TITLE: MATERNAL GROUP B STREPTOCOCCUS COLONIZATION AND THE ASSOCIATED EARLY MATERNAL AND NEONATAL OUTCOMES AT THE KISII TEACHING AND REFERRAL HOSPITAL

A RESEARCH STUDY SUBMITTED BY

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AS PART FULFILLMENT FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY OF THE UNIVERSITY OF NAIROBI

DECLARATION

This is to declare that this research work and dissertation is my original work and that it was done with the guidance of my supervisors. It has not been submitted to any other university for the award of a degree.

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LIST OF ABBREVIATIONS

GBS Group B Streptococcus

PROM Premature rupture of membranes

CDC Centers for Disease Control and Prevention

KNH Kenyatta National Hospital

CAMP Christie Artkins and Münch-Petersen

ICU Intensive Care Unit

KTRH Kisii Teaching and Referral hospital

AKUH Aga Khan University Hospital

NBU New Born Unit

DEFINITION OF TERMS

Maternal GBS colonisation: This is at 35-37 weeks gestation

Early maternal and neonatal outcomes: This is the 48-72 hours postnatal within which early onset neonatal sepsis occurs

Uneventful delivery: This describes normal labour and vaginal delivery with no intrapartum complications

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ABSTRACT

BACKGROUND

Group B streptococcus is a gram positive streptococcus that is a major cause of bacterial infections in the perinatal period including amnionitis,urinary tract infections,endometritis in the pregnant women carriers of the organism in the rectovaginal compartment. At birth,50-65% of infants born to colonised mothers have positive cultures taken from mucus membranes and the skin. 98% of the colonised newborns remain healthy but 1-2% develop invasive disease.

Published information about the prevalence of colonization by GBS among pregnant women in Kenya is scarce. Therefore the aim of the study was to determine the magnitude of GBS among ante natal women and the subsequent maternal and neonatal outcomes post-delivery. This is meant to stimulate research interest in this area which may indirectly impact the high maternal and infant mortality rate in the country.

OBJECTIVE

To determine the incidence of group B streptococcus among pregnant women 35-37 weeks gestation and the maternal and neonatal outcomes within 48 hours postnatal.

STUDY SETTING

This study was conducted in the antenatal clinic,antenatal and postnatal wards of the Kisii Teaching and Referral hospital.

SUBJECTS

Pregnant women 35-37 weeks gestation who meet the inclusion criteria

Neonates born to the study participants.

METHODS

This was a descriptive cohort study where consecutive sampling was used. Pregnant women 35-37 weeks gestation were sampled by taking rectovaginal swabs and culturing for growth of Group B Streptococcus. The rectovaginal swabs collected were transported to Aga Khan

University hospital, Kisumu where the process of culturing was commenced within 24 hours. The women were then followed up to determine the maternal and neonatal outcomes up to 48 hours post natal. The data was analysed using the SPSS software version 18.0 and evaluated statistically by Fischer exact test. Statistical significance was determined as P value < 0.05.

RESULTS

A total of 914 women were approached in the antenatal clinics during the study period, 714 women were eligible and 200 of them were recruited into the study after meeting the inclusion criteria. 182 women were followed up until the immediate postpartum period. In total, 6 out of the 200 pregnant women 35-37 weeks gestation attending ANC clinic at Kisii teaching and referral hospital had vaginal colonisation with group B streptococcus yielding a prevalence of 3% in this cohort. Majority of the colonised women (83.3%) had only primary level education and 16.7% had college education as compared to 28.4% of uncolonised women who had primary education and 22.7% who had college education. There was a statistically significant association between level of education and GBS colonisation(P=0.035). The findings of this study showed that there was a significant association between puerperal sepsis and GBS colonisation(P=0.046) as well as a significant association between birth weight and GBS colonisation (P=0.018). 50% of GBS positive mothers delivered neonates who weighed less than 2500g. No significant association was found between neonatal sepsis and GBS colonisation(P=0.259). In this study the GBS was sensitive to chloramphenicol, ampicillin, doxycycline, azithromycin, netilmycin and ciprofloxacin.

CONCLUSION

There was a low prevalence of maternal group B streptococcus infection among the pregnant women in the study. GBS colonisation was associated with adverse maternal outcomes like puerperal sepsis. Low level of education was significantly associated with GBS colonisation.

RECOMMENDATION

From the results, it would be recommended that Group B Streptococcus should be highly considered as one of the causative organisms in cases of puerperal sepsis where laboratory services are not readily available and treatment given accordingly .

In the event that neonates born with a birthweight of less than 2500g develop invasive disease, the clinician should have a high index of suspicion for GBS disease and treat accordingly especially in the resource poor settings.

INTRODUCTION

Group B streptococcus or Streptococcus agalactiae is a gram positive streptococcus characterized by the presence of Group B Lancefield antigen, hence the name (1)

Since the mid-1960's,group B streptococcus (GBS) has become the major cause of bacterial infections in the peri natal period including bacteraemia,amnionitis,endometritis and urinary tract infections in pregnant women (2). It is responsible for meningitis,pneumonia and sepsis in neonates. GBS can also pass through the cervix without causing cervicitis and cross intact amniotic membranes into the amniotic fluid thereby infecting the foetus in utero(3).

It constitutes one of the leading pathogens associated with both early and late neonatal sepsis (4). In early onset disease (age at onset 0-6 days) the neonate is infected by exposure to GBS before or during birth. For late onset disease (7-89 days) the pathogenesis is not yet clear (5).

The transmission is vertical from mother to child and the gastrointestinal tract is the source of vaginal GBS colonisation and many adults are colonized without showing any symptoms (2). GBS colonisation ,even when it is asymptomatic,has been associated with adverse pregnancy outcomes such as low birth weight,preterm delivery and premature rupture of membranes (3). Approximately 10-30% of women of childbearing age carry GBS in the rectovaginal compartment (2).

The prevalence may vary due to differences in the culture technique, the location and number of sites cultured and the population studied (6). Ethnicity, maternal age and parity, marital status, education and smoking are factors that have been reported to influence the prevalence of colonization (5). A role for ethnic or genetic factors is presumed since Caribbean Hispanics and black women were reported to be GBS carriers more frequently (6).

Treatment and prevention guidelines developed by the Centers for Disease Control and Prevention (CDC) in 1996 and revised in 2002 led to a significant decline in the incidence of early onset of neonatal disease in institutions that adopted and followed these guidelines strictly (2,7). The CDC recommendations are to screen all pregnant mothers before term (35-37 weeks gestation) and to administer intra partum prophylactic antibiotics to all who test positive for GBS

colonization(2). This has been established to lead to a 70% decline in the incidence of GBS disease (4).

This treatment of colonized mothers succeeded temporarily eradicating the organism but most of them were re-colonized within 6 weeks. At birth, 50-65% of infants born to colonized mothers had positive GBS cultures taken from mucus membranes and skin (external ear canal, oral and nasopharynx, umbilicus, ano-rectal sites).Approximately 98% of the colonized newborns remained healthy but 1-2% developed invasive GBS disease (2).

LITERATURE REVIEW

In 2010, the Centers for Disease Control and Prevention in collaboration with the American College of Obstetricians and Gynaecologists recommended universal screening of all pregnant women between 35-37 weeks gestation and administration of intrapartum antibiotic prophylaxis to all women who test positive for GBS (8). As a result, there is a 1 in 4000 chance of delivering a baby with group B streptococcus disease as compared to a 1 in 200 chance if no intrapartum antibiotic prophylaxis is given (9)

According to the CDC guidelines, testing within 5 weeks of delivery is most accurate at predicting GBS status at delivery with a negative predictive value of 95-98% and a positive predictive value of 87-100% if performed within that time period. Positive predictive value decreases significantly to 43% if done 6 weeks or more prior to delivery.

