

Diagnostic criteria and pregnancy outcomes in patients with cervical insufficiency at Kenyatta National Hospital from 2010 to 2013.

Dissertation submitted in partial fulfilment for the award of degree in Master of Medicine in Obstetrics and Gynaecology, University of Nairobi.

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I do declare that this research is my original work and has not been presented for award of degree or diploma at any other university.

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DEDICATION

To the late Irene Achieng, this is for you.

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ABBREVIATIONS

D&C.....	DILATATION AND CURRETAGE
ERC.....	ETHICS REVIEW COMMITTEE
EUA.....	EXAMINATION UNDER ANAESTHESIA
FSB.....	FRESH STILL BIRTH
KNH.....	KENYATTA NATIONAL HOSPITAL
ICD-10.....	INTERNATIONAL STATISTICAL DISEASE CLASSIFICATION (VOLUME 10)
MMED.....	MASTER OF MEDICINE
MRC.....	MEDICAL RESEARCH COLLEGE
MSB.....	MACERATED STILL BIRTH
MVA.....	MANUAL VACUUM ASPIRATION
NBU.....	NEW BORN UNIT
OBS & GYN.....	OBSTETRICS AND GYNAECOLOGY
PPROM.....	PRETERM PREMATURE RUPTURE OF MEMBRANES
RCOG.....	ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS
RCT.....	RANDOMISED CONTROLLED TRIAL
SHO.....	SENIOR HOUSE OFFICER
SOP.....	STANDARD OPERATING PROCEDURE
SPSS.....	STATISTICAL PACKAGE FOR SOCIAL SCIENCES
SVD.....	SPONTANEOUS VERTEX DELIVERY
UK.....	UNITED KINGDOM
UON.....	UNIVERSITY OF NAIROBI

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ABSTRACT

INTRODUCTION: Prematurity is the leading cause of perinatal mortality and morbidity in Kenya and globally. Cervical insufficiency has been known as among the causes of premature delivery and especially recurrent preterm pregnancy losses. Cervical cerclage has been reported to offer some benefit in management of cervical incompetence.

OBJECTIVE: To determine the diagnostic criteria and pregnancy outcomes in patients with cervical insufficiency at Kenyatta National Hospital between 1st January 2010 to 31st December 2013.

STUDY DESIGN: This is a hospital based Descriptive Cross-sectional study.

STUDY SETTING AND SITE: The study was conducted at the Department of Reproductive Health, KNH.

STUDY POPULATION: The study population was files of all women with a diagnosis of cervical insufficiency who underwent cerclage at KNH from 1st January 2010 to 31st December 2013.

SAMPLE SIZE: A total of 316 women had a diagnosis of cervical insufficiency and cerclage at KNH during the study period. Sample size was calculated to be 163. A total 168 files were reviewed.

DATA COLLECTION: Data was collected using a structured abstraction form prepared by the principal investigator. The abstraction form was administered by the principal investigator and a trained research assistant.

DATA ANALYSIS: Data was presented in tables, graphs and charts. Analysis was carried out using SPSS version 18.0. Statistical significance was based on alpha level of 0.05.

RESULTS: Prevalence of cervical insufficiency was 1.26% in the antenatal population. Only 3.2% had a trans vaginal ultra sound scan for cervical length evaluation. There were complications after cerclage with PROM and preterm labour being the commonest. Only 56.6% of the study population carried pregnancy to term after cerclage.

CONCLUSION: Ultra sonography as a tool for evaluation of women with cervical insufficiency was not fully and correctly utilised. Premature delivery remained a significant occurrence in women with cervical insufficiency after cerclage.

RECOMMENDATION: Development of a Standard Operating Procedure for diagnosis and management of cervical insufficiency at KNH.

Background

Prematurity is the leading cause of perinatal mortality and morbidity. Majority of prematurity related adverse outcomes relate to birth before 33 weeks of gestation. Mortality increases from about 2% for infants born at 32 weeks of gestation to more than 90% for those born at 23 weeks of gestation(1). In Kenya prematurity accounts for 28% of perinatal mortality according to Kenya Health situation and Trends 1994-2010.(4). World Health Statistics 2010 places prematurity as the leading cause of newborn death in Africa accounting for 29 %.(3) Preterm birth accounted for 7.6% of all live births in England and Wales in 2005. (2). Cervical insufficiency has been known as among the causes of preterm delivery and especially recurrent mid trimester and early 3rd trimester pregnancy losses.(5).

