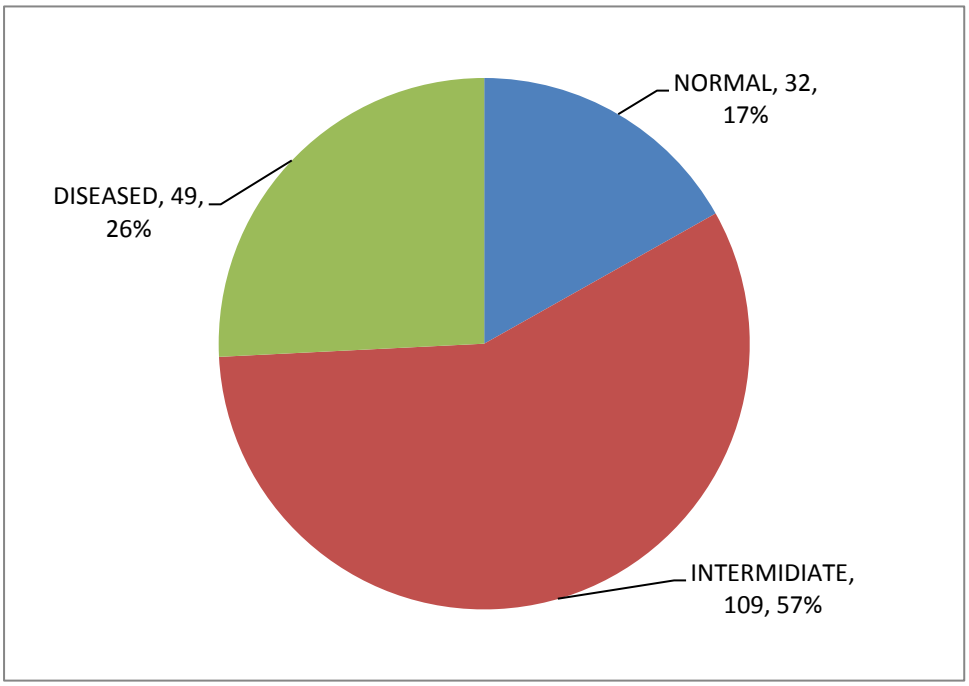
None of the participants reported prior history of PPROM/PROM in the previous pregnancies and 2.6% had preterm labor in a previous pregnancy (table 4.4).

Fig.1: Prevalence of Clue Cells



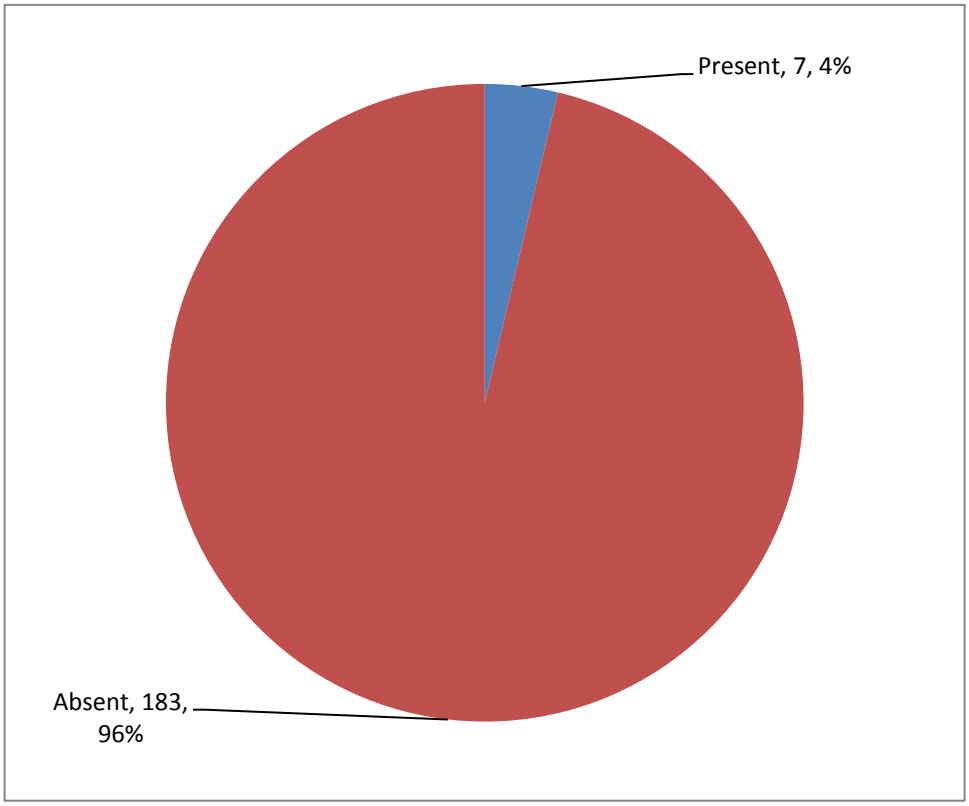
As shown in figure 1 above, Clue cells were present in 64/190 (34%) of the participants.

