THE INCIDENCE OF EPISIOTOMY AND ASSOCIATED MORBIDITY AMONG PRIMIGRAVID WOMEN AT MBAGATHI HOSPITAL

BY:

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DECLARATION

I Dr. Hellen K. Munyao hereby declare that this research is a bonafide and genuine work carried out by me and that it has not been presented for the award of a degree at any other university.

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This dissertation has been presented with our full approval as supervisors

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Hellen Kathini Munyao, Master of Medicine student in Department of Obstetrics and Gynecology, registration number H58/68566/2011, University of Nairobi. The research was carried out at Mbagathi Hospital, Nairobi, Kenya and has not been presented in any other university for an award of degree.

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DEDICATION

This research project is dedicated to my parents the Late Mr. Charles M Musili and Mrs. Joyce K Munyao for choosing to invest in me via education and to all wonderful mothers of the world.

LIST OF ABBREVIATIONS

APGAR	Appearance, Pulse, Grimace, Activity, Respiration
BWT	Birth Weight
C/S	Caesarian Section
FGM	Female genital mutilation
G	Gram
G A	Gestational Age
GBD	Gestation By Dates
KNH	Kenyatta National Hospital
LMP	Last Menstrual Period
M.MED	Master Of Medicine
ML	Milliliter
PND	Postnatal Day

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ABSTRACT

Background Episiotomy is the commonest obstetric surgical procedure after cord ligation that was introduced in practice in the 18th century without strong scientific evidence of its benefits, which included non reassuring fetal status, preterm delivery, assisted vaginal delivery and decreasing sexual, perineal and pelvic floor dysfunction. Episiotomy rates have been on decline in developed countries; however its rates remain higher than the recommended 10% (WHO) in developing countries despite the fact that few if any benefits to both the mother and the neonate exist.

Objective To determine the incidence of episiotomy, immediate and late outcomes and factors associated with morbidity at two weeks postpartum in primigravid women at Mbagathi Hospital.

Methodology The study was carried out at Mbagathi Hospital from May to July 2015 where 200 study participants who met the inclusion criteria were cumulatively recruited on first postnatal day and data on socio-demographic characteristics, obstetrics history, progress of labour, immediate neonatal and maternal outcomes recorded. One hundred and seventy four study participants turned up at two weeks postpartum for review and completion of data entry. Participants who did not turn up for review were dropped from the study. Data were analyzed via SPSS version 21 and presented as means medians and proportions in tables and figures together with discussion.

Results Episiotomy incidence rate in this study was 28.2% (49) and medio-lateral episiotomy was the only type practiced. Close to 48 % of study participants sustained posterior perineal tears. About 58% and 21% study participants sustained second and third degree perineal tears respectively. There was no association between immediate neonatal birth weight, baby□s sex, 5th minute apgar score and episiotomy. Women without episiotomy were more likely to sustain second and third degree posterior perineal tears. Episiotomy was significantly associated with delay in perineal wound healing, in that only 2% of participants with episiotomy had good wound apposition by two weeks postpartum compared to 53.6% of participants without episiotomy. The predictors of postpartum complications at two weeks were episiotomy and perineal tears OR 195.2; 95 % CI 40.8-933.2; P< 0.001.

Conclusion In this study episiotomy rate was found to be lower than rates of previous studies in K N H but higher than the 10% recommendation by WHO. Episiotomy was significantly associated with high maternal morbidity within two weeks postpartum; however women with episiotomy were less likely to sustain third degree perineal tears. The main predictors for postpartum maternal complications at two weeks in this study were presence of episiotomy and perineal tears

Recommendations There is need to emphasize on selective episiotomy practice in primigravid parturients. Hospitals need to invest more on continued medical education and training of birth attendants in basic surgical and delivery skills. Review of all postnatal mothers within two weeks will assist in timely diagnosis and management of complications. parturients with severe perineal trauma may benefit from prophylactic antibiotics.

INTRODUCTION AND LITERATURE REVIEW

Episiotomy is a surgically planned incision on the posterior vaginal wall and the perineum performed during the second stage of labor to aid in delivery of the neonate.[1] The procedure is performed with episiotomy scissors when the perineum is thin and outstretched, during a uterine contraction just prior to crowning i.e. When 3 to 4 cm of the fetal head is visible. It is the second most commonly performed obstetric operation after cord ligation. Recently rates have remained higher than evidence based recommendations for optimal patient care.[2]

Episiotomy was introduced as an obstetric procedure in the 18th century, by 1970s its rates were as high as 80 % in various parts of the world.[2] In recent years liberal episiotomy use has been discouraged, this has led to a sharp decline in anal sphincter laceration and operative vaginal delivery rates with associated increase in the rates of caesarean delivery as practitioners favor caesarean section delivery for difficult births.[3] Cochrane reviews in developed countries have shown that restrictive episiotomy has several benefits like less severe posterior perineal trauma, less suturing and fewer healing complications however it increases the risk of anterior perineal trauma[4]. There exists sparse data on episiotomy and perineal trauma from developing countries, but still it remains one of the most commonly performed procedure in obstetrics.[5]

Historical indications for episiotomy include; abnormal progress of labor, non-reassuring fetal status, prematurity, assisted vaginal delivery, shoulder dystocia. it was also believed to hasten second stage of labor, decrease perineal pelvic floor and sexual dysfunction, reduce urinary and fecal incontinence.[5] Studies carried out in the last 20 years or so show that common indications for episiotomy were based on limited data. Current

evidence based medicine practice recommends restrictive as opposed to liberal use of episiotomy for there is no evidence that routine episiotomy reduces perineal damage.[6]

Mwasiaji (1992) found out that episiotomy rate at K N H was 37.3%, and it led to considerable morbidity to the women who underwent the procedure. In his study there was a significant difference in the episiotomy rates for primiparae women versus multiparae women; 73.2% versus 15.3% respectively. Liberal versus restrictive episiotomy practice was not evaluated in this study.[7]

Guled (2007) found that the episiotomy trends in the era of H I V/ AIDS at K N H was more of a routine practice. He carried out a retrospective comparative hospital based study that compared episiotomy trends between the year 1995 and 2005 found out that episiotomy practice in the era of H I V /AIDS was more of routine procedure rather than restrictive with overall rates of 31.1% and 30.9% in 1995 and 2005 respectively. The episiotomy rate in primigravid women was 56.3% and 52.7% in 1995 and 2005 respectively.[8]

Chigbu et al (2008) evaluated factors influencing the use of episiotomy at the Abia State University Teaching Hospital (ABSUTH) in south eastern Nigeria. He found out that episiotomy rate then was 45%. Among the risk factors influencing episiotomy practice was absence of a previous pregnancy with 90% of primiparae parturients undergoing the procedure, other risk factors for episiotomy practice in this study were persistent occipital posterior position, instrumental delivery and previous history of caesarean section. Episiotomy was associated with major perineal lacerations and increased need for secondary re-suturing.[9]

Barnabas et al (2012) in a study on relative frequency and predictors of episiotomy in Ogbomoso Nigeria found out that absence of vaginal birth, nullparity, age and assisted vaginal delivery were predictors of routine episiotomy. Some episiotomy operations were being performed to allow midwifery and medical students the opportunity to learn and practice the procedure.[10]

Carvalho et al (2010) carried out a study on prevalence and factors associated with practice of episiotomy at a maternity school in Recife Pernambuco, Brazil. He found out that the procedure was practiced more in adolescents and in parturients who had other medical illnesses in pregnancy.[11]

There are two main types of episiotomy;

Medio-lateral episiotomy in which an incision is begun at the posterior fourchette and continued downward midpoint at an angle of at least 45^0 relative to perineal body. The incision can be performed on either side and is generally 3 - 4 cm in length. Medio lateral incision cuts through vaginal mucosa, transverse perinei, bulbocarvenosus and perineal skin.

Midline (median) episiotomy where by a vertical incision commences from the posterior fourchette and extends downwards along the midline towards the anus cutting through vaginal mucosa, perineal body and the junction of the bulbocarvenosus body. Midline episiotomy is approximately 2.5 cm long .[12]

Some of the benefits of midline episiotomy documented include, minimal blood loss, easy repair, better cosmesis and future sexual function upon healing when compared to medio-lateral episiotomy. This type of episiotomy is associated with high risk of extension to third and fourth degree perineal tear.