Historically, cervical insufficiency as a clinical entity was recognized in 1658 in a text titled 'Practice of Physick by Cole and Culpepper'. First use of term insufficiency has been attributed to Grean in an 1865 issue of lancet. The early 1900s saw the advent of operative procedures on the cervix for prevention of recurrent pregnancy loss. Herman (1902) performed the Emmet trachelorrhaphy on three women with recurrent pregnancy loss, two of whom later had successful pregnancies. Child (1922) described an operative procedure to restore functional integrity of internal cervical os. In the 1940s Palmer and Laconne (1948) and Lash & Lash (1950) reported surgical operations to repair anatomic defects in the non pregnant cervix. Shirodkar (1955) and McDonald (1957) introduced methods of transvaginal cervico-isthmic cerclage that remain the most commonly used procedures for treatment of cervical insufficiency to date. Benson and Durfee (1965) advocated a transabdominal approach for placement of a cerclage for patients in whom transvaginal approach had failed. (6)

Cervical insufficiency may complicate about 1% of pregnancies in the general obstetric population and 8% of a recurrent miscarriage population who have suffered mid trimester pregnancy losses. (7). However studies have reported varied results; a 2008 study in Nigeria, Port Harcourt Teaching hospital sampled 25,685 antenatal mothers reported an incidence of 0.17%.(11) In Denmark from 1980 to 1990,cervical insufficiency was diagnosed in 4.6 per 1000 women.(12)

Literature review

Cervical insufficiency is defined as inability to maintain an otherwise viable intrauterine pregnancy to term in absence of labour due to a structural and functional defect of the cervix. It is usually characterised by dilatation and shortening of the cervix before 37th week of gestation in the absence of preterm labour, and is most classically associated with painless, progressive dilatation of the uterine cervix in second or early third trimester resulting in membrane prolapse, premature rupture of membranes, midtrimester pregnancy loss, or preterm birth, which is recurrent with progressive decline of gestation at subsequent losses. (8, 9). The insufficiency is due to a structural or functional defect of the cervix. (10)

Several pre pregnancy diagnostic tests reported in literature have not found their way into routine clinical relevance. Previous authors have suggested a variety of diagnostic studies to confirm the presence of cervical insufficiency but none has been validated in rigorous scientific studies; widening of cervical canal demonstrated by hysterosalpingogram,ease of insertion of cervical dilators of various diameters, force required to withdraw a Foley 's catheter with its bulb inflated through the internal os and several different methods to measure the force required to stretch

the cervix using an intracervical balloon. These methods have significant flaws ranging from their requirement that they be performed when the subject is not pregnant, to ignoring the known effects of pregnancy on the dynamic response of the cervix. (13)

The advent of transvaginal ultrasonography has brought forth new concepts in understanding cervical changes in pregnancy and especially features that may suggest cervical insufficiency. Ultrasonographic features of cervical insufficiency may be summarised as cervical effacement, dilatation, shortening in absence of labor in 2nd trimester, funnelling of the endocervical canal, shortened cervical length in association with gaping internal os, membranes protruding into endocervical canal, foetal parts in the cervix or vagina. (14). Sonographic assessment of the cervix is usually performed between 14 and 24 weeks of gestation and a cervical length of 25mm or less is considered suggestive of insufficiency. (15)

The diagnosis of cervical insufficiency is considered in three clinical scenarios. The first is a patient with the typical history of recurrent mid-trimester painless pregnancy losses with declining gestation at subsequent losses. Second is the acute presentation during pregnancy of painless advanced cervical effacement and dilatation in a woman with no history of pregnancy loss. The third scenario is observation of cervical effacement, funnelling or length of less than 25mm on ultrasound at gestation less than 24 weeks, made either in the course of evaluating a patient with gynaecologic or obstetric history that suggests possibility of insufficiency or when the same sonographic features are found incidentally. (6, 16)

Cervical cerclage has become the standard treatment for cervical insufficiency. Other non invasive modalities, such as treatment with progesterone or beta

agonists, pessary insertion, and prolonged bed rest have been advocated by various investigators but have never gained widespread acceptance.(6). There is little consensus on the optimal cerclage method, though the technique described by MacDonald; a transvaginal purse-string suture placed at the cervico-vaginal junction without mobilisation of the bladder remains the most commonly performed because of the ease of insertion and removal of the suture. Shirodkar technique a high transvaginal purse-string suture placed following mobilisation of the bladder to allow insertion above the level of cardinal ligaments has also been in use. This technique requires regional anaesthesia during removal unlike the MacDonald. (25).

In a secondary analysis of singleton pregnancy data from four RCTs of cervical cerclage in women with short cervix there was no significant difference in rate of delivery before 33 weeks in those who had MacDonald stitch compared to Shirodkar stitch.(26). In 1965, Benson & Durfee described the placement of a cerclage at the cervical isthmus, positioned in the avascular space above the cardinal and uterosacral ligaments following laparotomy known as a trans abdominal cerclage. It is usually inserted following a failed vaginal cerclage or extensive cervical surgery. (27).