Because the performance of screening is best done within 5 weeks of delivery and most women deliver at term, the guidelines state that screening for GBS should be done between 35-37 weeks gestation. (8)

Most pregnant women who are colonized with GBS have no symptoms or health effects at all. A small number may develop a urinary tract infection, chorioamnionitis or preterm labour but the most serious health effect is that a woman colonized by GBS late in her pregnancy can pass it to her baby. GBS is responsible for affecting about 1 in every 2000 babies in the United States (8)

A hospital based retrospective cohort study carried out in Canada demonstrated that GBS vaginal colonization was independently associated with premature onset of labour, intrapartum pyrexia and prolonged rupture of membranes (18 hours or more). Compared with women without GBS

vaginal colonization, those with GBS colonization were about twice as likely to have premature onset of labour (10)

The study carried out in the Netherlands on prevalence of colonization with group B streptococci in pregnant women of a multi ethnic population who were between 35-37 weeks gestation showed a prevalence rate of 21% in the general population. However there were apparent differences in GBS carriage rate among women from different world regions. African women had the highest colonization rates of 29% followed by women originating from Europe and Latin America whose prevalence rate was 21%. Asian women had the least prevalence rate of 13%. There was no relationship between GBS colonization and age or parity. The Dutch Society of Obstetrics and Gynaecology and Dutch society of Paediatrics recommend intrapartum administration of antibiotics in women with risk factors that would lead to poor neonatal outcomes. These are women with intrapartum temperatures of more than 37.8 degrees centigrade, women with GBS bacteriuria during the current pregnancy and women who previously gave birth to an infant with early onset GBS irrespective of their current GBS status(6)

A hospital based study carried out at the Aga Khan University hospital in Karachi, Pakistan on the prevalence and risk factors for GBS genital tract infection in pregnant women showed a prevalence rate of 17% among the 405 patients studied. The colonization was found to be significantly associated inversely with the body mass index of the patient (11)

A study carried out in India to prove that screening is necessary in pregnant women 35-37 weeks gestation showed that GBS carriage was significantly increased with preterm birth, premature rupture of membranes, prolonged duration of rupture of membranes more than 10 hours and intrapartum temperature of more than 38 degrees centigrade. Birth weight less than 2.5 kg and neonatal intensive care admissions were significantly more in infants of GBS positive women. (12)

A Nigerian study on GBS carriage during late pregnancy in Ile Ife showed a prevalence rate of 11.3%. This study was carried out on 150 pregnant women at between 35-40 weeks gestational age from May to December 2010. The colonization rate was noted to increase with maternal age- 9.38% among women less than 30years as compared to 12.79% among women more than 30

years. The culture positivity among mothers less than 37 weeks gestation was far less than that among mothers who were more than 37 weeks gestation which implied that the vaginal colonization of GBS varies during the period of gestation and that screening earlier than six weeks before delivery may not be a true reflection at delivery and may not accurately predict the vaginal colonization at delivery (4)

A cohort study carried out in Zimbabwe on GBS colonization during pregnancy and maternal-fetal transmission showed that a total of 60.3% of pregnant women were colonized with GBS at any time during the pregnancy. The colonization rate declined through pregnancy. This change was observed among women living in the rural areas but not among those living mainly in an urban location. Having a positive GBS culture at 20 and 26 weeks gestation had a low positive predictive value for colonization at delivery and in the newborn infant. The low positive predictive value of early ante natal screening showed that colonization may be intermittent. Few women on this study were persistent carriers of GBS. Dwelling in a rural area was significantly associated with GBS colonization (5)

The prevalence of GBS colonization in antenatal women at the Queen Elizabeth central hospital in Blantyre, Malawi was 16.5% among 97 women studied. 87.5% of the patients who were GBS positive had a history of bad pregnancy outcomes indicating that such episodes could predispose to GBS colonization in subsequent pregnancies (3)

A study on maternal and neonatal colonization of group B streptococcus at Muhimbili National hospital in Dar es Salaam, Tanzania showed an overall GBS prevalence of 23% among pregnant women(n=300) and 8.9% among the neonates(n=180). High vaginal and rectal swabs were collected and the results showed a higher vaginal carriage rate (12.3%) than the rectal colonization rate (5%). The fact that GBS was isolated from one and not the other site indicates that it is important to sample both vagina and rectum when screening for GBS carriage. Samples cultured from mothers and neonates showed that 37% of the pairs had positive GBS culture results. In this study maternal colonization was higher in women between 41 and 42 gestational weeks as compared to the earlier gestations. GBS was also more frequently isolated among women in the 30-34 age group(32.1%) as compared to those less than 20 years of age(15.4%). This study revealed that women with no formal education were more likely to be colonized with GBS (34.8%) and the association could partly be explained by the difference in personal hygiene

which is likely to be better among the educated than less educated women. Prolonged duration of labour was a factor for GBS colonization in neonates probably due to prolonged exposure of the neonate in the birth canal. The strong association between prolonged labour and GBS colonization showed the importance of routine antibiotic prophylaxis in such women in order to decrease the chances of subsequent neonatal infection. (7)

The study carried out in Hawassa, Ethiopia on 139 pregnant women attending antenatal clinic showed an overall prevalence rate of 20.9%. In the study, no statistically significant association was observed for GBS colonization in the study subjects with any of the sociodemographic characteristics studied that is age, residential address and occupation(2)

A descriptive cross sectional study carried out in KNH in 2008 by Salat on the prevalence of group B streptococcus colonization in ante natal women showed a prevalence rate of 25.2%. This study was conducted by obtaining 2 samples,one from the lower vagina and the other from the anorectal canal. GBS colonization was significantly associated with history of stillbirth. No significant association was found between GBS colonization and age, parity, employment status, level of education and history of other bad pregnancy outcomes such as preterm delivery, premature rupture of membranes, early neonatal sepsis, early neonatal death and fever in the previous pregnancy. (13)

Few studies have been carried out in Kenya on the prevalence and outcomes of maternal GBS colonization. A study conducted at Kenyatta National Hospital (KNH) by Nazrat between May and August 1985 that was on the epidemiology of GBS carriage in 200 mothers and their neonates showed a vaginal colonization rate of 5% and a 14.5% carriage rate among the neonates. 60% of the GBS positive mothers had neonates who were also positive while only 12.1% of GBS negative mothers had neonates who were positive. No association was found between GBS colonization and maternal age, parity, contraceptive use or obstetrical complications. No association was found between colonization of the neonates and their gender, gestational age or birth weight. However, though the numbers were small the low birth weight neonates were more affected by GBS disease (14)

JUSTIFICATION

Published information about the prevalence of colonization by GBS among pregnant women in rural Kenya is scarce. Therefore the aim of the study was to determine the prevalence of GBS among ante natal women and the subsequent maternal and neonatal outcomes post-delivery among a rural population. The study is meant to stimulate research interest in this area which may indirectly impact the high maternal and infant mortality rate in the country.

The Centers for Disease Control and prevention (CDC) 2010 guidelines recommend that a pregnant woman be tested for group B streptococcus when 35-37 weeks pregnant. GBS carriage is best predicted by prenatal screening at 35-37 weeks gestation through combined low vaginal and anorectal swab for optimal detection within 5 weeks of delivery as culture results are less predictive at term if performed at earlier gestations.

In Kenya, as is the case in several other sub Saharan countries, no strategies have been formulated to screen maternal GBS infection and subsequent prevention of early neonatal disease. The reasons are still unclear but one of the possible contributing factors is the lack of local data. The study was meant to generate local data that will inform the development of rational interventions for GBS infection and disease.

The results of this study have potential in influencing health policy in Kenya as regards routine ante natal testing of all pregnant women so as to reduce maternal and neonatal morbidity from GBS infections.

RESEARCH QUESTION

What is the Group B streptococcus colonisation rate among pregnant women 35-37 weeks gestation and the associated maternal and neonatal outcomes within 48 hours postnatal?