Other reported episiotomy types in literature are lateral episiotomy which was condemned and also a J –shaped episiotomy incision that is not commonly practiced. [10- 12] Midline episiotomy is mainly practiced in United States while medio lateral episiotomy procedure is practiced in other parts of the world. Medio lateral episiotomy is associated with excess blood loss, difficult repair, poor wound healing and dyspareunia. [13]

In medio lateral episiotomy extension to involve the rectum is a rare occurrence compared to median episiotomy.[14]

Presence of episiotomy or perineal tear in first delivery has been shown to increase the risk of severe perineal injury in subsequent deliveries while selective episiotomy practice and restriction of forceps delivery enhance perineal integrity.[15-16]

According to the findings of Carroli et al (2009) on choice of episiotomy technique; median versus medio lateral episiotomy depends on what the accocheur is most familiar with.[17-19]

Episiotomy incision is generally repaired after delivery of placenta in order to achieve haemostasis and approximate lacerated tissues. The aseptic procedure is carried out in a well lit room with adequate exposure and appropriate instruments. Suture is placed approximately a centimeter proximal to the apex of the incision within the vagina and secured with a knot, vaginal mucosa and sub-mucosa are sutured up to hymeneal ring, perineal muscles are then approximated followed by closure of perineal skin using a continuous subcutaneous suturing technique[20].

Repair of fourth degree tear is begun at the rectal mucosa from the apex followed by apposition or overlapping of sphincter ani muscle. The other steps of repair procedure are similar to that of episiotomy or second degree perineal tear [21]

Christine Kettle (2012) conducted a cochrane review on continuous versus interrupted suturing techniques for repair of both episiotomy and second degree perineal tears. This Cochrane review found out that continuous suturing techniques for perineal closure was associated with less short term pain, easily performed by inexperienced operator and economical.[22]

The recommended technique for repair of vaginal and perineal muscles is non-locking continuous suturing using absorbable sutures; then continuous subcutaneous stitch is used to close the perineal skin.[23]

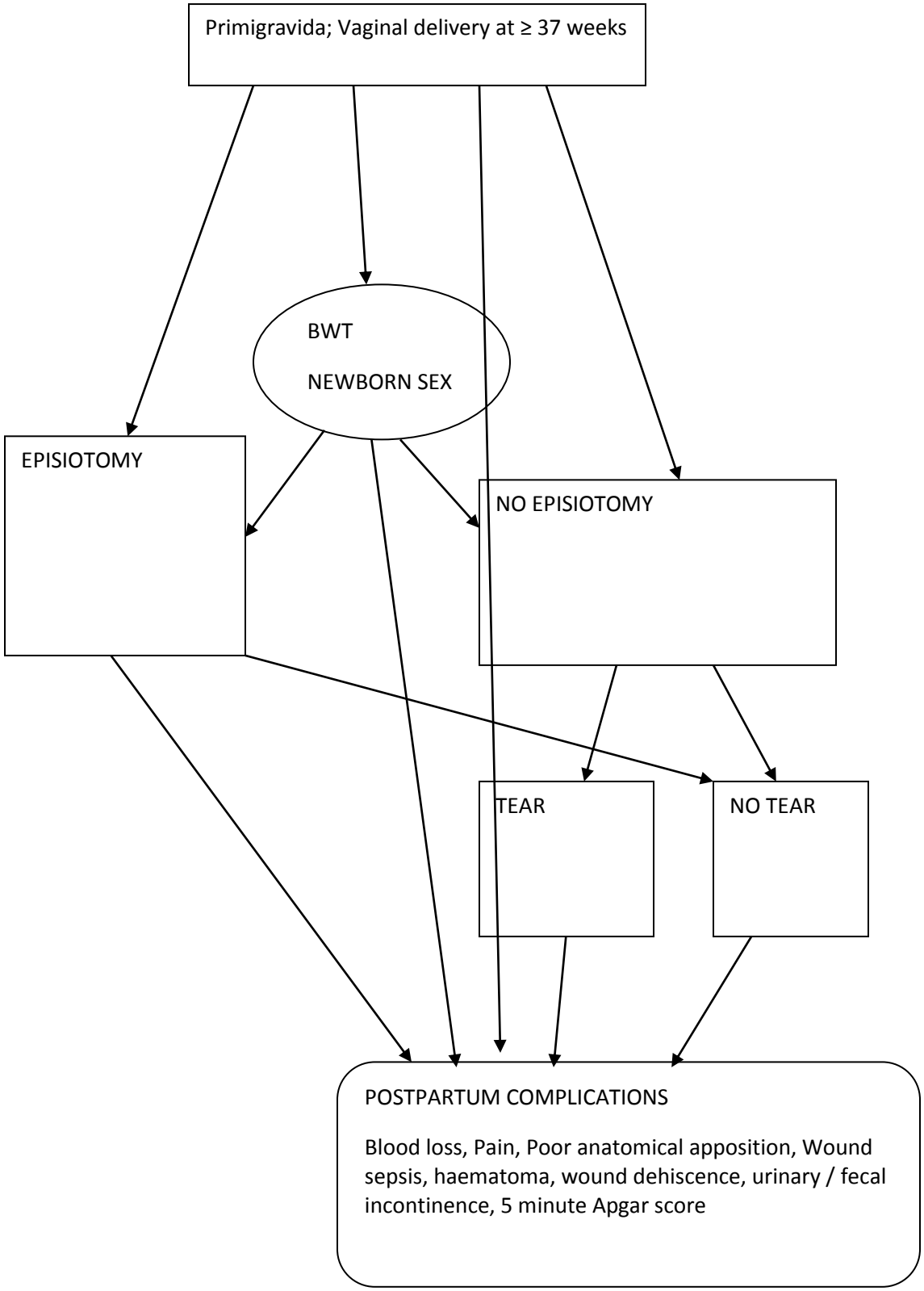
The suggested maternal benefits of episiotomy are as follows; reduction of likelihood of third degree perineal tears, preservation of pelvic floor and perineum integrity leading to improved sexual function, decreasing risk of both fecal and urinary incontinence, the incision is straight and clean making it easier to repair than a perineal tear. Episiotomy heals better than a laceration however this is an area where further research is required. Episiotomy procedure is thought to shorten duration of second stage; this quickens delivery of a neonate with fetal distress, reducing the risk of birth asphyxia, cranial trauma, cerebral hemorrhage and mental retardation.[24]

It is also suggested that episiotomy may reduce the possibility of shoulder dystocia [25] Episiotomy procedure has been shown to prevent anterior perineal lacerations but failed to accomplish any maternal or fetal benefits traditionally ascribed to its practice.

The incision substantially increases maternal blood loss, the average depth of posterior perineal injury, risk of anal sphincter damage, improper wound healing and increased amount of pain in the first several postpartum days.[26] It is of importance to bear in mind

about the extra costs and additional resources required to sustain the use of episiotomies.[27]

Figure 1: Conceptual framework



The conceptual framework was adopted and modified from Earp and Ennest model 1991[28]

The conceptual frame work describes association between episiotomy and risk of perineal tear among primigravid women at ≥ 37 weeks delivering vaginally. Among some of the parturients who achieve vaginal delivery episiotomy is practiced. The assumption would be that the birth weight and sex of the foetus have a relationship with the need for episiotomy and risk of perineal tears. All these are possible factors in postpartum complications which include the need for repair, amount of blood loss, and pain among others.

Rationale / Justification

Episiotomy is one of the most common procedures done in obstetrics coming second to umbilical cord ligation. Despite its introduction in practice in the 18^{th} century, its rates have been on the decline in developed countries but still remain high in developing countries.

Aiming to cut women delivering vaginally has no demonstrable benefit for the infant or the mother but causes the mother unnecessary pain, hemorrhage, infection and even refusal to breastfeed in some women. Most women in puerperium worry more of episiotomy than anything else including labor.

Episiotomy practice pattern vary widely as do professional opinions about maternal and fetal risks and benefits associated with it. Historically episiotomy has been used to facilitate delivery in cases of protracted second stage, instrumental delivery and suspected fetal compromise. However data supporting episiotomy as a facilitating procedure are sparse and evidence endorsing prophylactic episiotomy is largely anecdotal or descriptive with sparse data supporting the indications.

Timing of episiotomy to shorten second stage of labor may be less relevant in an era of decreasing instrumental delivery and with improved neonatal outcomes.

Episiotomy and especially midline episiotomy remains the greatest risk to sustaining third and fourth degree lacerations.