Cerclage remains a commonly performed prophylactic intervention used by most obstetricians despite the absence of a well defined population for whom there is clear evidence of benefit.(15). It is not clear why dilatation and effacement of the cervix occur prematurely, but it is thought that forced mechanical closure of an insufficient cervix with a suture maintains the cervical length as well as mucus plugs both of which have a role in preventing labour. (17)

There are varied results reported in literature with cervical cerclage in preventing preterm delivery due to cervical insufficiency. While various observational studies report different levels of successes with cerclage, most randomised trials have shown no or very marginal benefit of cervical cerclage.

The MRC/RCOG Multicentre Randomised Trial of Cervical Cerclage recruited a total of 1318 women across several countries i.e. UK, France, Hungary, Norway, Italy, Belgium, Zimbabwe, South Africa, Iceland, Ireland, Netherlands and Canada with a diagnosis of cervical insufficiency based on previous history and examination findings. Twenty six women were lost to follow up leaving 1292 for the final analysis of whom 647 women had cervical cerclage inserted while 645 were allocated to control group with no cerclage. The primary measures of outcome were length of pregnancy specifically deliveries before 33 and 37 weeks of gestation. Delivery tended to be later in the cerclage group. 13% of women in cerclage group compared to 17% in the control group were delivered before 33 completed weeks. Similar pattern was observed between 33 to 36 completed weeks. Overall therefore preterm delivery rates were 26% in cerclage group and 31% in control group. There were 4% fewer preterm deliveries in cerclage group compared to the non cerclage group, which would translate to prevention of one preterm delivery for every 25 sutures inserted.(18)

Another Randomised Controlled Trial of Cervical Cerclage in Women at High Risk of Spontaneous Preterm Delivery by RUSH et al conducted in Groote Schuur Maternity Centre, Cape Town South Africa, recruited 194 women and randomly allocated 96 women to have cerclage and 98 women to be followed up without cerclage. The eligibility criteria being two or more previous pregnancies which ended spontaneously before 37 weeks and at least one pregnancy which ended between

14 and 36 weeks of gestation. The overall preterm delivery for the total study population was 33% thus confirming that the women who entered the study were at significantly increased risk of preterm delivery. There was however no evidence that cervical cerclage reduced the risk of preterm delivery. The proportion of preterm deliveries (<37 weeks gestation) was slightly higher in cerclage group (34%) than in the no cerclage group (32%). This difference was not statistically significant. (19)

TO MS et al conducted a Randomised controlled Trial on Role of Cervical Cerclage in Preventing Preterm Delivery in women with Short Cervix on Ultrasound. This was a multicentre study involving 47 123 women with singleton pregnancy who were screened for short cervix across several countries; Brazil, UK, South Africa, Slovenia, Greece and Chile. A transvaginal ultrasound scan was offered at between 22-24 weeks of gestation as a screening test for spontaneous preterm delivery. Women with cervical length of 15mm or less were recruited to the study. This cut off was selected because the risk of preterm delivery increases exponentially below this length. A total of 470 women were found within the cut off out of which 253 recruited and randomised as 127 with cerclage inserted and 126 with expectant management. Delivery before 33 weeks of gestation was at 22% in cerclage group as compared to 26% in expectant group; a 4% difference. (20)

A Cochrane Meta analysis of six Randomised trials with a pooled study population of 2175 women for cervical cerclage for prevention of preterm pregnancy loss showed no difference in percentage of preterm delivery before 37 weeks between the cerclage and the no cerclage groups.(7).

While randomised trials have shown marginal or no benefit of cervical cerclage, several retrospective studies have reported varied significant success rates in

reducing preterm delivery due cervical insufficiency. A Kenyan study by UON, Dept. of Human Anatomy reviewed 199 files of women attended to at KNH with a diagnosis of cervical insufficiency. It reported delivery at term post cerclage was 53.3%, preterm delivery at 19.6%.The study acknowledges inconsistencies in diagnosis of cervical insufficiency in the some of the reviewed cases. (21). Another retrospective study at Port Harcourt Teaching Hospital, Nigeria reported pregnancy carried to term at 68.8% ,preterm delivery at 21.8% and a miscarriage rate of 9.4%.(11).

A study conducted at department of Obstetrics and Gynaecology Aga Khan University Hospital Karachi from 2007 to 2009 recruited 70 women to undergo cerclage due to cervical insufficiency, severe preterm delivery (before 34 weeks) was 15.7% while 62.8% of the women delivered at or beyond 37 weeks, 21.5% delivered between 34 to 36 weeks.(22). These results are similar to those observed in the Port Harcourt study. U Onwediegwu et al at Ile-Ife, Nigeria reported term deliveries at 68%, preterm delivery at 17% and abortions at 10% with cerclage. (23).