BROAD OBJECTIVE

To determine the colonisation rate of group B streptococcus among pregnant women 35-37 weeks gestation and the maternal and neonatal outcomes within 48 hours post partum.

SPECIFIC OBJECTIVES

1. To determine the colonisation rate of group B streptococcus among pregnant women 35-37 weeks gestation
2. To determine the maternal and neonatal outcomes within 48 hours postnatal among colonised and non colonised women
3. To determine sociodemographic characteristics of pregnant women colonised with group B streptococcus.

METHODOLOGY

STUDY DESIGN

The study was a hospital based cohort study involving pregnant women between 35 and 37 weeks gestation attending antenatal clinic for routine visits at the KTRH. The data was collected prospectively after initial assessment for GBS. Those eligible for the study and had consented had rectovaginal swabs taken and sent to AKUH, Kisumu for processing. The study also involved their neonates delivered at the labourward and the mothers together with their neonates were followed up in the postnatal wards for any outcomes of interest. The main exposure variable was GBS colonization while the main outcome variables were either early maternal like PROM, chorioamnionitis, preterm labour and puerperal sepsis or early neonatal like neonatal sepsis.

STUDY AREA

The study was carried out in the antenatal clinic, antenatal and postnatal wards of Kisii Teaching and Referral hospital and the rectovaginal samples collected were transported to the Aga Khan University hospital laboratory, Kisii branch.

Kisii Teaching and Referral hospital is a regional referral hospital covering South Nyanza, South Rift and entire Gusii region. It has a catchment of 3 million people and the reproductive health department conducts an average of 600-800 deliveries a month with an average of 8-10 caesarian sections and 20-30 normal deliveries conducted daily. The average antenatal clinic attendance is about 20-30 per day.

The Aga Khan University hospital laboratory in Kisii is a satellite branch of the Aga Khan University hospital, Kisumu. It was a collection point for the samples collected prior to them being transported to Aga Khan University hospital, Kisumu for culture. The Aga khan laboratory services conform to the ISO standards. The laboratory results were sent to the Kisii branch for collection.

STUDY POPULATION

Pregnant women between 35 and 37 weeks gestation who met the inclusion criteria had rectovaginal swabs taken following ethical approval of the study. The patients' consents were sought and gained by explaining to them the objectives of the study and the benefits there in. Questionnaires were filled using information from the study participants to acquire demographic and other relevant obstetric history.

INCLUSION CRITERIA

All consenting pregnant women with gestational age between 35-37 weeks and their neonates born in the labour ward.

EXCLUSION CRITERIA

Pregnant women who had been on antibiotic treatment in the preceding two weeks prior to recruitment were excluded from the study.

Pregnant women who had been diagnosed and were on management for premature rupture of membranes, antepartum haemorrhage and pre-eclampsia were also excluded from the study.

Pregnant women who have diabetes and HIV in pregnancy were not recruited.

Pregnant women noted to have sexually transmitted infections and genital ulcers on examination were not recruited into the study.

SAMPLE SIZE CALCULATION

Cochran's formulae for estimating sample size in prevalence studies was used with a finite population correction as suggested by Daniels (23). The prevalence used to calculate the sample size in this study was that of the study conducted at Muhimbili National Hospital on Maternal and Neonatal colonization because both studies involve pregnant women and their neonates. (7)

$$n = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

N = The population of women delivering at KTRH per month is estimated at between 600-800. Therefore an average population size of 700 was used in the calculation of sample size

P = Prevalence of GBS colonization in women delivering in Tanzania (23%)

1-P = 1 minus the prevalence of GBS colonization in women

Z = Z statistic representing 95% level of confidence (1.96)

d = desired level of precision set to 5%

$$n = \frac{700 \times 1.96^2 0.23(1-0.23)}{0.05^2(700-1) + 1.96^2 \times 0.23(1-0.23)}$$

n = 197

A sample size of 197 women was arrived at.

MATERIALS AND METHODS

All pregnant mothers attending ante natal clinic who met the inclusion criteria were approached and the study explained to them. Those who were willing to participate in the study signed consent forms and rectovaginal samples were taken after filling out laboratory request forms that bore study numbers corresponding to the respective questionnaires. The questionnaires had the client's hospital numbers and the corresponding hospital files had colour coded stickers for easy identification during follow up for outcomes and also to avoid double recruitment during subsequent antenatal visits.

Eligible participants had a rectovaginal swab for GBS culture collected by initially swabbing the vaginal introitus and thereafter the rectum (through the anal sphincter) using a sterile swab stick (6).

Swabs were placed in a transport medium (amies transport medium) and sent to the AKUH laboratory in Kisii. They were then refrigerated at 4°C before being transported in cooler boxes to AKUH laboratory in Kisumu for processing. The samples were immediately inoculated into 5% sheep blood agar and incubated at 37°C for 24 hours. Where there was evidence of hemolysis on the blood agar plate a quick gram stain smear was done. If the gram smear showed evidence of gram positive cocci then it was subcultured and CAMP (Christie, Artkins and Münch-Petersen) test was prepared from the primary plate using the pure colonies. A woman was deemed positive when the culture results showed growth of GBS.

The sample results were divided into the two arms of exposed (GBS positive) and unexposed (GBS negative) groups with unequal sample size and the two groups followed up for any possible outcomes.

The women were followed up during delivery and the immediate 48 hours post-delivery together with their neonates and data collected promptly on all the outcomes noted.

Data on any obstetric outcome prior to or during delivery was collected. Data on mode of delivery and the neonatal outcome was collected. Postnatally, data on any maternal and neonatal outcome for the first 48 hours was collected for analysis.

OUTCOME MEASURES

The primary maternal outcomes as a result of GBS colonisation are urinary tract infections,chorioamnionitis,stillbirths,miscarriages,preterm labour and premature rupture of membranes.

The primary neonatal outcomes as a result of maternal vaginal GBS colonisation are early onset neonatal sepsis,pneumonia and meningitis.

RECRUITMENT AND SAMPLING PROCEDURE

Study participants were recruited from women who met the inclusion criteria and agreed to participate in the study by giving an informed written consent.

DATA COLLECTION PROCEDURE

Data was collected by the principal investigator and research assistants using a pre-tested structured questionnaire which was administered verbally to the study subjects at the ante natal clinics and ante natal wards. The information obtained was entered into the questionnaire by the principal investigator.

Eligible participants had a rectovaginal swab for GBS culture collected by initially swabbing the vaginal introitus and thereafter the rectum (through the anal sphincter) using a sterile swab stick. The samples were then transported to the Aga khan university laboratory where they were processed for GBS growth. The laboratory results were entered into a laboratory request form that was attached to its respective questionnaire by matching the study numbers.

Follow up phone calls to find out maternal and neonatal outcomes were made to the participants discharged from hospital before 48 hours and the responses filled out in the questionnaire.

DATA COLLECTION INSTRUMENT

Data was collected using a precoded structured questionnaire administered to the study population by the principal investigator and research assistants and filled promptly.

DATA MANAGEMENT AND ANALYSIS

Data collected was coded and entered into a password protected Microsoft Access Database. The hard copy data forms were stored in a lockable cabinet in the principal investigator's office. Upon completion of Data entry, hard copy forms were compared with the entered data to identify errors and corrections made appropriately.