W H O recommends restrictive as opposed to routine episiotomy use which is associated with less posterior perineal trauma, less need for suturing and fewer complications during healing. This study therefore aims to carry out an appraisal towards current episiotomy practice in primigravid women in the era of evidence based medicine practice.

Research question

What is the incidence of episiotomy and factors associated with morbidity among primigravid parturients at Mbagathi Hospital?

Alternative hypothesis

There is a difference in morbidity between the primigravid parturients who do and do not undergo episiotomy at Mbagathi Hospital.

Broad objective

To determine the incidence of episiotomy and factors associated with morbidity at two weeks postpartum in primigravid parturients at Mbagathi Hospital.

Specific objectives

1. To determine the incidence of episiotomy among primigravid women who deliver at Mbagathi Hospital.
2. To compare the immediate neonatal outcomes in primigravid women undergoing episiotomy procedure versus those who do not get episiotomy at Mbagathi District Hospital.
3. To determine the difference between perineal healing among cases who had episiotomy procedure and those who did not have episiotomy procedure at Mbagathi Hospital
4. To determine the factors associated with complications at two weeks postpartum.

DESIGNS AND METHODOLOGY

Study Site

The study was conducted at Mbagathi District hospital which is found at Golf course location, Dagoretti Division, Dagoretti District in Nairobi County, which is run by the Ministry of Health. It provides preventive, diagnostic and curative health care.

It is run by consultants assisted by medical officers, medical officer interns, clinical officers and clinical officer interns, nurses and nursing trainees.

It draws its clientele mainly from Kibra slum which closely neighbors the hospital. It also acts as a referral center from primary health care facilities within Dagoretti District. Being a district hospital, it also receives clients from other corners of Nairobi County.

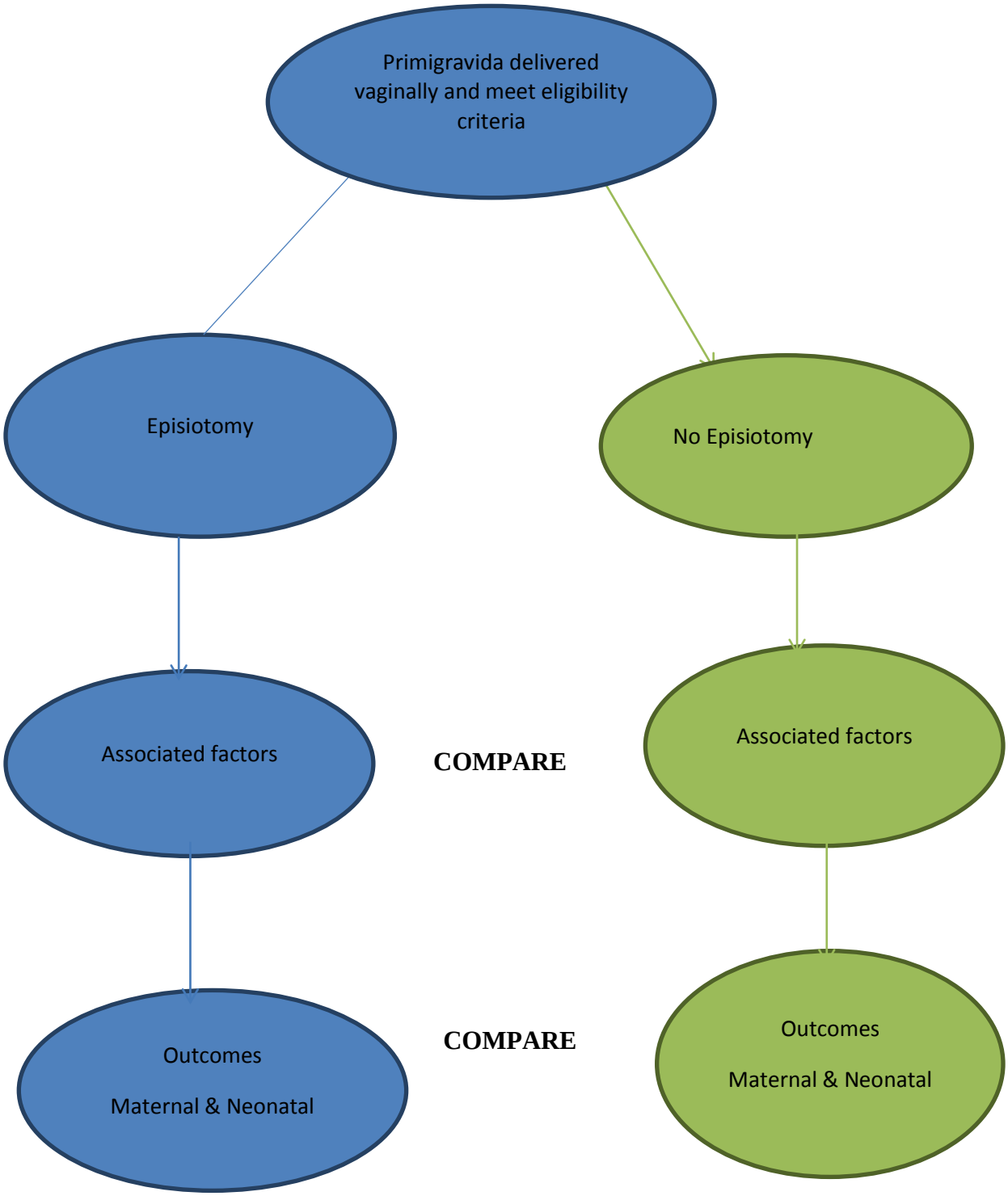
Mbagathi Hospital obstetric department currently performs about 500 deliveries monthly with an estimated caesarean section rate of about 30%. Among these clients approximately one third are nulliparous.

Study design

This was a hospital based cohort study in which 174 parturients were recruited on the first post natal day. Among these parturients; 49 had undergone episiotomy, 83 had sustained perineal tears and 42 had intact perineum. The immediate outcomes were blood loss and 5 minute Apgar score birth weight and sex. At 2 weeks postnatal follow – up / review, maternal complications were determined.

Figure: 2

Study design algorithm



Sample Size

Sample Size was estimated using the Fishers formula and the size of the sample was calculated as follows[29]

$$N = \frac{Z^2 \times P\,q}{D^2}$$

$$= \frac{1.96^2 \times 0.53\,[1-0.53]}{0.05^2} = 382.78383$$

$$nf = n/1+[n/N]$$

$$= 383/1 + [383/300] = 167.98$$

A minimum of **168** primipara parturients were to be sampled for this study.

n= Desired sample size

Z=1.96 {95 % confidence interval}

P=53 % Estimated prevalence of episiotomy in primipara parturients in K.N.H in 2007 by Guled.[4]

D= Margin of error =5 %

q= 1-p

nf=The desired sample size [when the population is less than 10000

n=the desired sample size when the population is more than 10000

N= population estimate

According to Mbagathi Hospital records, approximately 150 primipara vaginal deliveries occur each month. This study ran for two months and therefore 300 deliveries were accessible for sampling. This was less than 10000 finite population, the cut off for a simple randomized sample; therefore a representative sample was drawn from the population in the study period and adjusted for a finite population using finite population correction formula.[29]

Study Period

This study was conducted for two months, from May to July 2015.

Study Personnel

Before the study commenced, one research assistant was trained for two days on ethical guidelines, objectives and procedure of the study, importance of informed consent and filling of questionnaire.

Study population

Inclusion criteria

Primigravid parturients 18 years and above with singleton pregnancy at ≥ 37 weeks who delivered vaginally at Mbagathi Hospital on their first postnatal day.

Exclusion criteria

All multipara parturients, primigravid parturients admitted for other reasons other than labor. All primipara parturients who were delivered via caesarian section, parturients who

had delivered vaginally but before arrival, Primipara parturients who did / could not give consent; e.g. less than 18 years.

Procedure

There were 200 participants who met the inclusion criteria and they were enrolled into the study upon signing an informed consent form, after explanation about the study's purpose, procedure, benefits and risks and they were cumulatively assigned a study number (001..200). In patient number was recorded separately to avoid double entry.