Fig.2: Gram Stain Diagnosis (Nugent's criteria)



The prevalence for Bacterial Vaginosis was found to be 26% using the Gold standard Gram Stain scored using Nugents criteria.Majority were in the intermediate bacterial count group (57%) (figure 2).

Fig.3: Clinical Diagnosis (Amsels criteria).



As shown in figure 3, the prevalence of BV by the Amsel clinical criteria was 4%. (i.e positive for three out of the four variables i.e KOH Amine smell, vaginal Ph >4.5, Prescence of clue cells, and Greyish white discharge).

Table 4.5

Clinical Diagnosis Against Gram Stain

		Gram Stain +VE	Gram Stain -VE	Total	Sens/spec	PPV	NPV
Clinical	**+VE**	4	3	7	8.2		
	-VE	45	138	183	97.9	57.1	75.4
Total		49	141	190			

In table 4.5, the results from clinical diagnosis were validated against gram stain which is the gold standard for diagnosis of BV.The Sensitivity was low (8.2%) but the specificity was very high (97.9%) for the clinical criteria.

We then looked at the individual variables validated against gram stain and also paired variables against gram stain to ascertain the most sensitive and specific variable.

Table 4.6: Diagnostic Performance of Individual Clinical Components against Gram Stain.

		Gram Stain +VE	Gram Stain -VE	Total	Sens/spec	PPV	NPV
CLUE CELL	**PRESENT**	26	38	64	53.1		
	ABSENT	23	103	126	73	40.6	81.7
Fishy Smell	**Present**	2	3	5	4.1		
	Absent	47	138	185	97.9	40.0	74.6
Discharge	**Grey**	2	7	9	4.1		
	Other	47	134	181	95	22.2	74.0
PH >4.5	**+VE**	47	132	179	95.9		
	-VE	2	9	11	6.4	26.3	81.8
Total		49	141	190			

Each of the components of the Amsel clinical Criteria for diagnosis of BV was evaluated against the gram stain in table 4.6

The Vaginal PH had the highest Sensitivity (95.9%) and a high negative predictive value of 81.8%. All the other variables individually had high specificity of more than 95% except for clue cell which had a specificity of 73%.

Table 4.7: Diagnostic Performance of pairing the clinical components against Gram Stain.

		Gram Stain					
		+VE	-VE	Total	sens./spec.	PPV	NPV
CLUE+PH	**+VE**	26	34	60	53.1		
	-VE	23	107	130	75.8	43.3	82.3
CLUE+FISHY SMELL	**+VE**	2	3	5	4.1		
	-VE	47	138	185	97.9	40.0	74.6
CLUE+GREY DISCHARGE	**+VE**	2	0	2	4.1		
	-VE	47	141	188	100	100.0	75.0
PH+FISHY SMELL	**+VE**	2	3	5	4.1		
	-VE	47	138	185	97.9	40.0	74.6
PH+GREYISH DISCHARGE	**+VE**	2	7	9	4.1		
	-VE	47	134	181	95	22.2	74.0
Total		49	141	190			

According to table 4.7, different combinations of the Amsel criteria components for BV diagnosis were evaluated against Gram stain.

Combining variables lowered the sensitivity for PH but improved the specificity maintaining a specificity of more than 95% .Clue cells and KOH Amine smell combination was as good as the gold standard Gram stain for BV diagnosis with a specificity of 100%.

Table 4.8

Association between Gram Stain and Bio data and Obstetrics/Gynaecology Characteristics.