Cervical cerclage being an invasive surgical procedure has been noted to be associated with a number of immediate and late complications. Winnie Saumu et al in a Kenyan study, reported severe vaginal haemorrhage following insertion of Macdonald stitch in 4% of the total cases. Urinary tract infections were common at 20.1%. Late complications included vaginal discharge at 12.1% and premature labour/threatened abortion at 6.5 %.(21)

In a Nigerian population, a single case of chorioamnionitis preceded by premature rupture of membranes at 32 weeks gestation out of 60 cerclages inserted was observed. (23). In Karachi, Pakistan Saba Mubasshir et al reported premature

rupture of membranes in 10% of the study population, 4.3% developed chorioamnionitis, 15% had per vaginal bleeding while 15.7% preterm labour. (22)

Higher rates of complications have been noted in patients who had cerclage inserted as compared to control groups with no cerclage in randomised controlled trials. 10% of patients developed fever of greater than 38 degrees Celsius in cerclage group as compared to 3% in no cerclage group in a South African population as reported by RUSH et al. 6% more patients had premature rupture of membranes in the cerclage group. (19). MRC/RCOG Working Party on Cervical Cerclage noted trauma to the cervix and difficulty in removal of stitch in 6% of women with cerclage. A single incident of rupture of membranes during insertion of stitch occurred. Pyrexia of greater than 38 degrees Celsius was observed in 6% of the cerclage group as compared to 3% in control group. (18)

Latasha et al compared pregnancy outcomes in history indicated cerclage and ultrasound indicated cerclage. The first group cerclage insertion based on previous history of recurrent midtrimester losses while the second group were asymptomatic women with ultrasound findings of features suggestive of insufficient cervix. Pregnancy prolongation beyond 36 weeks of gestation was 73.1% in the history indicated compared to 57.7% in ultrasound indicated cerclage group. Difference was also detected in rate of complications with PPROM rate of 19.3% and 38.5%. (24).

Althusius SM et al in a RCT that compared outcomes of emergency cerclage versus bed rest in women with cervical dilatation at time of presentation between 20 to 23 weeks of gestation noted that emergency cerclage prolonged gestation at delivery by up to 4 weeks and there was a significant reduction in delivery before 34 weeks of

gestation (53% versus 100% $P=0.02$). Premature rupture of membranes at time of cerclage has been reported as a common complication.

RCOG recommends that History indicated cerclage should be offered to women with three or more previous preterm births and/or second trimester losses. It also recommends Ultrasound indicated cerclage in women with a previous one or more spontaneous mid-trimester losses or preterm birth who have a cervical length of 25mm or less before 24 weeks of gestation. On rescue cerclage it advises that this should be individualised since though it may delay preterm delivery by up to 5 weeks chance of failure and complications are high.(15).

Justification

Reproductive failure is a social stigma in most African societies where child bearing is a cardinal expectation. It is particularly distressing if such failure arises from repeated middle trimester loss because each pregnancy brings new hope that is soon frustrated.

Varied levels of success with cervical cerclage as a management for cervical insufficiency has been reported in previous studies. The absence of unanimity in the efficacy of cervical cerclage has been attributed to the difficulty in making the diagnosis of cervical insufficiency due to lack of confirmatory diagnostic tests and therefore selection of patients who would actually benefit from cervical cerclage remains a challenge.

A previous study at KNH that reviewed complications of cervical cerclage noted the diagnostic inconsistencies in this group of patients and recommended evaluation of the diagnostic criteria in our set up and ultimately development of a standardised protocol for diagnosis and management of patients with cervical insufficiency .(21). Currently there are no standard operating procedure/protocol for diagnosis and management of cervical insufficiency at KNH. No national guideline exists on the same.

This study will be the first to review the diagnostic criteria and document patient selection for cerclage in our set up and form a basis for development of SOP thus ensuring standardised cost effective care for the patients.

KNH being a national referral facility receives patients from all parts of the country and therefore not only are a significant number of patients with cervical insufficiency

managed at this facility but also those managed are of a mixed population from different regions of the country.