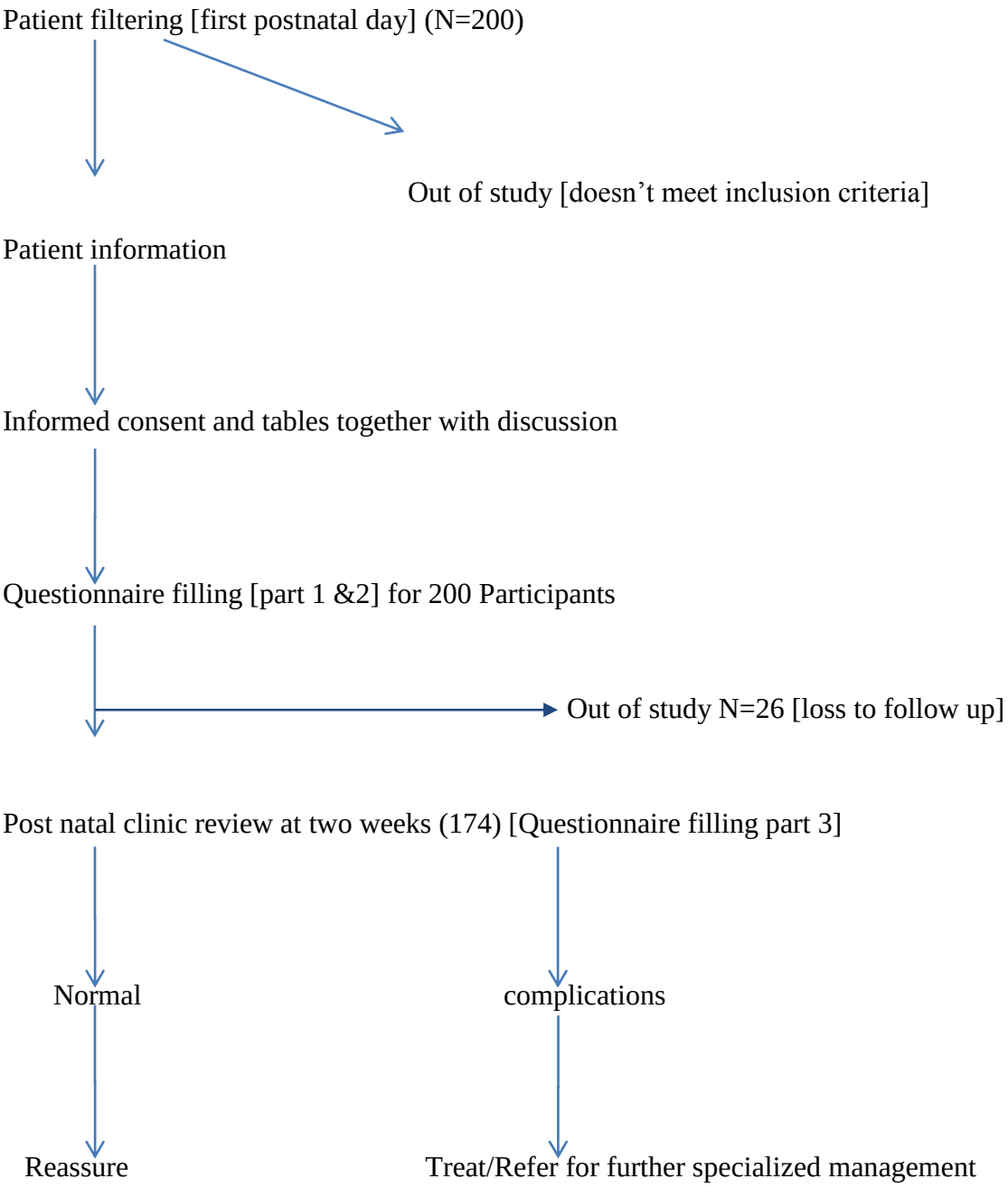
Out of all the 200 study participants, 26 failed to turn up for review within two weeks and they were dropped from the study. Recruitment of the participants was cumulative until the required sample size was achieved, therefore study time was limited to sample size i.e. May to July 2015.

Consent

A written consent was obtained from each of the 200 eligible participants in a private room, then a questionnaire was administered to the client that assessed socio-demographic and clinical characteristics of the participants, some details on management and immediate outcomes of labor were obtained from participants records. At two weeks postpartum, a total of 174 participants were reviewed at the postnatal clinic to assess for morbidity pattern and completion of data collection.

Figure 3

Study flow chart recruitment and consenting procedure



Data variables

The main data variable was episiotomy; other variables included socio-demographic characteristics perineal tears, babys birth weight, sex and apgar score at 5^{th} minute.

Procedures

This was carried out by the principal investigator with the help of a research assistant who was trained by the principal investigator a week before the study commenced

Participants were recruited into the study in a private room during first postnatal day using the inclusion criteria, upon signing an informed non coerced consent and they were allocated study numbers cumulatively. A total of 200 participants were recruited however 174 turned up for review at around two weeks and completion of data entry. The 26 study participants who were lost to follow-up were dropped out of the study.

A standardized questionnaire was filled out by the principal investigator and / or research assistant, in which participants responded to questions orally, underwent physical examination including examination of perineum to check for the presence or absence of episiotomy wounds , tears and female genital mutilation. Part of the data was collected from the participant's in patient file so as to complete the questionnaire.

Participants reviewed at around two weeks postpartum at the postnatal clinic were assessed for morbidity and the data entry into the questionnaire was completed.

Findings were explained to the participant and any complication diagnosed was managed accordingly.

Data was stored in a password protected computer with backup, while the data collecting tools were kept in a safe under lock and key by the principal investigator.

Data management

Data was entered into an MS access data base by the statistician. Each record was assigned a unique identifier and names dropped to maintain participants confidentiality. Quality of data was assessed by conducting consistency checks. Data was stored in a password protected computer and analyzed using SPSS version 21 [IBM]. Descriptive characteristics of the patients were analyzed and presented as means or medians for continuous data and proportions [%] for categorical variables. Incidence of episiotomy procedure was presented as a proportion within 95% confidence interval with maternal characteristics using chi - square test for categorical data or students T-test for comparison of means. Immediate and late outcomes were analyzed and presented as proportions within 95 % confidence interval. Outcomes were compared between those with episiotomy versus those without using chi-square test and odds ratio calculated as estimates of relative risk. Multivariate analysis was conducted using multiple logistic regression analysis to control for confounding variables. All statistical tests were interpreted at 5% level of significance [p value $\leq$ 0.05]. Results were presented in charts, graphs, percentages and tables together with discussion and recommendations.

Ethical consideration

The study was approved by Kenyatta National Hospital and University Of Nairobi Ethics and research committee and also Mbagathi Hospital ethics and research committee before it commenced. Each participant signed a written non- coerced informed consent after detailed explanation of the study purpose, procedure, benefits and risks. There was no financial gift given to induce participants for enrollment into the study. All information was strictly confidential. Counseling and examination were conducted in a private room and maintaining anonymity was the principal investigators responsibility and participants management was as per the hospital protocol, participants who required further management were treated accordingly.

Study Limitations

The study site was not randomly selected therefore the study is not representative of the country's episiotomy practice.

Some participants did not turn up for review and this loss to follow up could bias the study results. This was minimized via increasing the sample size by > 10 %.

RESULTS

During a period of 2 months 174 primigravid women delivered at Mbagathi District Hospital and constituted the study sample.

Table 1: Overall socio-demographic characteristics

Variable	Frequency (%) N =174
Marital status	
Married	123 (70.7)
Single	48 (27.6)
Separated/Divorced	1 (0.6)
Widowed	2 (1.1)
Level of education	
None	1 (0.6)
Primary	43 (24.7)
Secondary	105 (60.3)
University/College	25 (14.4)
Occupation	
Housewife	86 (49.4)
Employed	43 (24.7)
Business	35 (20.1)
Students	10 (5.7)
Religion	
Christian	172 (98.9)
Muslim	2 (1.1)

As shown in table 1 the mean age of the participants in this study was about 21.7 years (SD 3.1) with a minimum age of 18 and maximum of 33 years as shown in table. Close to 71 % of the primigravid women in the study were married. About 60% of the participants had acquired secondary education but only around 14 % managed to attain university/ college education and this could explain why almost 50% of the study participants were housewives. Close to 99 % of the primigravid women enrolled in this study were Christian.