Data analysis was conducted using the SPSS software version 18. The initial univariate analysis involved calculating a frequency distribution to determine the percentage of mothers with GBS colonization. All subsequent analyses were stratified based on the presence or absence of GBS colonization. Univariate statistics were used to analyze the demographic factors characteristics of mothers with and without GBS colonization. The mean maternal age and standard deviation was calculated in each group, and the frequency distribution for maternal age and demographic factors including marital status, employment, income and education calculated. Maternal reproductive history and perinatal events during the index pregnancy were described using frequency distribution of variables including parity and mode of delivery and perinatal

complications. Neonatal outcomes and drug susceptibility was also analysed using univariate methods in each group. GBS colonization was used in cross tabulations with maternal demographic factors, obstetric history and perinatal events in bivariate analysis to determine risk factors of GBS colonization. The bivariate analysis was conducted using Fisher exact test to compare percentages of pregnant women colonized with GBS and those not colonized with GBS according to levels of each risk factors. Statistical significance was determined as P value < 0.05.

ETHICAL CONSIDERATIONS

Ethical approval was sought from the Kenyatta National Ethics and Research Committee and the Kisii Teaching and Referral hospital Ethical committee before the study was carried out. A written consent was obtained before participating in the study and potential participants were informed that participation was voluntary and that standard care would be provided to all women regardless of whether they consented or declined to participate in the study. The patient's records were coded and patient's name was not used to maintain confidentiality. The information obtained remained confidential and was not to be used for any other purposes other than the study. The interview and sampling procedure was conducted in a private environment to ensure confidentiality. The women who tested positive for GBS colonization were not offered prophylaxis at the time of delivery as the culture results had not been made available to the investigator as at the time of their delivery. However, the investigator did not interfere with the standard operating procedures of the hospital and prevailing clinical guidelines for the management of the participants' conditions and outcomes applied for all the mothers.

STUDY LIMITATIONS

There was loss to follow up due to some women delivering in other facilities other than KTRH. The loss to follow up was mitigated by using an average population size number to calculate the sample size and the number arrived at was adequately representative of the study population

RESULTS

914 women were approached during the period of the study from January 2015 to April 2015, 714 women were eligible and 200 were recruited into the study after meeting the inclusion

criteria. Of these, 182 women delivered at KTRH while 18 were lost to follow as they delivered in other facilities.

6 out of the 200 pregnant women 35-37 weeks gestation attending ANC clinic at KTRH tested positive for group B streptococcus yielding a prevalence of 3%.

Sociodemographic characteristics and streptococcal colonization

Table 1: Socio-demographic characteristics and streptococcal colonisation status

	Streptococcal colonization (N=200)		
	Yes (n=6)	No (n = 194)	**P value**
Maternal age			
Less than 20	2(33.3)	54(27.8)	0.554
21 – 30	3(50.0)	120(61.9)	
31 – 40	1(16.7)	20(10.3)	
Marital status			
Single	0(0.0)	26(13.4)	1.000
Married	6(100.0)	168(86.6)	
Type of marriage			
Monogamous	6(100.0)	163(84.0)	1.000
Polygamous	0(0.0)	7(3.6)	
Education			
Primary	5(83.3)	55(28.4)	0.035
Secondary	0(0.0)	77(39.7)	
College	1(16.7)	44(22.7)	
University	0(0.0)	18(9.3)	
Employment			
Unemployed	3(50.0)	91(46.9)	0.617
Self employed	3(50.0)	53(27.3)	

Salaried Employment	0(0.0)	35(18.0)	
Casual Laborer	0(0.0)	14(7.2)	
Monthly income			
Less than Ksh 10000	3(50.0)	112(57.7)	0.708
Ksh 10000 – 50000	3(50.0)	81(41.8)	
Ksh 50000 – 100000	0(0.0)	1(0.5)	

Table 1 summarises the demographic characteristics of women delivering at Kisii Teaching and Referral hospital according to colonisation status. Most mothers in colonised and uncolonised groups were aged 21-30 years (50% versus 61.9%). The mean age for presentation with colonisation was 23.7 years (SD 5.1) compared to a mean age of 23.6 years (SD 4.6) for the uncolonised group.

GBS colonisation was significantly associated with education level with 5 (83.3%) colonised mothers reporting primary level education compared to 55 (28.4%) of the uncolonised mothers(P=0.035). All six mothers with colonisation were in monogamous marriages and 168 (86.6%) of non-colonised mothers were married. The unemployment rates were 50% in the six colonised mothers compared to 91 (46.9%) in the uncolonised mothers, p = 0.617. Most mothers in the colonised group (50%) and the uncolonised 112 (57.7%) reported monthly incomes less than Ksh 10,000 (p =0.708).

Reproductive history and streptococcal colonisation

Table 2Gravidity and gestation of antenatal women at Kisii Teaching and Referral Hospital according to GBS colonization

	Streptococcal colonization(N=200)		
	Yes (n=6)	No (n = 194)	P value
Gravidity			
Primigravida	1(16.7)	67(34.5)	0.666
Multigravida	5(83.3)	127(65.5)	
Gestational age for index pregnancy			
35 weeks	2(33.3)	69(35.6)	0.191
36 weeks	4(66.7)	65(33.5)	
37 weeks	0(0.0)	60(30.9)	

There was no significant association between GBS colonisation and gravidity (p = 0.666) or GBS colonisation and gestational age of index pregnancy (p = 0.191). One (16.7%) mother with GBS colonisation was primigravid compared to 67 (34.5%) of the non-colonised mothers who were also primigravid. The current gestational age for colonised mothers was either 35 weeks (33.3%) or 36 weeks (66.7%) while the non-colonised mothers had gestational ages between 35 and 37 weeks, (Table 2).

Table 3: Reproductive history of antenatal women at Kisii Teaching and Referral Hospital according to streptococcal colonization

	Streptococcal	P value

	colonization (N=200)		
	Yes (n=6)	No (n = 194)	
Number of previous pregnancies			
1	4(66.7)	58(29.9)	0.480
2	0(0.0)	31(16.0)	
3	1(16.7)	18(9.3)	
4	0(0.0)	11(5.7)	
5	0(0.0)	2(1.0)	
>6	0(0.0)	6(3.1)	
None	1(16.7)	68(35.1)	
Number of pregnancies delivered after 7 months			
1	4(66.7)	60(30.9)	0.426
2	0(0.0)	31(16.0)	
3	1(16.7)	18(9.3)	
4	0(0.0)	10(5.2)	
5	0(0.0)	1(0.5)	
>6	0(0.0)	3(1.5)	
None	1(16.7)	71(36.6)	
Number of pregnancies delivered before 7 months			
1	0(0.0)	12(6.2)	1.000
2	0(0.0)	1(0.5)	
4	0(0.0)	2(1.0)	
>6	0(0.0)	1(0.5)	
None	6(100.0)	178(91.8)	
Outcome of previous pregnancies			
Live birth	5(83.3)	171(88.1)	1.000
Still birth	0(0.0)	5(2.6)	

Abortion	0(0.0)	16(8.2)

Table 3 shows that among factors documented as part of maternal reproductive history, no factors showed a statistically significant association with GBS colonization. Four (66.7%) of the mothers with colonisation had only one previous delivery compared to 58 (29.9%) of uncolonised mothers who also had a single previous delivery. All the four previous deliveries in the colonised mothers had been delivered after 7 months while 60(30.9%) of previous deliveries in uncolonised mothers occurred after 7 months.

Maternal outcomes and GBS colonisation

Table 4: Outcomes of mothers delivering at Kisii Teaching and Referral Hospital according to colonization status

	Streptococcal colonization(N=200)		
	Yes (n=6)	No (n = 194)	**P value**
Maternal outcomes (n = 182)			
Uneventful delivery	4(66.7)	130(67.0)	0.608
Premature rupture of membranes	0(0.0)	1(0.5)	1.000
Still birth	1(16.7)	3(1.5)	0.141
Meconium stained liquor	1(16.7)	15(7.7)	0.395
Prolonged labor	0(0.0)	18(9.3)	1.000
Obstructed labor	1(16.7)	5(2.6)	0.172
PPH	0(0.0)	3(1.5)	1.000

Most deliveries among both GBS colonised 4 (66.7%) and uncolonised 130 (67%) mothers were uneventful (p = 0.608), Table 4. Overall, prolonged labour (9.3% of uncolonised mothers), meconium stained liquor (7.7% for uncolonised and 16.7% for GBS colonised mothers) and obstructed labour (2.6% and 16.7%) were the most common poor maternal outcomes reported.