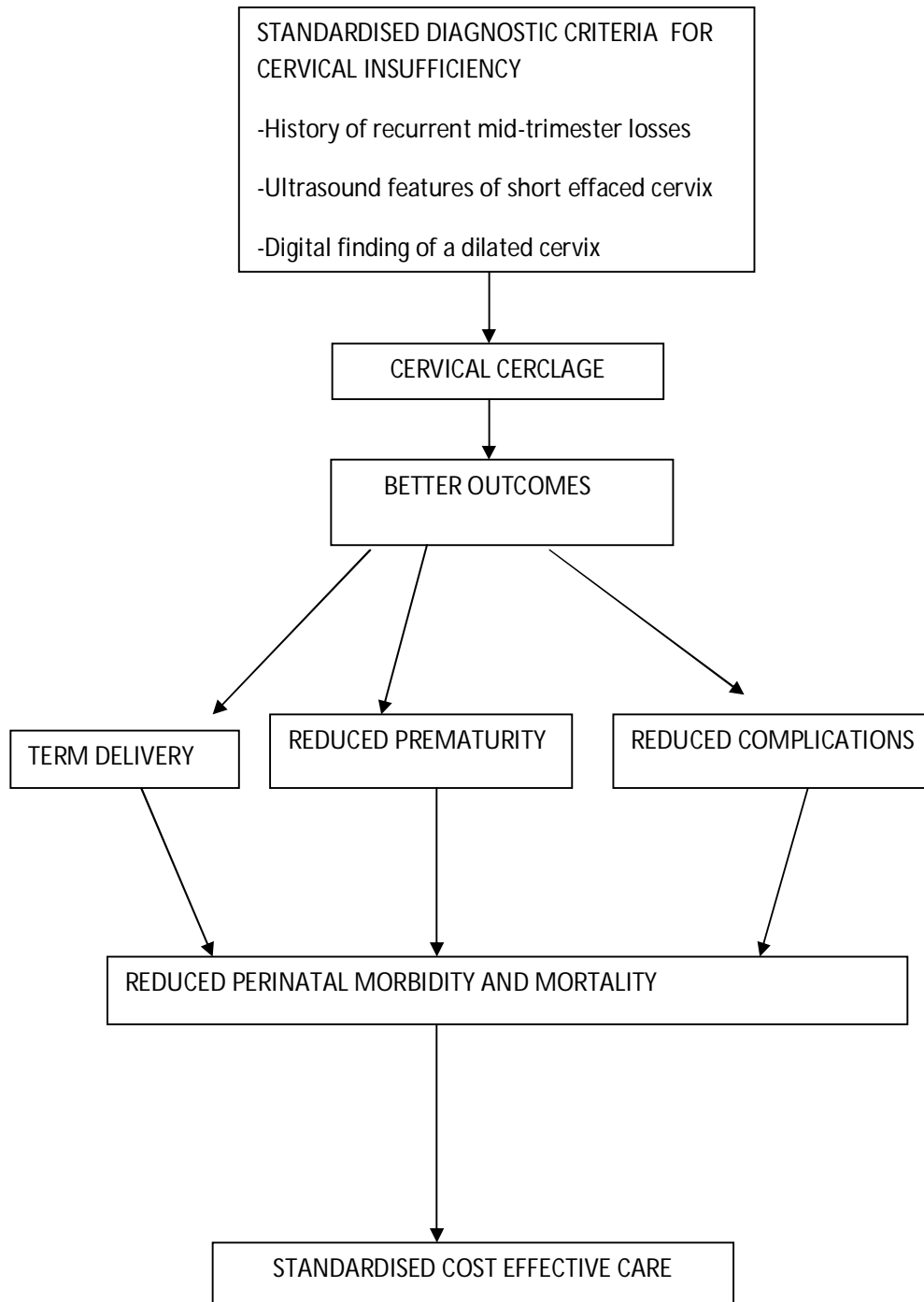
Management of cervical insufficiency with the ultimate desired favourable outcome of ensuring pregnancy reaches term will reduce rates of recurrent pregnancy losses and prematurity which is the greatest cause of perinatal morbidity and mortality in Kenya, Africa and globally thus reducing the huge costs to the health services because of both the need for intensive neonatal care, often for several weeks, and continuing support necessary after discharge from hospital.

Conceptual framework – Narrative

Cervical insufficiency results in recurrent pregnancy losses. Cervical cerclage reduces the chance of premature delivery. Standardised diagnostic criteria based on 3 or more midtrimester losses, cervical length of less than 25mm or cervical dilation in absence of contractions ensures better selection of patients for cervical cerclage and thus avoid unnecessary cerclages.

Cervical cerclage in well selected patients results in term deliveries with reduction in complications post cerclage. The good outcomes with the lowered rates of preterm deliveries leads to reduction in perinatal morbidity and mortality. The end result of a standardised diagnostic criteria is standardised cost effective care to all patients with cervical insufficiency.

CONCEPTUAL FRAMEWORK – SCHEMATIC PRESENTATION



Research Questions

1. What was the diagnostic criteria and pregnancy outcomes in patients with cervical insufficiency at Kenyatta National Hospital from 1st January 2010 to 31st December 2013?

Broad objectives

To determine the diagnostic criteria and pregnancy outcomes in patients with cervical insufficiency at Kenyatta National Hospital from 1st January 2010 to 31st December 2013.

Specific objectives

1. To describe the socio-demographic & reproductive characteristics.
2. To determine the diagnostic criteria for cervical insufficiency.
3. To determine immediate and late complications of cervical cerclage.
4. To describe the pregnancy outcomes.