		Finding			
Factor	**Level**	**+ve, n (%)**	**-ve, n (%)**	**OR (95% CI)**	**p-value**
Age	≥ 30	21 (42.8)	46 (32.6)		
	< 30	28 (57.1)	95 (67.4)	1.5 (0.8-3.0)	0.197
Marital Status	Yes	5 (10.2)	13 (9.2)		
	No	44 (89.8)	128 (90.8)	1.1 (0.4-3.3)	0.839
Education	Primary	5 (10.2)	9 (6.4)		
	Secondary & Above	44 (89.8)	132 (93.6)	1.7 (0.5-5.2)	0.378
Employment Status	Not Employed	20 (40.8)	47 (33.3)		
	Employed	29 (59.2)	94 (66.7)	1.4 (0.7-2.6)	0.345
Gestation Age	< 28	13 (26.5)	52 (36.9)		
	≥ 28	36 (73.5)	89 (63.1)	0.6 (0.3 - 1.3)	0.188
Parity	Zero	22 (44.9)	63 (44.7)		
	≥ 1	27 (55.1)	78 (55.3)	1.0 (0.5-1.9)	0.979
Miscarriage	Yes	20 (40.8)	47 (33.3)		
	No	29 (59.2)	94 (66.7)	1.4 (0.7-2.7)	0.345
No. of Partners	≤ 1	49 (100)	139(98.5)		
	> 1	0	2 (1.4)	-	0.402
Previous STI	Yes	7 (14.3)	24 (17.0)		
	No	42 (85.7)	117 (82.9)	0.8 (0.3-2.0)	0.655
HIV	+ve	7 (14.3)	10 (7.1)		
	-ve	40 (85.1)	131 (92.9)	2.2 (0.8-6.4)	0.10

According to table 4.8, the statistical association was not significant but odds for BV were found to be higher with Older participants below >30 years, unemployed participants with lower academic level achievement.

Higher odds for BV were seen in participants with prior history of miscarriages, Previous STIs and in those positive for HIV

DISCUSSION

Bacterial Vaginosis is a common medical problem in women that can be associated with significant morbidity and complications. Bacterial Vaginosis being one of the important causes of vaginal discharge during pregnancy merits early and accurate diagnosis as it can lead to serious complications like premature rupture of membranes, chorioamnionitis, preterm delivery postpartum endometritis.

The diagnosis of bacterial Vaginosis is based on clinical findings and laboratory testing. Clinically Amsel criteria are used for the diagnosis of bacterial Vaginosis. Alternatively bacterial Vaginosis (BV) can be diagnosed by gram stain which is the gold standard method for diagnosis of BV. The same authors (Nugent et al) also developed a grading system for gram stain of vaginal discharge based on presence or absence of certain bacterial morphocytes (and their relative numbers), which gives more objective assessment of BV. Vaginal culture has got no role in the diagnosis of BV.

In this study we aimed to evaluate the prevalence of BV, the associated sociodemographic factors and correlation of Amsel criteria with Nugent criteria for diagnosis of BV in asymptomatic pregnant women.

A total of 190 women were included in the study. BV was diagnosed in 49/190(26%) using Nugent criteria (Fig.2) and 7/190(4%) using Amsel criteria (Fig.1). The reported prevalence in literature varies from 9 to 23% in studies from academic medical centres and teaching hospitals; prevalence in community clinical settings is not well studied [2]. Tolosa et al. [5] in a Multicentric study reported that the prevalence of BV and distribution of bacterial morphotypes in vaginal smears of asymptomatic pregnant women varies significantly in populations from different studies with higher rate reported among African –American women, low-income women or women with prior sexually transmitted diseases (6) which is similar to the distribution in our study population (table 4.7).

The sensitivity and specificity of Amsel's criteria compared to gram stain were 8.2% and 97.9% respectively. Schwebke et al. reported the sensitivity and specificity of Amsel criteria compared to Nugent score to be 70% and 94% respectively, in a cohort of non-pregnant women (7). The sensitivity of Amsel criteria in our cohort was poorer and than the sensitivity of 70% reported by Schwebke et al. However, in two pregnant cohorts the sensitivity of Amsel criteria compared to Gram stain was only 35% and 46% (8).

Lower sensitivity of clinical diagnosis compared with Gram stain-based diagnosis could be explained by the subjective nature of the clinical test. Clinician interpretation variability could also be a factor.Vaginal infections are common reason for women seeking medical care. Simple and inexpensive methods of testing can be used as a first line approach to evaluation to reduce the associated morbidities in pregnancies. In a study, Wiesenfeld and Macio [9] reported that in 150 office visits of 52 women seeking care for symptoms of vaginitis, microscopy of vaginal fluid was not performed in 37%, in more than 90% of office visits pH and whiff test was not done and vaginal cultures were done in 17%.Treatment was deemed inappropriate in less than half the cases.