GBS colonisation was not significantly associated with maternal outcomes presented in Table 4: Premature rupture of membranes (p = 1.000), still birth (p = 0.141), meconium stained liquor (p = 0.395), prolonged labour (p = 1.000), obstructed labour (p = 0.72) and PPH (p = 1.000).

Table 5: Post-delivery complications in mothers delivering at Kisii Teaching and Referral Hospital according to colonization

	Streptococcal colonization(N=200)		
	Yes (n=6)	No (n = 194)	**P value**
Post-delivery complications (n = 182)			
Fever	1(16.7)	1(0.5)	0.06
Chills and general malaise	0(0.0)	1(0.5)	1.00
Lower abdominal pain	2(33.3)	7(3.6)	0.034
Purulent, foul smelling lochia	1(16.7)	1(0.5)	0.06
Puerperal sepsis	1(16.7)	1(0.5)	0.046

There were statistically significant associations between GBS colonization and one out of the four post delivery complications: lower abdominal pain (p = 0.034), associated with a diagnosis of pueperal sepsis. Three of the complications associated with sepsis occured more frequently in GBS colonised mothers compared to uncolonised mothers (Fever and purulent, foul smelling lochia 16.7% versus 0.5%; and lower abdominal pain 33.3% versus 3.6%), Table 5.

Two patients had at least two of the four post delivery complications and were therefore diagnosed with pueperal sepsis. The diagnosis of puerperal sepsis was significantly associated with GBS colonisation (p < 0.046), Table 5.

Neonatal outcomes and maternal GBS colonisation

Table 6: Neonatal outcomes among deliveries to mothers with and without streptococcal colonization in Kisii Teaching and Referral Hospital

	Streptococcal colonization(N=200)		
	Yes (n=6)	No (n = 194)	**P value**
Neonate's gender (n = 182)			
Male	2(33.3)	98(50.5)	0.411
Female	4(66.7)	78(40.2)	
Number of births (n = 180)			
Singleton	6(100.0)	169(87.1)	1.000
Twins	0(0.0)	5(2.6)	
Delivery mode (n = 182)			
Vaginal	3(50.0)	130(67.0)	0.345
Caesarian section	3(50.0)	46(23.7)	
Delivery outcome (n = 182)			
Live birth	5(83.3)	173(89.2)	0.126
Still birth	1(16.7)	3(1.5)	
Place of delivery (n = 200)			
Kisii level 5	6(100.0)	176(90.7)	1.000
Other facility	0(0.0)	18(9.3)	
Birth weight (n = 182)			
<2500	3(50.0)	10(5.2)	0.018
2501 – 3000	1(16.7)	46(23.7)	
3001 – 3500	1(16.7)	89(45.9)	
3501 – 4000	1(16.7)	27(13.9)	
>4000	0(0.0)	4(2.1)	

APGAR score (n = 180)			
0-3	0(0.0)	3(1.5)	0.273
4-6	1(16.7)	7(3.6)	
7-10	4(66.7)	165(85.1)	

Most deliveries were singleton, (100% in colonised group versus 87.1% in the uncolonised group), live (83.3% colonised versus 89.2% uncolonised) births, and occurred in Kisii Level 5 Hospital (100% colonised versus 90.7% uncolonised), Table 5. Still births were not significantly associated with GBS colonisation status (16.7% versus 1.5%, p = 0.126). Low birth weight was significnatly associated with GBS colonization status (50% versus 5.2% of GBS colonised and uncolonised deliveries, respectively weighed < 2500 gms, p = 0.018). APGAR scores at 1, 5 and 10 minutes (p = 0.273), place of delivery (p = 1.000), neonates gender (p = 0.411) and number of births (p = 1.000) were not significantly associated with GBS colonisation status, Table 6.

Table 7: Outcomes within the first hour of life in neonates delivered to streptococcal colonised and uncolonised mothers at Kisii Teaching ans Referral Hospital

	Streptococcal colonization(N=200)		
	Yes (n=6)	No (n = 194)	**P-value**
Early neonatal outcomes (n = 182)			
Uneventful	4(66.7)	158(81.4)	0.343
Resuscitation	1(16.7)	4(2.1)	0.144
Admitted to NBU	1(16.7)	10(5.2)	0.293
Neonatal death	1(16.7)	3(1.5)	0.141

For most births there were no major events occuring within the first hour of life (66.7% in GBS uncolonised versus 81.4% in colonised groups). Of the three immediate events namely, resuscitation, admission to NBU and neonatal death, the most common event was admission to NBU documented in 10 (5.2%) uncolonised and 1 (16.7%) colonised birth, p = 0.293.

Resuscitation (16.7 verus 2.1%, p = 0.144) and neonatal deaths (16.7 versus 1.5%, p = 0.141) were not significantly associated with GBS colonisation, Table 7.

Table 8: Development of signs of neonatal sepsis in neonates delivered to streptococcal colonised and uncolonised mothers at Kisii Teaching and Referral Hospital

	Streptococcal colonization		
	Yes (n=6)	No (n = 194)	**P-value**
Signs of neonatal sepsis (n = 182)			
Lethargy	1(16.7)	10(5.2)	0.295
Poor breastfeeding	1(16.7)	6(3.1)	0.198
Fever	1(16.7)	8(4.1)	0.250
Poor cry	1(16.7)	6(3.1)	0.199
Not arousable	0(0.0)	1(0.5)	1.000
Neonatal sepsis	1(16.7)	9(4.6)	0.259

Neonatal sepsis occurred in 9 (4.6%) neonates born to uncolonised mothers and 1 (16.7%) neonate delivered by a GBS colonised mother, p = 0.259. There were also no significant differences in the development of clinical features of neonatal sepsis presented in Table 8, among neonates delivered by GBS colonised and uncolonised mothers (all p values > 0.05).