Table 2: Frequency distribution of medical illness during pregnancy and overall obstetric history

Variable	Frequency (%)
History of medical illness during pregnancy	7 (4.0)
Type of illness	
Asthma	1 (0.6)
Hypertension	3 (1.7)
Urinary tract infection	1 (0.6)
Hyper emesis gravidarum	1 (0.6)
Treatment for medical illness during pregnancy	
Antihypertensive	3 (1.7)
Inhaler	1 (0.6)
Antibiotic	2 (1.1)

Type of vaginal delivery	
Spontaneous vertex delivery	173 (99.4)
Breech delivery	1 (0.6)
Female Genital Mutilation	
Yes	15 (8.6)
No	159 (91.4)
Attendant	
Midwife trainee	33 (19.0)
Midwife	106 (60.9)
Clinical officer intern	21 (12.1)
Medical officer intern	8 (4.6)
Medical officer	3 (1.7)
Midwife& clinical officer	1 (0.6)
Midwife& midwife trainee	1 (0.6)

Table 2 illustrates that the mean gestational age at delivery for the study participants was 39.1 weeks (SD 2.3) while the mean BMI was 24.7 (SD 3.63).

About 4% of the participants had history of medical illness in pregnancy with a majority of them being low risk mothers during the antenatal care follow-up. Up to 99% of the study participants were delivered via spontaneous vertex delivery. On average second stage of labor for the study participants lasted 50.5 minutes (SD;15.9) with a range of about 10-90 minutes. Close to 80% of the primigravid women were delivered by midwives. Approximately 9% of the study participants had history of female genital mutilation.

Table 3: Overall immediate delivery outcomes

Variable	Frequency (%)
Amount of blood loss (ml), mean (SD)	298.6 (133.7)-
Min-Max	100-650
Baby's sex	
Male	88 (50.6)
Female	86 (49.4)
Baby's weight (g), mean (SD)	2979.1 (368.9)
perineal care teaching	
Yes	163 (93.7)
No	11 (6.3)
pelvic floor exercises (kegel) teaching	
Yes	163 (93.7)
No	11 (6.3)
Hospital stay (days)	
1	3 (1.7)
2	157 (90.2)
3	14 (8.0)

The mean amount of blood loss in the study participants was about 300 ml (SD;133.7) with an estimated minimum of 100 ml and maximum of 650 ml (table 3). About 51% of the neonates born by the study participants were male and the mean birth weight for all neonates was 2979.1 g (SD; 368.9). Majority of the study participants (90.2%) were in hospital for two days only.(table 3)

Table 4: Incidence rates of episiotomy and perineal tears

Variable	Frequency (%)
Episiotomy given	49 (28.2)
Type (n=49)	
Mediolatral	49 (100.0)
Perineal tear	83 (47.7)
Degree of tear (n=83)	
One	8 (9.7)
Two	48 (57.8)
Three	17 (20.5)
Episiotomy and tear	8 (4.6)
Primary repair done	124 (71.3)

As shown in table 4, the episiotomy rate in this study was about 28% and medio-lateral episiotomy is the only type practiced at Mbagathi Hospital. It was also noted that about 48 % of the study participants sustained posterior perineal tears, which were mainly second and third degree at approximately 58 % and 21 % respectively. Repair was carried out in all study subjects with episiotomy, second and third degree tears.

Table 5: Immediate neonatal outcomes in women with episiotomy versus those without

Variable	Episiotomy		OR (95% CI)	P value
	Yes	No		
Mean baby's weight in g (SD)	2977.6 (372.1)	2979.7 (369.1)	-	0.973
Baby's sex				
Male	23 (26.1)	65 (73.9)	0.7 (0.4-1.4)	0.347
Female	26 (30.2)	60 (68.8)	1.0	
Apgar score at 5^{th} min, median (IQR)	9 (9-10)	9 (9-10)	-	0.264

In table 5 sub group analysis was undertaken to compare maternal and neonatal outcomes between participants who underwent episiotomy and those who did not.

In this table there was no significant difference in neonatal birth weight for neonates of mothers with and without episiotomy, 2977.6g and 2979.7g respectively. (P value = 0.973). There was no difference in neonatal sex between mothers with and without episiotomy (p value = 0.347).

Further analysis and categorization of neonatal outcome was carried out and represented in figure 4. Women who had sustained tears delivered neonates with highest birth weight (3072.4 g) compared to those with episiotomy (2977.6 g) and intact perineum (2897g). (P value= 0.030)

There was no difference in terms of Apgar score at the 5th minute of the neonates among the three categories of study participants for the average score was 9 (9-10) (P value = 0.529).

There was no statistically significant difference in baby's sex among participants with episiotomy 22 (44.9 %) male versus 27 (55.1 %) female, tears 42 (50 %) male and 42 (50 %) female or intact perineum 14 (55.4 %) male versus 16(44.6%) female; P value = 0.538

Figure 4: Immediate neonatal outcomes in women with episiotomy tears intact perineum

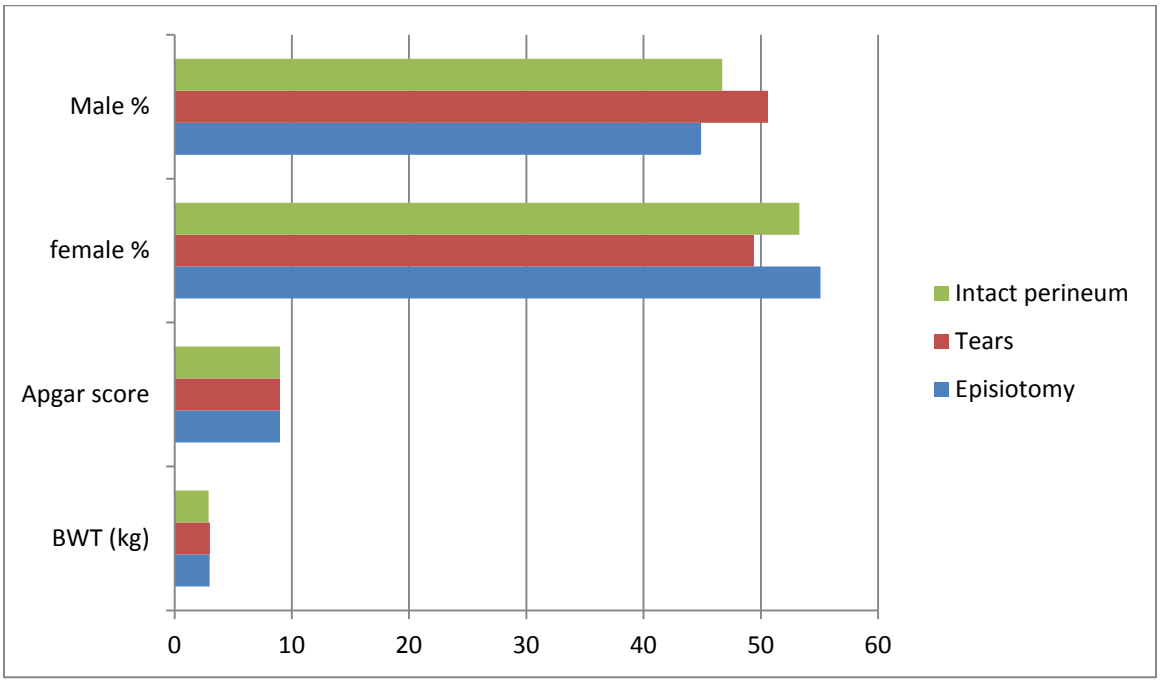


Table 6: Overall maternal outcomes at two weeks postpartum

Variable	Frequency (%) N=174
Wound well apposed	68 (39.1)
Wound not well apposed	106 (60.9)
Complications	
Pain	104 (59.8)
Swelling	14 (8.0)
Discharge(sepsis))	17 (9.8)
Breakdown(dehiscence)/	- --
Poor anatomical results	40 (23)
Treatment	
Analgesics	105 (60.3)
Antibiotics	39 (22.4)
Secondary repair	25 (14.4)

As illustrated in table 6, upon review at two weeks postpartum, perineal wounds of about 61% women were not well apposed. It was found that close to 60 % of the study participants complained of pain, while about 23 % had poor anatomical results. (gaping wounds with hanging, loose sutures or poor alignment of the tissues). Around 60 % of the study participants required analgesics while about 22 % needed antibiotics. Close to 14% had secondary wound repair carried out.