Methodology

Study design:

This is a hospital based descriptive cross-sectional study. File numbers of patients who had a diagnosis of cervical insufficiency and cervical cerclage at KNH between 1st January 2010 and 31st December 2013 were identified from the database of department of Health Information KNH. A total of 297 files were retrieved and 19 files could not be traced at the time of study.

A total of 41 files did not have the requisite information for analysis and so was excluded from the study. The remaining 256 files were arranged sequentially based on the in-patient number and assigned serial numbers the first being number one to the last. Computer software for random number generation was used to generate simple random numbers from all the assigned serial numbers. A total of 168 random numbers were generated from the assigned serial numbers and used to sample the files for analysis.

Study site and setting:

The study was conducted at the Department of Reproductive Health, Kenyatta National Hospital located in Upper Hill, Nairobi city, the commercial and administrative capital of Kenya. It's a major referral hospital for the whole country and receives patients in the wider region of East and Central Africa being the largest hospital in this region with a bed capacity of 2500. It serves as a teaching hospital for The University of Nairobi College of Health Sciences and Kenya Medical Training College.

The department of reproductive health KNH is managed by about 40 specialist consultant obstetrician gynaecologists, 50 senior house officers in post graduate training, medical officer interns, clinical officers and several senior nurses and midwives divided into 3 Firms.

There are 4 antenatal clinics each week one for each Firm and an extra antenatal booking clinic for the first visit. There is also a consultation room at the hospital casualty open on a 24 hr basis covered by a SHO from reproductive health department, handling acute obstetrics and gynaecology cases. These are the entry point for patients with cervical incompetence. Patients with a diagnosis of cervical insufficiency usually have a pelvic ultra sound scan to ascertain foetal viability, confirm gestation, and document cervical length and rule out gross foetal anomalies.

Cervical cerclage is done as an elective procedure in maternity operation theatre that runs from Monday to Friday by a Consultant Gynaecologist or SHO usually at 12-14 weeks gestation under general or regional anaesthesia. Removal of cerclage suture is usually done by the SHO covering labour ward in the procedure room of labour ward under no anaesthesia at 37 weeks of gestation or earlier if complications occur.

Kenyatta National Hospital is the Largest Teaching and Referral Hospital in the country and region receives a large pool of patients with complicated obstetrical conditions and offers specialised high standard care is appropriate site for this study with the aim of pace setting in good clinical practice.

Study population:

Files of patients with a diagnosis of cervical insufficiency who had cervical cerclage and subsequently followed up until delivery or end of pregnancy at KNH Department of Reproductive Health between 1st January 2010 and 31st December 2013.

Inclusion criteria:

1. Women with a diagnosis of cervical insufficiency who had cervical cerclage and antenatal follow up till delivery/ end of pregnancy at KNH between 1st January 2010 and 31st December 2013.

Exclusion criteria:

1. Patients with incomplete data on pregnancy conclusion/outcome.
2. Patients who had diagnosis of cervical insufficiency and cervical cerclage at other facilities but were followed up at KNH.

Sample size:

The sample size was calculated using Fishers formula with finite population correction.

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

n = sample size with finite population correction

N=Population size; 316 women that had a diagnosis of cervical insufficiency and cerclage at KNH between 1st January 2010 and 31st December 2013.

Z=Statistic for 95% confidence=1.96

P= Expected proportion of women with delivery at 37 weeks and above after cervical cerclage. (Prevalence=68.5% P= 0.685) in a Nigerian study.(11)

d =precision (desired precision = 5%, d = 0.05).

$$n = \frac{316 \times 1.96^2 \times 0.685(1 - 0.685)}{0.05^2 (316 - 1) + 1.96^2 \times 0.685(1 - 0.685)}$$

$$n = 163$$

Data collection:

After obtaining ethical approval from ERC, permission was granted by the head of KNH Health information Department to the Principal investigator and a trained research assistant to access patients files.

KNH Health information Department maintains a database of all disease conditions and medical procedures as coded by the WHO International Statistical Classification of Disease and related Problems (ICD -10) and International Classification of Procedures in Medicine .

ICD-10 Code for Cervical insufficiency is O34.3 and procedure code for cervical cerclage is 5-674. All files of patients with a diagnosis of cervical insufficiency are assigned the code O34.3 and patients who undergo cerclage are assigned code 5-674. A print out from the database of In- Patient numbers under the above codes from 1st January 2010 to 31st December 2013 will be used to retrieve the files.

Information from the selected files was retrieved by a pre tested structured questionnaire/abstraction form prepared by the principal investigator. Information collected included socio-demographic data, previous gynaecological and obstetric history. Information on current pregnancy; records of radiological tests done, gestation at cerclage, type of cerclage, type of suture material, use of antibiotics and tocolytics, immediate and late complication, gestation at removal of cerclage, gestation at delivery, mode of delivery, birth weight, APGAR score at 5min.

The abstraction form was filled by the principal investigator and a trained research assistant.