Microscopes may not be available in clinics, but simple tests like pH and whiff test can be easily done and are inexpensive, and can help in diagnosis and appropriate management of BV.Keeping this in view, and because of the poor sensitivity of clinical diagnosis in this population we evaluated single and two of Amsel's criteria variables against the gold standard- Nugent's criteria in the diagnosis of bacterial Vaginosis.

Vaginal pH of >4.5 had the highest sensitivity (95.9%) individually for diagnosing BV compared to the other three components of the Amsel criteria. The other Variables individually had higher specificity with KOH Amine test and Greyish Discharge being >95% (Table 4.6). Combining the individual variables decreased the sensitivity but maintained a high specificity (Table 4.7). The Vaginal PH can thus individually be used as a screening tool for BV.

This is similar to Gutman et al. [10] who also evaluated whether 2 clinical criteria could be used for diagnoses of BV. They enrolled 269 women, of which 35 were pregnant. Vaginal pH was most sensitive criteria at 89%, and at 93% amine test was most specific. Similar specificity was seen with combinations of two variables for the diagnosis of BV (91–95%) and Amsel's criteria (93%) against Gram Stain (Table 4.7). Similar study in 135 non-pregnant women showed that the combinations of two criteria had sensitivity of 83–93% and specificity of 82–94% and were as accurate as Amsel's three criteria [10a].

The socio demographic factors considered in this study had no statistical significant for higher risk for BV infection. The social factors depict a middle level economic class as opposed to most populations in previous studies which are low socioeconomic class. Other studies have also been based in high risk population such as sexually transmitted infections clinics (10b) which could explain the variability. This study was carried out in asymptomatic antenatal women in contrast to previous studies done in symptomatic and high risk antenatal women.

The odds for having BV were however higher for older women >30 years 1.5 fold, unmarried with lower education level and unemployed. Previous history of STI treatment, miscarriage and infection with HIV also showed higher odds for having BV 1.4 – 2.2 fold increases (Table 4.8). This relates to the previous studies showing increased risk for BV infection with similar bio data and obstetrics/gynaecology characteristics. [10b].

CONCLUSION:

1. The prevalence for Bacterial Vaginosis in our population is 26% which lies within the reported range for this region.
2. Higher odds for BV is seen in previous history of miscarriage, Previous STI treatment, HIV infected women, and in older women of more than 30 years, lower education level and unemployed.
3. Amsel criteria had low sensitivity but very high specificity (97.9%).
4. Individually Vaginal PH had a very high sensitivity (95.9%) when compared to the gold standard Gram stain, while KOH Amine test and Greyish Vaginal discharge individually had very high specificity of more than 95%
5. Combination of the variables in twos lowered the sensitivity but had high specificities with KOH Amine test in combination with Greyish discharge having the highest specificity at 100%.

RECOMENDATTIONS:

1. High Prevalence of BV in our population (26%) should necessitate screening in ANC women since BV is associated with significant maternal and Neonatal morbidity and mortality.
2. Vaginal PH on its own can be used as a screening tool in low resource setting thus the antenatal clinic and wards should be equipped with PH strips for screening for BV.This is cheap and easy to use screening tool.
3. A High risk approach for screening can be used for asymptomatic women who are older (more than 30 years) with prior history of STI treatment, previous miscarriage, and are HIV positive.

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Q APPENDIX 1

1. Questionnaire

Date ☐ Code Number ☐

SECTION A: BIO-DATA / SOCIO-ECONOMIC STATUS

1. Age ☐

2. Marital Status (Tick Appropriate)

   1.Single ☐

   2.Married ☐

   3.Separated / Divorced ☐

   4.Widowed ☐

   5.Other (Specify) ☐

3. Highest level of Education level Attained (Tick one)

   1.Informal ☐

   2.Primary ☐

   3.Secondary ☐

   4.College ☐

   5.University ☐

4. Main type of Occupation (Tick one)

   1.Employed ☐ (specify)----------

   2.Unemployed ☐ (specify)----------

5. Residence (Tick Appropriate)

1.Rental ☐

2.Owned ☐

1.Permanent ☐

2.Semi-permanent (Specify below)