DRUG SUSCEPTIBILITY

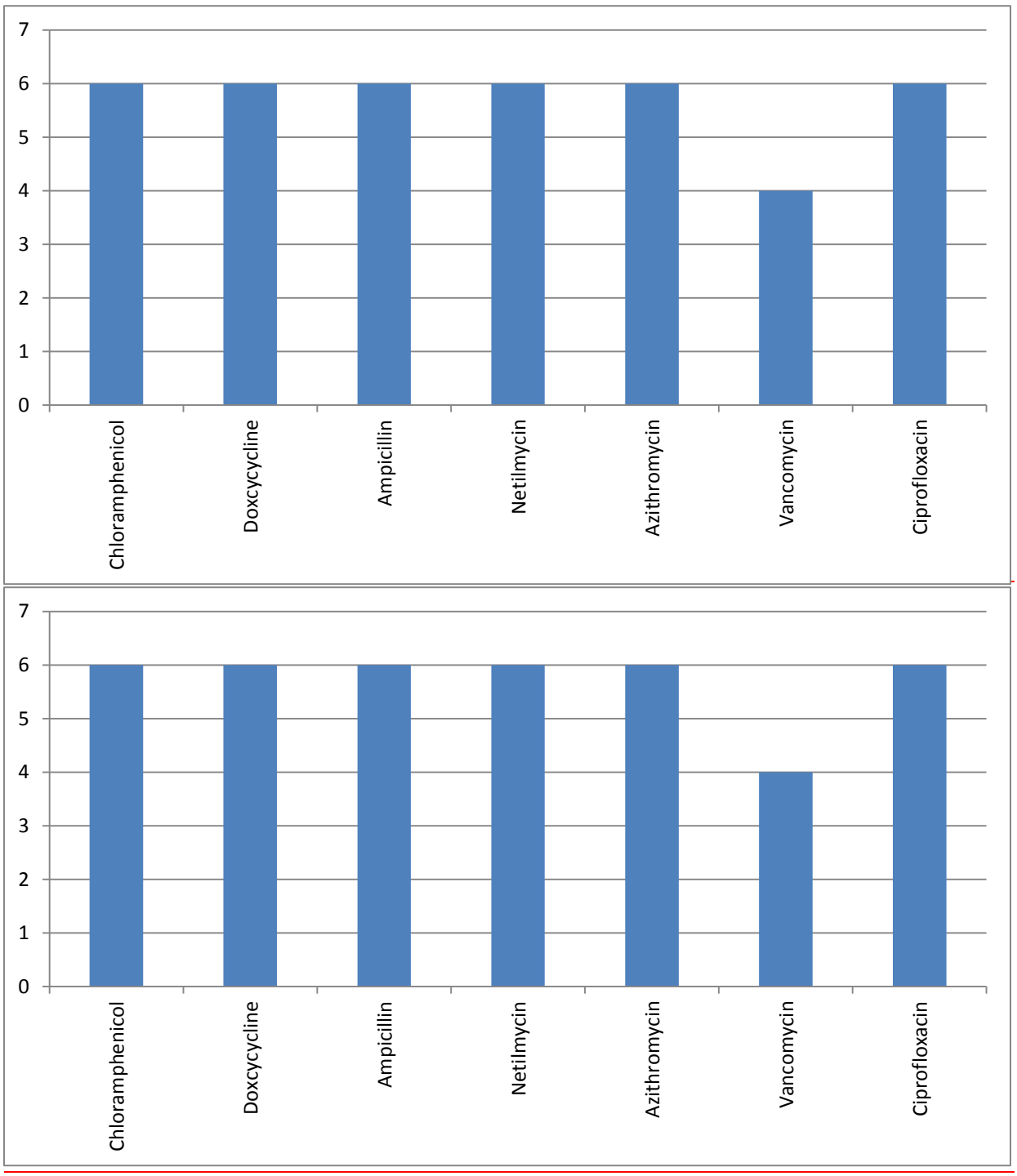

Figure 1: Antibiotic susceptibility in GBS isolates cultured among women delivering at KTRH

The GBS isolates (n = 6) from mothers delivering at KTRH were tested for susceptibility to seven antibiotics. All the six isolates were susceptible to six of the antibiotics namely

chloramphenicol, doxycycline, ampicillin, netilmycin, azithromycin and ciprofloxacin (Figure 3). Four out of the six tested isolates were sensitive to vancomycin while two isolates were resistant to vancomycin.

DISCUSSION

A total of 914 women were approached in the antenatal clinics during the study period, 712 of them were eligible and 200 were recruited into the study after meeting the inclusion criteria. 182 women were followed up until the immediate postpartum period. There was a loss to follow up of 18 women due to their choice of delivering in another facility. In total, 6 out of the 200 pregnant women 35-37 weeks gestation attending ANC clinic at Kisii teaching and referral hospital had vaginal colonisation with group B streptococcus yielding a prevalence of 3% in this cohort.

The low prevalence rate has been noted in other study sites like Taiwan whose colonization rate was 6.21%. In that study it was noted that prevalence of colonization in Taiwan ranged from 4-21% depending on the culture sites (18). The reasons for the low prevalence rate were unclear but contributory factors were thought to include differences in culture sites, specimen collection techniques and culture medium. Those factors as well as differences in the study population, ethnic and genetic factors, environmental and nutritional factors may also have played a role in the low colonization rate in this study.

This is also in contrast to the study carried out at KNH by Salat et al whose prevalence rate was 25.2 %.(13) This difference could be attributed to the different geographical locations, Nairobi being urban and Kisii being rural and the nature of their populations, urban and rural respectively.

Majority of the colonised women (83.3%) had only primary level education and 16.7% had college education as compared to 28.4% of uncolonised women who had primary education and 22.7% who had college education. A significant association was found between level of education and GBS colonisation (P=0.035). Regan et al found that GBS was less common among women with a higher level of education(16).

In this study no association was found between employment status and GBS colonisation(P=0.617)neither was there any association between the income bracket and GBS colonisation(P=0.708). Dr Girad Salat in a study on prevalence of GBS colonisation at the Kenyatta National hospital did not also find a significant association between maternal age,parity,marital status,education,employment and GBS colonisation(14)

In this study,there was no statistically significant association between vaginal GBS colonisation and maternal reproductive history. However, multigravid women were more likely to be colonised (83.3%) as compared to 34.5% of primigravid and 65.5% of multigravid women among the uncolonised group. This is comparable to a study done in Trinidad where colonisation was significantly greater in multigravid than in the primigravid(17).

E. Were et al in a study at Moi Teaching and Referral hospital Eldoret, Kenya also found no significant association between sociodemographic and obstetric characteristics and GBS colonisation(15)

There was no statistically significant association between GBS colonisation and still birth as a subsequent outcome(P=0.141). In Dr Salat's study there was a significant association between history of stillbirth and GBS colonisation. There was also a review that identified GBS as a common cause of stillbirth(19)

Pregnancy outcomes like premature rupture of membranes that have been associated with GBS colonisation(20) were found not to be associated with GBS colonisation in this study(P=1.000). This was also demonstrated in study carried out in Australia where no positive correlation could be found between antenatal GBS colonisation and PROM as well as premature labour(21).

In this study,there was a significant association between puerperal sepsis and GBS colonisation(P=0.046). Anouk E. Muller et al found that among cases of puerperal infection,bacteraemia occurred in 31-35% with 5-25% progressing to sepsis. GBS was a commonly isolated organism in 38% of cases(22).

There was a significant association between birth weight and GBS colonisation (P=0.018). 50% of GBS positive mothers delivered neonates who weighed less than 2500g. There was no association between the neonates gender(P=0.411),number of neonates (P=1.000)and APGAR score(P=0.273). This is comparable to a study carried out in Zimbabwe where 10.6% of the infants weighed <2500g,58.8% of these were colonised with GBS(7).

There was no significant association between any of the neonatal outcomes within the first hour of life and GBS colonisation(all P values >0.05)

No significant association was found between neonatal sepsis and GBS colonisation(P=0.259).

The GBS isolates were sensitive to Chloramphenicol, Azithromycin, Ciprofloxacin, Netilmycin, Doxycycline, Ampicillin with some resistance to Vancomycin. This is comparable to the Tanzanian study where all isolates were sensitive to Ampicillin and Vancomycin(6). This is in contrast to the Nigerian study where all isolates were 100% resistant to ampicillin and 70% resistant to Vancomycin(3).

CONCLUSION

There was a low prevalence of maternal group B streptococcus infection among the pregnant women in the study. GBS colonisation was associated with adverse maternal outcomes like puerperal sepsis. Low level of education was significantly associated with GBS colonisation. No significant association was found between neonatal sepsis and GBS colonisation.

RECOMMENDATION

From the results, it would be recommended that group B streptococcus should be considered as one of the likely causative organisms in suspected cases of puerperal sepsis especially in resource poor settings where laboratory services are not readily available and treatment given accordingly. In this study the GBS was sensitive to chloramphenicol, ampicillin, doxycycline, azithromycin, netilmycin and ciprofloxacin.

In the event that neonates born with a birthweight of less than 2500g develop invasive disease, the clinician should have a high index of suspicion for GBS disease and treat accordingly especially in the resource poor settings.