Data analysis and presentation:

Raw data was cross checked and cleaned, entered into excel spreadsheet and exported to SPSS version 18.

Data analysis was done using statistical package for social sciences software (SPSS version 18). Univariate analysis involved summarization and graphical presentation of both categorical and continuous variables. Categorical variables were summarized using frequency distributions while descriptive statistics (mean, median, standard deviation) was used to summarize continuous variables (e.g. age, gestation at cerclage insertion).

Categorical variables (e.g. delivery outcome) were presented using bar charts and frequency distribution tables. Bivariate analysis done to test for association between the variables and preterm delivery after cerclage. Statistical significance based on alpha level of 0.05.

Quality assurance

The data abstraction form was pretested and reviewed accordingly to ensure all requisite data was captured. A clinical officer trained on obtaining data using this specific data abstraction tool was the research assistant and together with the principal investigator obtained the required data from the patient's files.

The principal investigator counter checked all data abstraction forms filled on a daily basis for completeness and consistency, and was available to guide the research assistant on any challenges encountered.

The completed questionnaires were stored in a designated cabinet with secure locks accessed only by the principal investigator. Data from the questionnaires was exported to the computer data analysis tool (SPSS) in a designated password protected computer. The computer password was only available to the principal investigator.

Ethical considerations:

The study proposal was approved by the Department of Obstetrics and Gynaecology before submission to ethics committee. Ethical approval from the Ethics and Research Committee of KNH /UON was granted for this study. Permission to conduct the study was granted by the KNH Head of Department Reproductive

Health, KNH Reproductive Health Research Coordinator, KNH Research and Programmes Coordinator and KNH Health Information Department.

Any information obtained from the files about the patient was only used for the sole purpose of this study. No names, telephone number, postal or physical address or any other identifying information was retrieved from the files. The principal researcher and the research assistant maintained strict confidentiality at all times.

The final copy of this study will be availed to ERC, Department of Obstetrics and Gynaecology, UON, and UON main library. No external source of funding was sort or received, the study fully funded from the principal investigators savings.

Limitations

The main limitation of this study was missing files. Missing data from retrieved files was also a drawback. Since the study relied on patients files poor documentation of clinical information and barely legible writings limited full evaluation of certain variables. It's however noted that the missing files occurred at random and therefore did not prejudice the final analysis.

Mitigation of limitations

Missing files were reported. Files with missing significant information were excluded from the final analysis. Certain missing data on the included files were reported as such and effect on final analysis noted.

Results

From 1st January 2010 to 31st December 2013 a total of 25,020 women attended KNH antenatal clinic, during the same period 316 women had a diagnosis of cervical insufficiency and insertion of cerclage translating to prevalence 1.26% of the antenatal population. A total of 168 files for women who had cervical insufficiency were reviewed.

Table 1: Socio-demographic characteristics women with cervical insufficiency at KNH

Demographic characteristics	Frequency(N=168)	Percent(%)
Age		
21-25	38	22.6
26-30	73	43.5
31-35	35	20.8
36-40	15	8.9
41-47	5	3
Formal education		
Primary	37	22
Secondary	74	44
College & University	54	32.1
None	3	1.8
Marital status		
Single	9	5.4
Married	159	94.6
Occupation		
Formal employment	51	30.4
Self-employment	59	35.1
Unemployed	58	34.5

The mean age of participants was 29.1 years (SD = 5) with a range from 21 to 47 years. Majority of the women were aged 21 to 35 years with only 8.9% aged 36-40 years and 3% aged 41 years and above. Two women had their age unspecified.

Most of the women had either secondary education at 44% or tertiary education at 32.1%. There was almost even distribution of the women's occupation among formal employment, self employment and unemployed. Majority of the women were married. (94.6%).

Table 2: Reproductive characteristics of women with cervical insufficiency at KNH.

Characteristics	Frequency(n=168)	Percentage(%)
Previous term deliveries		
none	95	56.5
1	49	29.2
2	17	10.1
3 or more	7	4.2
2nd trimester loss & preterm deliveries(14-36weeks)		
none	21	12.5
1	56	33.3
2	56	33.3
3 or more	35	20.9
Loss at <14 weeks gestation		
none	87	51.8
1	36	21.4
2	30	17.9
3 or more	15	8.9
Previous cervical surgical procedures		
D&C	25	14.9
Cervical tear repair	2	1.2
MVA	48	28.6
Cervical cerclage	52	31

Of the study population 56.5% had not carried a pregnancy to term. 33.3% had a single pregnancy loss at 14 and 36 weeks of gestation another 33.3% had lost 2 pregnancies while 20.9% had lost 3 or more pregnancies at the same gestation.

Slightly less than half of the women had lost one or more pregnancies at less than 14 weeks of gestation.