Figure: 5

Outcomes at two weeks postpartum among participants with episiotomy tears and intact perineum

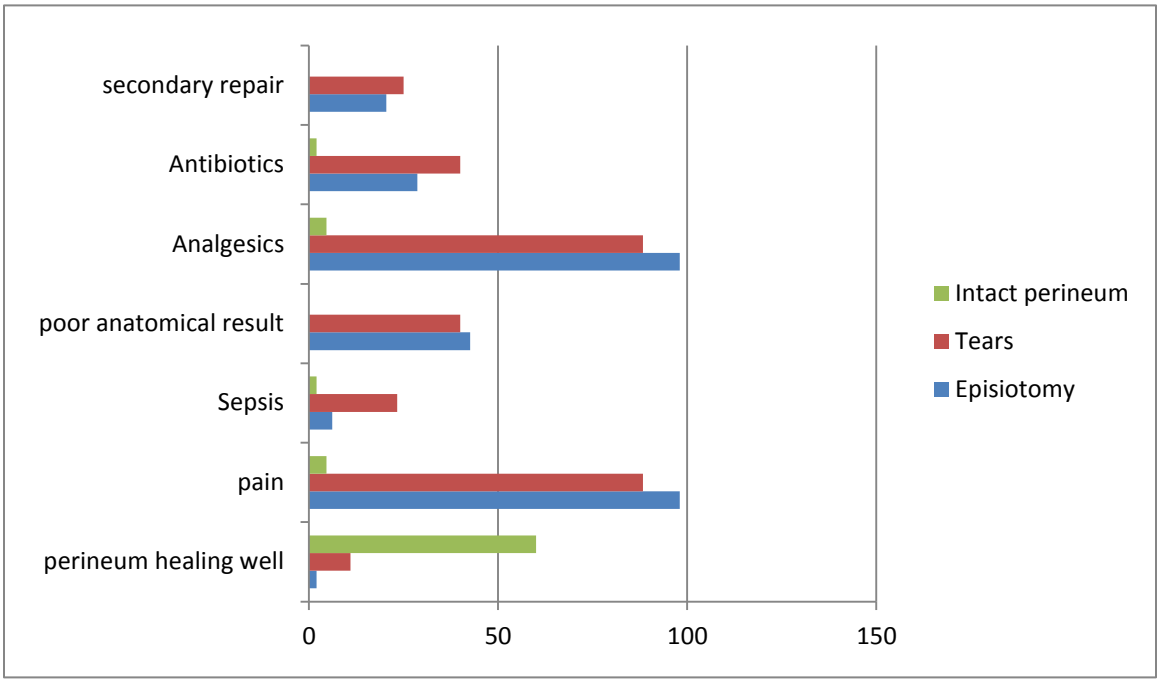


Figure 5 represents further analysis of data on maternal outcomes and categorization into, those with episiotomy, tears and intact perineum respectively.

Close to 98 % of participants with episiotomy had pain compared to about 88 % of those with tears and around 5 % of those with intact perineum (P< 0.001) and hence the need for analgesia (p<0.001).

Up to 23 % of women with tears had discharge compared to around 6 % of participants with episiotomy and 0 % of those with intact perineum (p< 0.001) and hence the need for antibiotics (p<0.001).

On average 15 % of participants with tears had wound breakdown compared to about 12 % of those with episiotomy and 0% of those with intact perineum (p< 0.001) and hence the need for secondary repair (p<0.001).

Table 7 : Associations between episiotomy and maternal outcomes at two weeks postpartum

Variable	Episiotomy		OR (95% CI)	P value
	Yes	No		
Wound well apposed				
Yes	1 (2.0)	67 (53.6)	0.0 (0.0-0.1)	<0.001
No	48 (98.0)	58 (46.4)	1.0	
Complications				
Pain	48 (98.0)	56 (44.8)	59.1 (7.9-442.0)	<0.001
Swelling	8 (16.3)	6 (4.8)	3.9 (1.3-11.8)	0.025
Discharge	3 (6.1)	14 (11.2)	0.5 (0.1-1.9)	0.403
Breakdown	6 (12.2)	9 (7.2)	1.8 (0.6-5.4)	0.367
Poor anatomical result	10 (20.4)	15 (12.0)	1.9 (0.8-4.5)	0.155
Treatment				
Analgesics	48 (98.0)	57 (45.6)	57.3 (7.7-427.9)	<0.001
Antibiotics	14 (28.6)	25 (20.0)	1.6 (0.7-3.4)	0.223
Secondary repair	10 (20.4)	15 (12.0)	1.9 (0.8-4.5)	0.155

Women with episiotomy were less likely to have a well apposed wound within two weeks postpartum compared to those without episiotomy at about 2% and 54 % respectively OR 0.0 (95 % CI, 0.0-0.1 p<0.001) as shown in table 7.

There was a higher likelihood of having pain at two weeks in 98 % of women who had episiotomy compared to about 45 % amongst those without episiotomy, OR 59.1 (95% CI 7.9-442.0, p<0.001). Women who had undergone episiotomy were more likely to be put on analgesics compared to those who had no episiotomy at about 98% and 46 % respectively, OR 57.3 (95% CI , 7.7-427.9, P< 0.001). There was no difference at 2 weeks between both groups for swelling, discharge, breakdown, poor anatomical result, use of antibiotics and the need for secondary repair.

Table 8: Factors associated with complications at two weeks postpartum

Variable	Complications	No complications	OR (95% CI)	P value
Age	21.5 (3.1)	22.1 (3.0)	-	0.188
Marital status				
Married	69 (56.1%)	54 (43.9%)	1.0	
Unmarried	39 (76.5%)	12 (23.5%)	2.5 (1.2-5.3)	0.012
Level of education				
No college	96 (64.4)	53 (35.6)	2.0 (0.8-4.6)	0.117
University/College	12 (48.0)	13 (52.0)	1.0	
Occupation				
Unemployed	59 (61.5)	37 (38.5)	1.2 (0.6-2.2)	0.459
Employed	37 (57.8)	27 (42.2)	1.0	
Medical illness during pregnancy				
Yes	4 (57.1%)	3 (42.9%)	0.8 (0.2-3.9)	1.000
No	94 (61.4%)	59 (38.6%).	1.0	
Mother undergone FGM				
Yes	12 (80.0%)	3 (20.0%)	2.6 (0.7-9.7)	0.134
No	96 (60.4%)	63 (39.6%)	1.0	
Perineal tear				
Yes	70 (93.3%)	5 (6.7%)	22.5 (8.3-60.7)	<0.001
No	38 (38.4%)	61 (61.6%)	1.0	
Baby's sex				
Male	50 (57.5%)	37 (42.5%)	0.7 (0.4-1.3)	0.257
Female	56 (65.9%)	29 (34.1%)	1.0	
Counseled/taught on perinea care				
Yes	103 (63.2%)	60 (36.8%)	2.1 (0.6-7.0)	0.336
No	5 (45.5%)	6 (54.5%)	1.0	
Taught about pelvic floor exercises				
Yes	101 (62.0%)	62 (38.0%)	0.9 (0.3-3.3)	1.000
No	7 (63.6%)	4 (36.4%)	1.0	
Duration of second stage (hrs), mean (SD)	50.8 (15.9)	49.8 (16.0)	-	0.696
APGAR at 5mins, mean (SD)	9.2 (1.1)	9.2 (1.4)	-	0.927
Baby's weight (g), mean (SD)	3027.4 (353.4)	2901.5 (382.5)	-	0.029
Amount of blood loss (ml), mean (SD)	361.7 (124.3)	196.6 (70.6)	-	<0.001
Episiotomy given				
Yes	49 (100.0%)	0 (0.0%)	-	<0.001
No	59 (47.2%)	66 (52.8%)		

Table 8 shows that the unmarried women were more likely to have complications at two weeks compared to the married women in this study OR 2.5 (95% CI 1.2-5.3 P <0..001). It is also shown that women who had perineal tears had a higher likelihood of complications at two weeks 93.3 % OR 22.5 (95% CI 8.3-60.7 P<0.001). The mean neonatal birth weight among women with complications was significantly higher than for those without complications (p=0.029). Women with complications at two weeks were more likely to have lost more blood (361.7 ml SD 124.3) compared to those without complications (196.6 ml SD 70.6) p<0.001. Episiotomy procedure was significantly associated with complications at two weeks postpartum P< 0.001. Complications at two weeks postpartum was not significantly associated with maternal age, level of education, history of FGM, medical illness in pregnancy, baby's sex, duration of 2nd stage, APGAR Score and teaching on pelvic floor exercises or perineal care.

Table 9: Predictors of complications at two weeks postpartum [Logistic Regression Model]

Variable	OR (95% CI)	P value
Married status	0.4 (0.1-2.5)	0.356
Weight	1.0 (0.998 - 1.002)	0.884
Blood loss	1.01 (1.00-1.02)	0.019
Episiotomy/tear	195.2 (40.8-933.2)	<0.001

Logistic regression analysis did show that the predictors of postpartum complications in all the study participants in this study were episiotomy and perineal tear (see table 9).