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APPENDIX 1

PARTICIPANTS INFORMATION/CONSENT FORM

ENGLISH LANGUAGE VERSION

Project title: **PREVALENCE OF GROUP B STREPTOCOCCUS AMONG PREGNANT WOMEN 35-37 WEEKS GESTATION AND THE MATERNAL AND NEONATAL OUTCOMES WITHIN 48 HOURS POST NATAL AT THE KISII LEVEL 5 HOSPITAL**

INVESTIGATOR

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The Chairperson,KNH-ERB

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INTRODUCTION

My name is Dr Caroline Kaminja. I am a postgraduate student in the department of Obstetrics and Gynaecology at the University of Nairobi and I would like you to participate in this study. If you agree to join this study, you will be required to undergo a test called rectovaginal swab test. This shall then be taken to the Aga Khan University Laboratory for processing and analysis. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about what we will ask you to do, the risks, the benefits and your rights as a volunteer or anything about the

research or in this form that is not clear. When all your questions have been answered, you can decide whether to be in this study or not. This process is called "informed consent"

BACKGROUND INFORMATION

Group B streptococcus (GBS) is a bacterium that may be found in the vagina (birth canal). Women who have GBS in their vagina often do not show any signs or symptoms of disease. This bacterium is not a sexually transmitted infection. One third of all pregnant women have been found to carry these bacteria in their vagina during pregnancy. When present during pregnancy, GBS may increase the chances of a woman giving birth before the expected day of delivery. It also increases the chances of the water breaking before labour and infection of the womb after birth. Half of the babies born to women who have GBS in their vagina during pregnancy,get infection. These infections include pneumonia and blood infections.

Why is this study being done?

This study will help us find out how common GBS is among pregnant women attending clinic and admitted in the ante natal wards of Kisii level 5 hospital and what are the possible outcomes in the mother and newborn during delivery and in the immediate post natal period. If we find that GBS is common amongst our pregnant mothers and we note any adverse outcomes associated with its presence in the vagina,we will advocate for routine testing of all pregnant women and mandatory treatment of those found with the organism during labour.

Study procedure

If you agree to participate, a medical history will be taken and physical examination done. This will entail inquiry about age, history of current pregnancy, previous miscarriages and still births. The doctor will collect a swab specimen from you (from the vagina and anorectal region). The swabs for collecting specimens are sterile and non-traumatic. Your result will be shared with your primary care physician(s) for possible interventions where appropriate. The KNH Research and Ethics Board have given us permission to invite you to participate in this study.

Confidentiality

All information obtained will be strictly confidential and will not be revealed to other persons other than your primary care physician(s). The quality of care given to you in the hospital will not be compromised by your refusal to participate in this study. Participation in this study is voluntary (at your own will) and you are free not to participate or to withdraw at any time. About 200 pregnant women will take part in this study. The first visit will be required for research and the subsequent visit will be during delivery and in the immediate post-delivery period.

BENEFITS AND RISKS

Benefits

This study will help us know and understand the burden of GBS among pregnant women and the adverse outcomes, if any, to the mother and newborn during delivery and after.

This study will benefit the society by providing information that might influence health policy by making routine testing and treatment for GBS during ante natal visits mandatory.

You will not pay for the laboratory charges

Risks

By participating in this study no risks to you or to your baby are anticipated

Compensation

There will be no costs to you for any of the activities in this study. There shall be no monetary gain on participating.

Other information

If you have a problem that may be related to taking part in this research or any questions, you can contact Dr Caroline Kaminja on 0721 885 037 and I will be glad to help where I can. If you have any questions about your rights as a research participant you may contact the chairperson of the Ethics Board on 2726300 ext. 44102

Signatures for Consent

The above information describing the research, its benefits ,risks and procedures has been read to me and explained. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study.

Name of Patient_____Date_____

Signature or thumb print of the patient_____

I certify that the nature and purpose, benefits and potential risks associated with participating in this research have been explained to the above volunteer.

Name of person obtaining the consent_____

Signature of the person obtaining the consent_____

Thank you for agreeing to participate in this research.

APPENDIX II

IDHINI YA USHIRIKI KATIKA UTAFITI: MAKALA YA KISWAHILI

MAELEZO KWA MHUSIKA NA NAKALA YA KIBALI

UTAFITI: KIWANGO CHA MAAMBUKIZI YA GROUP B STREPTOKOKASI MIONGONI MWA WANAWAKE WAJAWAZITO 35-37 WIKI UJAUZITO NA UZAZI NA WATOTO WACHANGA MATOKEO NDANI MASAA 48 BAADA YA KUJIFUNGUA AT KISII LEVEL 5 HOSPITAL

MTAFITI MKUU

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KIANZILISHI

Jina langu ni Dkt Caroline Kaminja. Mimi ni mwanafunzi katika Idara ya Uzazi na Magonjwa ya wanawake katika Chuo Kikuu cha Nairobi na ningependa wewe ushiriki katika utafiti huu. Ikiwa utakubali kujiunga na utafiti huu, utahitajika kupimwa kipimo kiitwacho rectovaginal swab.Kipimo hiki kitatumwa katika maabara ya Chuo Kikuu cha Aga Khan kwa ajili ya uchambuzi. Madhumuni ya hati hii ya idhini ni kukupa maelezo unayohitaji kukusaidia kuamua kama kuwa utashiriki katika utafiti. Tafadhali soma hati hii kwa makini. Unaweza kuuliza

maswali kuhusu utafiti huu, madhara, manufaa na haki yako kama mhusika au kitu chochote kuhusu utafiti au katika hati hii ambayo si wazi. Maswali yote yakiwa yamejibiwa, unaweza kuamua kama utashiriki katika utafiti huu au la. Mchakato huu ni wito wa ridhaa

Taarifa za msingi

Kundi B Streptokokasi (GBS) ni bakteria ambayo inaweza kupatikana katika uke. Wanawake walio na GBS katika uke wao mara kwa mara hawaonyeshi dalili zozote za ugonjwa huo. Bakteria hii si ugonjwa wa zinaa. Theluthi moja ya wanawake wote wajawazito wameonekana kubeba bakteria hii katika uke wao wakati wa ujauzito. Katika wakati wa ujauzito, GBS inaweza kuongeza nafasi ya mwanamke kujifungua kabla ya siku inayotarajiwa kwa kujifungua. Pia inaongeza nafasi ya kuvunja maji kabla ya wakati wa kujifungua na maumivu ya nyungu ya uzazi baada ya kujifungua. Nusu ya watoto wanaozaliwa na wanawake ambao wana GBS katika uke wao wakati wa ujauzito huambukizwa. Watoto hawa wanaweza kuambukizwa pneumonia na marathi ya kimwili.

Kwa nini utafiti huu unafanyika?

Utafiti huu utatusaidia kujua kiwango cha GBS miongoni mwa wanawake wajawazito wanaohudhuria kliniki na waliolazwa katika wodi za hospitali ya kuu ya Kisii. Pia tutaweza kujua matokeo kwa mama na watoto wachanga wakati wa kujifungua na kipindi cha baada ya kujifungua. Kama tutagundua kwamba kiwango cha GBS kiko juu miongoni mwa akina mama wajawazito na kuna matokeo mabaya yanayohusiana na uwepo wake katika uke, tutapendekeza upimaji wa mara kwa mara ya wanawake wote wajawazito na matibabu ya lazima kwa wale watakaopatikana na GBS wakati wa kujifungua.

Utaratibu wa Utafiti

Kama utakubali kushiriki, historia ya matibabu itachukuliwa na uchunguzi wa kimwili kufanyika. Suala hili litahusisha uchunguzi kuhusu umri, historia ya mimba ya sasa, mimba zilizopita na mimba za watoto waliozaliwa kama wamefariki. Daktari atakusanya sampuli ya usufi kutoka kwako (ukeni na kanda ya haja kubwa). Sufi kwa ajili ya kukusanya vielelezo ni kuzaa na mashirika yasiyo ya kiwewe. Matokeo yako yatapatiwa daktari wako kwa ajili ya hatua

iwezekanayo kuchukuliwa pale inapobidi. Utafiti KNH na Maadili Bodia imetupa ruhusa ya kukukaribisha kushiriki katika utafiti huu.