1.Wooden ☐

2.Iron sheets (mabati) ☐

3.Mud ☐

SECTION B: REPRODUCTIVE HISTORY

6. Gestational Age (Weeks from LNMP) ☐

7. Parity ☐ + ☐

8. Previous miscarriages / pre-term births Yes ☐ No ☐

9. Number of miscarriages / pre-term births ☐

10. Gestation of miscarriages / pre-term births (Tick appropriate below)

1. < 16 weeks ☐

2. 16 – 28 weeks ☐

3. > 28 weeks ☐

SECTION C: SEXUAL HISTORY

11.Age at first intercourse (Tick appropriate below)

1. < 18 years ☐

2. 18 – 25 years ☐

3. 25 – 35 years ☐

4. > 35 years ☐

12. Number of sexual partners in (Tick appropriate below)

1. Last 6 months ☐
2. Lifetime ☐

13.Previous history of STI treatment (Tick appropriate below)

1. Yes ☐
2. No ☐

14.HIV status (Tick appropriate below)

1. Positive ☐
2. Negative ☐
3. Unknown ☐

SECTION D: HYGIENE

15. Water source (Tick appropriate below)

1. Running tap water ☐
2. Well / community tap ☐

16. Frequency of bathing (Tick appropriate below)

☐ Times per Day

☐ Times per Week

17.Douching Yes ☐ No ☐

SECTION E: VAGINAL EXAMINATION FINDINGS

18.Vaginal discharge (Tick appropriate below)

1. Present (fill sections below) ☐
2. No discharge ☐

19. Discharge colour (Tick appropriate below)

1. Clear ☐
2. White ☐
3. Greyish white ☐
4. Other (specify) ☐

20.Odour (Tick appropriate below)

1. Present ☐
2. No odour ☐

21.Consistency (Tick appropriate below)

1. Thick ☐
2. Curd-like ☐
3. Watery ☐
2. No odour ☐

SECTION F: LABOUR

22.Pre-term labour (Tick appropriate below)

1. Yes ☐
2. No ☐

23. PROM (Tick appropriate below)

1. Yes ☐

2. No ☐

SECTION H: LABORATORY FINDINGS

24. VAGINAL PH

1. <4.5 ☐ 2. >4.5 ☐

25. KOH + Discharge= Fishy smell

1. Yes ☐

2. N0 ☐

GRAM STAIN

26. Clue cells

1. Present ☐ 2. Absent ☐

27. Gram negative rods

1. Present ☐ 2. Absent ☐

28. Gram Positive rods

1. Present ☐ 2. Absent ☐

29.Others (specify)

Appendix 2

Certificate of Informed Consent

University of Nairobi- Department of Obstetrics and Gynaecology

CONSENT TO PARTICIPATE IN A STUDY ON THE PREVALENCE OF BACTERIAL VAGINOSIS IN ANTE-NATAL MOTHERS AT KNH

Principal Investigator: Dr. Kuruga Martha

I am conducting the above-stated study at ANC Clinic, KNH. You are being requested to participate in the study because you meet the inclusion c*riteria.*

Benefits of participating in the study:

The results of the study will help us get important information that may help in formulating policy at National level on prevention of associated morbidity and complications of Bacterial Vaginosis in pregnancy.

This will require that I administer to you a questionnaire at the beginning of the study during the Ante-natal visit in which we make contact.

I will also conduct a pelvic exam in which I will take samples for microscopic diagnosis of Bacterial Vaginosis. This poses no risk to your pregnancy.

The research study does not offer you any financial benefit. However, you will be provided with any health information that you request.

Your participation in the study is voluntary and there are no consequences in case you decline participation.

All information will be kept confidential and all the laboratory results will be explained to you comprehensively.

Contact information

For further information or clarification, please contact Dr. Kuruga Martha, Department of Obstetrics and Gynaecology, University of Nairobi. Tel. 0721 – 297 300.

1.Consent form - English

Code Number

I Mr. / Mrs. / Miss. _____, agree to the above and give consent for myself / daughter / sister/ wife to be included in this study as explained to me by _____.

I understand the purpose of the study and conditions of participation.

Signature _____ Date_____

Witness

Signature _____ Date_____

2. Consent form - Kiswahili

Code Number

Mimi _____, nimekubali kushiriki katika utafiti huu kama nilivyo elezwa na _____.

Nimeuelewa umuhimu wa utafiti huu na masharti yanayoandamana nayo.

Sahihi _____

Tarehe _____

Shahidi

Sahihi _____

Tarehe _____