DISCUSSION

Episiotomy is a planned incision on the posterior vaginal wall and the perineum, performed during second stage of labor to increase the outlet's diameter in order to aid in delivery of the neonate. Restrictive as opposed to liberal episiotomy use is recommended. In previous studies, Primiparity has been shown to be a major risk factor for this procedure. The episiotomy rate among primiparae at Mbagathi Hospital in this study was found to be 28.2 % which is higher than WHO recommendations, but when compared to studies conducted at K.N.H, the rate is much lower. Mwasiaji (1992) found that 73.2% of primigravidae had received episiotomy incision while Guled (2007) found episiotomy rates of 56.3 % (1995) and 52.7% (2005) among primiparae women at KNH. This shows a declining trend in the practice of episiotomy among primigravid women over the years possibly due to increased awareness of episiotomy demerits among health workers. There is evidence that operative , difficult, and breech vaginal deliveries are being abandoned with associated increase in the caeserian section delivery rates.

Apart from nullparity other risk factors for episiotomy in literature include adolescence, prematurity, assisted vaginal delivery, female genital mutilation and medical illnesses in pregnancy however the mean age of participants in this study was 21.7 years with a range of 18-33 years. The mean gestational age was 39 weeks with almost all participants being delivered via spontaneous vertex delivery. Close to 97 % of study participants were low risk mothers during the antenatal period. Only 8.6 % of primigravid women in this study had history of female genital mutilation. All these

characteristics could be contributing to the lower episiotomy rates of episiotomy found in this study.

It was found that overall 47.7 % of the study participants sustained posterior perineal tears which were mainly (57.8%) second and (20.5%) third degree tears respectively. None of the study participants sustained a fourth degree tear. Out of all the study subjects who were given episiotomy approximately 5 % sustained secondary perineal tears which were mainly first degree, a finding that corresponds to other studies like Cochrane reviews in developed countries that have shown that restrictive episiotomy procedure minimizes the risk of posterior perineal tears.

All the episiotomy incisions performed in this study were of the medio-lateral type that has been shown to rarely extend to third and fourth degree tears. This episiotomy type cuts across tissue planes and is therefore associated with more blood loss than perineal tears which often occur along tissue planes. This is supported by the finding that women who had episiotomy incision on average lost 360 ml of blood compared to those who did not have episiotomy incision fashioned, who on average lost 200 ml of blood. Perineal repair for all women who had episiotomy or sustained perineal tears was carried out after delivery of the placenta by the birth attendant using vicryl number one (1), a synthetic absorbable suture which is associated with less short-term pain, reduction in the use of analgesia, less wound breakdown and less need for perineal re-suturing compared to cut-gut. (W H O)

There was no statistical difference in APGAR score in the fifth minute between neonates born to women with episiotomy compared to those who did not, the mean apgar score for both groups was 9-10. There was also no significant difference in mean neonatal birth weight between women with or without episiotomy , 2977.6 g and 2980 g respectively. This finding supports previous studies that found that episiotomy practice has failed to accomplish neonatal benefits ascribed to it; hence the need for selective episiotomy practice.

Literature has shown that an episiotomy procedure substantially increases risk of increased blood loss, improper wound healing and pain in the first several post partum days. This study has similar findings; up to 98% of women with episiotomy had poor wound apposition, pain, increased need for analgesia and antibiotics at two weeks postpartum. Factors associated with postpartum complications in this study include the presence of episiotomy, a perineal tear, blood loss $\geq$ 360 ml, neonatal birth weight of more than 3000g and being unmarried. The main predictors of postpartum complications within two weeks postpartum in this study were presence of episiotomy and perineal tears.

CONCLUSION

The incidence rate of medio-lateral episiotomy in this study was 28.2%, it was also found that the rate of perineal tears was high (47.7%). There was no statistical difference in immediate neonatal outcome in regards to neonatal birth weight, apgar score at the fifth minute and sex between study participants with episiotomy and those without in this study. Women with episiotomy had high amount of blood loss upon delivery, complained of pain and required analgesia up to two weeks postpartum; however they were less likely to sustain a third degree perineal tear compared to those without. Study participants who were unmarried with episiotomy or perineal tear were more likely to develop post partum complications.

RECOMMEDATIONS

1. There is need to emphasize on selective / restrictive episiotomy practice.
2. Parturients who sustain severe perineal trauma require to be put on prophylactic antibiotic and analgesics.
3. It is important that all postnatal reviews are carried out within 1-2 weeks postpartum so as to identify and manage complications on time.
4. More resources need to be invested on Continued medical education for midwives especially in regards to basic surgical skills and delivery techniques for this will help in reducing the high rates of second and third degree tears and also the need for episiotomy incision, hence reducing the morbidity and the cost associated with vaginal delivery.
5. Further research is required to evaluate the need for episiotomy use in women with female genital mutilation.
6. There is a need to evaluate long-term effects of episiotomy on sexual satisfaction and pelvic floor disorders in our setting

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APPENDICES

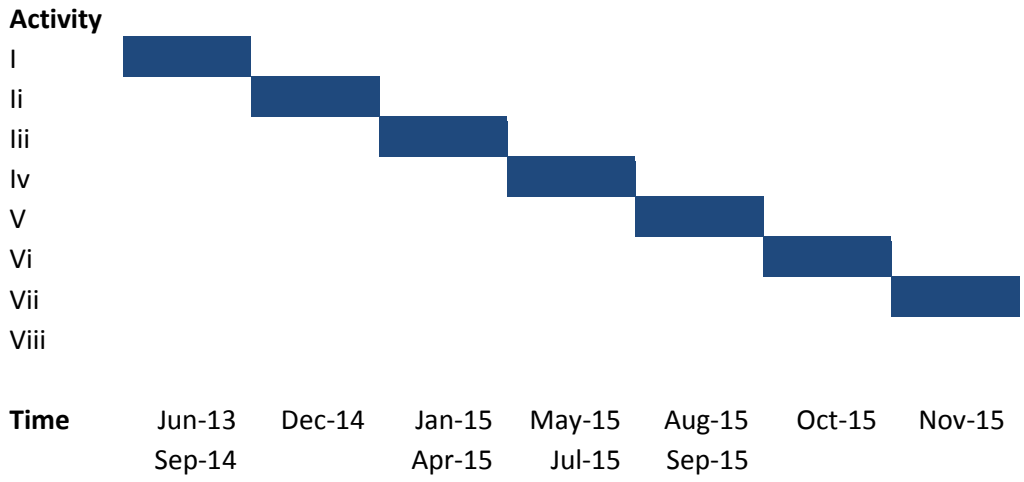
APPENDIX I: BUDGET

ACTIVITY	COST IN KSHS
Ethical committee fee	2 500
Secretarial work	20 000
Research assistants	50 000
Stationary	20 000
Data entry and analysis	40 000
Book writing/binding	30 000
Grand total	162 000

APPENDIX II: STUDY LIMITATIONS

1. The study site was not randomly selected therefore it was not a representative of the countr's episiotomy incidence rate
2. Loss to follow-up was minimized by increasing the sample size number by ≥ 10%

APPENDIX III: TIME LINES



	y-Axis	X- Axis- Time
I	proposal development	
Ii	presentation at the department	
Iii	Ethical considerations	
Iv	Data collection	
V	Data Analysis	
Vi	Result presentation at the department	
Vii	Compiling of dissertation and handing in	

APPENDIX IV: CONSENT FORMS

(a) Consent Explanation Form

English Version

Study number…….

Hello my name is……..I am working with Dr Munyao a postgraduate student from the University of Nairobi, department of obstetrics and gynecology. Carrying out a study entitled " Episiotomy for vaginal birth among primigravid women, at Mbagathi District Hospital"

The procedure of carrying out the study is as follows: Participants will be recruited on first postnatal day, after signing an informed consent Two out of three questionnaire sections will then be filled on the same day .Participants will undergo a review on the fourteenth postnatal day at the postnatal clinic and the third section of the questionnaire filled.

We are requesting you to participate in the study, you are free to choose to participate or not. There will be no penalty if you withdraw from the study. All the information you provide will be treated with utmost confidentiality.

We do not anticipate any risks to the participants as there will be no other procedure carried out to them and they will benefit from this study due to the fact that any complication found will be managed accordingly or referred for further specialized management if need be. The information gathered will also be of help in improving services provided to mothers during their pregnancy labor and delivery. Participants will not be charged any extra fee during this study and also there will be no compensation for participating in this study.