Siri

Taarifa zilizokusanywa kutoka utafiti huu utatunzwa binafsi na siri. Ubora wa huduma unaopewa katika hospitali hautaathirika ukikataa kushiriki katika utafiti huu. Kushiriki katika utafiti huu ni hiari (katika mapenzi yako mwenyewe) na uko na haki ya kutoshiriki au kujiondoa wakati wowote. Wanawake 200 wajawazito watashiriki katika utafiti huu. Ziara ya kwanza itakuwa inahitajika kwa ajili ya utafiti na ziara inayofuata itakuwa wakati wa kujifungua na katika kipindi cha baada ya kujifungua.

Faida na Hatari

Faida

Utafiti huu utatusaidia kujua na kuelewa mzigo wa GBS miongoni mwa wanawake wajawazito na matokeo mabaya, kama iwapo, kwa akina mama na watoto wachanga wakati wa kujifungua na baada ya kujifungua.

Manufaa ya utafiti huu kwa jamii ni kutoa taarifa ambayo itaweza kushawishi sera za afya kwa kufanya kupimo cha wanawake wajawazito na matibabu kwa ajili ya GBS wakati wa kujifungua kuwa ya lazima.

Hutalipia gharama ya maabara.

Hatari

Hatutarajii hatari yoyote kwako au kwa mtoto wako utakaposhiriki katika utafiti huu.

Fidia

Hakutakuwa na gharama yoyote kwako katika shughuli ya utafiti huu. Hakutakuwa na faida ya fedha juu ya kushiriki.

Taarifa Nyingine

Kama unatatizo linalotokea kwa sababu ya kuhusiana na kushiriki katika utafiti huu au maswali yoyote, unaweza kuwasiliana na Dkt Caroline Kaminja nambari ya simu 0721 885 037. Kama una maswali yoyote kuhusu haki zako kama mshirika wa utafiti unaweza kuwasiliana na Mwenyekiti wa Bodi ya Maadili ukitumia nambari 020-2726300 mwendelezo 44102

Saini kwa ajili ya Ridhaa

Nimeelezewa habari juu ya utafiti,faida zake,hatari na taratibu. Maswali yangu yote yamejibiwa na nimeridhika. Nakubali kuhusika kwa huu utafiti kwa hiari bila kusurutishwa kwa njia yoyote.

Jina la Mhusika wa
utafiti_____Tarehe_____

Sahihi au alama ya kidole gumba ya mhusika wa utafiti_____

Ninathibitisha kwamba asili na lengo, faida na uwezekano wa hatari zinazohusiana na kushiriki katika utafiti huu wamekuwa alielelzea kujitolea hapo juu.

Jina la anayeomba utafiti_____

Sahihi la anayeomba utafiti_____

Asante kwa kukubali kushiriki katika utafiti huu.

APPENDIX III

DATA COLLECTION QUESTIONNAIRE

DATE: _____

STUDY NUMBER: _____

HOSPITAL NUMBER: _____

PHONE NUMBER: _____

SECTION A: SOCIODEMOGRAPHIC DATA

1. What is your age in years?

- Less than 20
- 21-30
- 31-40
- 41-50

2. What is your marital status?

- Single
- Married
- Cohabiting
- Divorced
- Separated
- Widowed

If married, what type of marriage set up are you in?

- Monogamous
- Polygamous

3. What is your education level?

- None
- Primary

- Secondary
- College
- University

4. What is your employment status?

- Unemployed
- Self employed
- Salaried employment
- Casual labourer

5. What is your monthly income?

- Less than ksh 10,000
- Ksh 10,000-50,000
- Ksh 50,000-100,000
- Above Ksh 100,000

SECTION B: REPRODUCTIVE HISTORY

1. How many times have you been pregnant?

A. 1 B. 2 C. 3 D. 4 E. 5 F. 6 G. >6

2. Number of pregnancies delivered after 7 months?

A. 1 B. 2 C. 3 D. 4 E. 5 F. 6 G. >6

3. Number of pregnancies delivered before 7 months?

A. 1 B. 2 C. 3 D. 4 E. 5 F. 6 G. >6

4. Based on question 1 above, what is the patient's gravidity?

- Primigravida
- Multigravida

5. Based on questions 2 and 3 above, what is the patient's parity?

_____

6. What is the gestational age of the current pregnancy in weeks?

A. 35 weeks B. 36 weeks C. 37 weeks D. 38 weeks E. 39 weeks F. 40 weeks

7. For the multigravida, what were the outcomes of the previous pregnancies?

- live birth

- still birth
- abortion

SECTION C: MATERNAL OUTCOMES

1. What was the gestational age at delivery?

A. 35weeks B.36weeks C.37weeks D.38weeks E.39weeks F.40weeks G.41weeks H.42weeks

2. Was the labour spontaneous or induced?.....
3. What was the mode of delivery?

- vaginal
- caesarian section

4. What were the complications during delivery?
    - Preterm labour
    - Chorioamnionitis
    - Premature rupture of membranes
    - Still birth
    - Meconium stained liquor
    - Others
5. Did you develop any of the following symptoms post-delivery?

- Fever
- Chills and general malaise
- Lower abdominal pain
- Sub involution of the uterus
- Purulent, foul smelling lochia

Any 3 of the symptoms above will constitute a diagnosis of puerperal sepsis.

SECTION E: NEONATAL OUTCOMES

1. What is the gender of the neonate?

- Male
- Female

2. What was the outcome of the delivery?

- Live birth
- Still birth

3. What was the birth weight at delivery?

- <2500g
- 2501-3000g
- 3001-3500g
- 3501-4000g
- >4000

4. What was the APGAR score at delivery?

- 0-3
- 4-6
- 7-10

5. What were the outcomes within the first hour of life?

- Uneventful
- Neonatal Resuscitation
- Admission into the New Born Unit
- Admission into the Neonatal ICU

  Neonatal death

6. Did the neonate develop any of the following symptoms post-delivery?

- Lethargy
- Poor breastfeeding
- Fever
- Hypothermia
- Poor cry
- Not arousable

Any 3 symptoms above will constitute a diagnosis of neonatal sepsis

APPENDIX IV

LABORATORY REQUEST/REPORT FORM

STUDY
NUMBER:……

HOSPITAL
NUMBER:……

DATE SPECIMEN
COLLECTED:…..……/……/…….

TIME SPECIMEN
COLLECTED:…….....

TIME SPECIMEN
RECEIVED:……..

TYPE OF
SPECIMEN:…….....

REPORT:

GROUP B STREPTOCOCCUS STATUS

- POSITIVE
- NEGATIVE

NAME OF LABORATORY TECHNOLOGIST:……

SIGNATURE:……,,,,,,,,,,,,

APPENDIX V

DR CAROLINE KAMINJA
DEPARTMENT OF
OBSTETRICS/GYNAECOLOGY
UNIVERSITY OF NAIROBI
H58/68573/2011
Email: ckaminja@yahoo.com
July 22, 2014

THE MEDICAL SUPERINTENDENT
KISII LEVEL 5 HOSPITAL
P.O BOX 92-40200
KISII.

Dear Sir/Madam,

RE: REQUEST FOR PERMISSION TO CARRY OUT RESEARCH IN KISII LEVEL 5 HOSPITAL

I am a postgraduate student in the department of Obstetrics & Gynaecology, University of Nairobi. I am required to write a thesis on a researched topic of my choice as a fulfillment for my degree. My topic of interest is on the prevalence of Group B streptococcus among pregnant women 35-37 weeks gestation and the maternal and neonatal outcomes within 48 hours postnatal. I intend to collect my data from the antenatal clinics, antenatal wards, labourward and postnatal wards.

I am kindly requesting for permission to access these areas of the hospital.

Yours faithfully,

Dr. Caroline Kaminja
0721885037