Any questions regarding this study may be directed to Dr Munyao on telephone number 0722481808 and/ or Prof Anastasia Guantai, The chairperson, Ethics Committee U.O.N/K.N.H, telephone number 2726360/27263600 ext 44102.

Thank you

(b) Consent Form

I, study number ……. Having been informed about the study/ having read all the above and understood all that it entails do willfully consent to participate in the study.

Client Name…….

Signature/Thumb print…… Date……

Investigator who informed the client……Date……

SWAHILI FORMAT

(a) Fomu Ya Maelezo Ya Idhini

Nambari ya utafiti…….Nambari ya simu……..Habari gani ?jina langu ni…… ..……,nafanya kazi na Dkt Munyao ambaye ni mwanafunzi wa shahada ya uzamili ya udaktari kwenye chuo kikuu cha Nairobi,idara ya uzazi na uzima wa wanawake.Tunatafiti kuhusu UONGEZAJI WA NJIA YA UZAZI WAKATI WA KUZAA KWA WAMAMA WANAO PATA WATOTO MARA YA KWANZA. Jinsi tutakavyofanya utafiti huu ni kama ifuatavyo.Washiriki watatia sahihi fomu ya idhini baada ya kuelezewa kwa makini kuhusu huu utafiti,kisha tutajaza fomu yenye maswali, sehemu mbili za maswali hayo zitajazwa siku ya kwanza ya kujifungua kwa mshiriki na baada ya majuma mawili sehemu ya tatu itajazwa kwenye kliniki.

Tunakuomba ushiriki kwenye utafiti huu kwa hisani yako,kuna uhuru wa kushiriki na kutoshiriki,pia kuna uhuru wa kutojibu swali au maswali yoyote na hata kujiondoa kwenye utafiti huu wakati wowote na hakuna adhabu yoyote.utapata matibabu yoyote utakayoitaji.

Taarifa zote utakazotupa zitatuzwa na zitakua siri.Hatutarajii madhara yoyote kwa washiriki wa pia wao watafaidika kwa sababu magojwa yatakayo patikana yatatibiwaviilivyo au mshiriki kutumwa kwa matibabu zaidi.Hautalipishwa na pia hautalipwa kwa kushiriki.

Huu utafiti utasaidia wafanyi kazi wa idara ya afya kudhibiti matibabu ya uzazi na uzima wa wanawake vilivyo.

Elekeza swali/ maswali yoyote kwake Dkt Munyao ,Nambari ya simu 0722-481-808 au kwa Profesa Anastasia Guantai, nambari ya simu 2726360 ext 44102 [mwenye kiti kamati la idara ya maswali ya utafiti [Chuo kikuu cha Nairobi / K N H]

Asante.

(b) Fomu Ya Idhini

Mimi……..[nambari ya utafiti]nimeelezewa/nimesoma kuhusu huu utafiti na nimeelewa vizuri na naitikia kushiriki.

Jina la mshiriki……..

Sahihi/Dole gumba ya mshiriki…….. Tarehe……..

Mtafiti/Mtafiti msaidizi …….. Tarehe……

APPENDIX V: QUESTIONNAIRE

Date……

Study number……

Phone number…….

SOCIO DEMOGRAPHIC CHARACTERISTICS

1.Age {years}……

2.Marital status [insert code in the box] ☐

[A] Married

[b] Single

[C] Separated/divorced

[d] Widowed

3. Level of education level [insert code in the box] ☐

[A]None

[b]Primary

[c]Secondary

[d]University/College

4. Occupation [Insert code in the box] ☐

[a]Housewife

[b] Employed

[c]Business

5. Residence……..

6. Religion [Insert code in the box] ☐

[a]Christian

[b]Muslim

[c]Other

7. Obstetric history:

Last menstrual period [L M P] Date month year

….. ……. ……..

Gestation [weeks] …….. ……

Body mass index [BMI] ……..

8. Has she had any medical illness during this pregnancy?

State.……

9. If yes above, what treatment has she been on? State.

LABOR AND DELIVERY:

10. Duration of first stage {hours}…….

11. Duration of second stage {hours}…….

12. Type of vaginal delivery [Insert code in the box] ☐

[a] Spontaneous vertex delivery

[b] Vacuum delivery

[c] Breech delivery

13. Has the mother undergone female genital mutilation?

[Insert code in the box] ☐

[a]yes

[b]No

14. Was episiotomy given? [Insert code in the box] ☐

[a]Yes

[b]No

If yes answer below,

[i] Episiotomy type…….

[ii] Episiotomy and tear……

If no episiotomy answer below

Any perineal tear? [Insert in code box] ☐

[a] Yes

[b] No

If yes, what was the degree of perineal tear? [Insert in code box] ☐

[a] one [b] Two [c] Three [d] Four

Was primary repair done? [Insert in code] ☐

[a] yes [b] No

Amount of blood loss [ml]……

15. Baby's APGAR score ……

Baby's sex……. Baby's weight…… [g]

16. Who conducted the delivery? [Insert code in the box] 

[a] midwife trainee

[b] Midwife

[c] Clinical officer intern

[d] Medical officer intern

[e] Medical officer

[f] specialist

17. Any medicines given after delivery? State 

……..

…….

18. Has she been taught on perineal care? [insert code into the box] 

[a] Yes

[b] No

19.Has she been taught about pelvic floor exercises? [Kegel]

Insert code into the box 

[a] Ye [b] No

TWO WEEKS POSTPARTUM REVIEW

20. How many days did you stay at the hospital? ……..

21. Has the wound healed? [Insert code in the box] ☐

[a] Yes [b] No

22. If no to above, what is the complication? [Insert code into the box] ☐

[a] Pain [b] swelling [c] discharge [d] Breakdown

[e] Flatus/stool leakage [f] Urine leakage

23. Treatment given [insert code in the box] ☐

[a]Analgesics [b] Antibiotics [c] Secondary repair [d] Referral

APPENDIX VI: AUTHORIZATION LETTER

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info@mbagathi.org ,
mdhnairobi@yahoo.co.uk

Mbagathi Hospital P.O.
Box 20725- 00202
Nairobi

Our Ref: MS/VOL.1/2015

27th April 2015

Dr. Hellen Munyao Kathini Dept, of
Obstetrics and Gynaecology School of
Medicine University of Nairobi

Dear Madam,

RE: RESEARCH AUTHORIZATION

This is in reference to your application for authority to carry out a research on "Episiotomy for vaginal birth among primigravida women at Mbagathi District Hospital"

I am pleased to inform you that your request to undertake the research in the hospital has been granted.

On completion of the research .you are expected to submit one hard copy and one soft copy of the research report / thesis to this office.

Medical Superintendent

27 APR 2015

Dr. A. J. Suleh
Mbagathi Hospital

APPENDIX VII: STUDY TITLE APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/ Mod&SAE/351

17th November 2015

Dr. Hellen K. Munyao
H58/68566/11
Dept.of Obs/Gynae
School of Medicine
University of Nairobi

Dear Dr. Munyao

Re: Approval of study title – study titled "The incidence of Episiotomy for vaginal birth and associated morbidity among primigravida women at Mbagathi Hospital (P8/01/2015)

Refer to your communication of November 2, 2015.

The KNH-UoN ERC has reviewed and approved the change of study title from "Episiotomy for vaginal birth among primigravida women at Mbagathi Hospital" to "The incidence of Episiotomy for vaginal birth and associated morbidity among primigravida women at Mbagathi Hospital"

This change has been reflected in the revised proposal.

Yours sincerely

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College f Health Sciences, UoN
The Deputy Director C
The Chairperson, KNH-UoN ERC

Protect to Discover

APPENDIX VIII: KENYATTA NATIONAL HOSPITAL ETHICS & RESEARCH COMMITTEE STUDY APPROVAL

KENYATTA NATIONAL HOSPITAL APPROVED 17 APR 2015 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
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Website: http://erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/179

17th April, 2015

Dr. Hellen Munyao Kathini
Dept. of Obstetrics and Gynaecology
School of Medicine
University of Nairobi

Dear Dr. Hellen

Research Proposal: Episiotomy for Vaginal Birth among Primigravida Women at Mbagathi District Hospital (P8/01/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 17th April 2015 to 16th April 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chair, KNH/UoN-ERC
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics & Gynaecology
Supervisors: Prof. Zahida Quereshi, Dr. Gathari Ndirangu