Table 4: Diagnostic elements of cervical insufficiency in the index pregnancy

Elements	Frequency (N=168)	Percent (%)
History of 2 nd trimester and early preterm loss (14-36wks)		
none	21	12.5
1	56	33.3
2	56	33.3
3 or more	35	20.8
Ultrasound scan		
yes	126	75
No	42	25
Length of cervix mm (N=126)		
<25mm	11	11.5
26-35mm	36	37.5
36-45mm	24	25
46mm and above	25	26
Not documented	30	23.8
Dilatation/ funnelling	13	13.5
Dilatation at digital exam		
closed	160	95.2
2-3 cm	6	3.6
4 cm	2	1.2
Membrane prolapsed	3	1.8
Previous history of cerclage	52	31

Diagnosis of cervical insufficiency was mostly based on previous history of pregnancy losses before term but with no strict adherence to the gestation at loss or number of losses. While all the 168 women whose files were reviewed had lost at least one pregnancy before term, 12.5% had not lost any pregnancy between 14-36

weeks of gestation,33.3% had lost 1 and a similar number of 33.3% had lost only 2 during the said gestations. Only 20.8% had lost 3 or more pregnancies at between 14-36 weeks gestation. The nature of the previous losses was either scantily described or not described at all in most files so it was not possible to characterise the specific losses.

A total of 126 women had ultrasound examination between 9-24 weeks of gestation. Only 4 (3.2%) were trans- vaginal scans,122(96.8%) were trans-abdominal scans, of the 126 ultrasound reports 30(23.8%) either had no measurement of length of cervix or described the cervix as long, short or adequate in length with no specific measurement documented. Of 96 who had cervical length documented, 11.5% had a had a length of 25mm and below and 13.5% had features suggestive of dilatation and funnelling.

There were a total of 8 patients with cervical dilatation on digital examination , 6 having a a dilatation of 2-3cm and 2 patients having a dilation of 4cm. 3 of these patients had prolapsed membranes.

Patients who had their diagnosis based on history of cervical insufficiency and cerclage in a previous pregnancy were 31%.

Table 5: Cerclage technique in women with cervical insufficiency at KNH

Technique	Frequency(n=168)	Percent (%)
Gestation at cerclage (weeks)		
9-12	18	10.7
13-16	108	64.3
17-20	33	19.6
21-24	9	5.4
Cerclage material		
silk	86	51.2
Mersilene tape	4	2.4
Nylon	4	2.4
Not specified	74	44
Gestation at removal of cerclage(weeks)		
20 and below	13	8.9
21-28	24	14.3
29-36	47	28
37-38	81	48.2
39 above	2	1.2

Cerclage technique for all the 168 women was a transvaginal cerclage as described by Mac Donald .Majority of the cerclages were inserted at between 13 and 16 weeks gestation (64.3%).significant number of files had no documentation of suture material(44%) with silk being the most frequently used suture (51.2%%).

One stitch was not located in the examination room and after EUA and so documented as misplaced. All the stitches removed at 36 weeks of gestation and below were due to complications, 48.2% of the patients had stitches removed electively at between 37 and 38 weeks gestation. Only 2 stitches were removed beyond 39 weeks gestation.

Table 6 : Complications after cerclage women with cervical insufficiency at KNH

Complications	Frequency (N= 168)	Percent (%)
Iatrogenic rupture of membranes	2	1.2
Excessive bleeding	14	8.3
PPROM	39	23.2
Preterm labour	49	29.2
Chorioamnionitis	3	1.8
Annular amputation	1	0.6
Deeply embedded suture removed in theatre	4	2.4
Displaced suture	1	0.6
Excessive vaginal discharge	21	12.5

Iatrogenic rupture of membranes occurred in 2 patients while excessive bleeding was reported in 8.3% of the patients at insertion of cerclage. Spontaneous preterm premature rupture of membranes occurred in 23.2% while 29.2% developed preterm labour. 3 cases of chorioamnionitis were noted. One case of partial annular amputation of the cervix occurred in a patient who went into labour at 37 weeks with stitch in situ.

Deeply embedded sutures requiring removal under anaesthesia in operating theatres were noted in 4 patients and in a single case the cerclage suture could not be identified at examination under anaesthesia and so was reported as a displaced suture.

Table 7 : Obstetric/Medical complications in women who had cerclage at KNH

Obstetric/medical complications	Frequency (N=168)	Percent (%)
Preeclampsia/eclampsia	17	10.1
Gestational diabetes	2	1.2
Ante partum haemorrhage	5	2.8
Post partum haemorrhage	4	2.3
Retained placenta	3	1.8
Pyelonephritis	2	1.2
Cardiac disease	4	2.3
Maternal mortality	1	0.6

A single case maternal death occurred intra operatively at caesarean section due to anaesthetic complications. The diagnosis pre operatively was delayed 2nd stage with bad obstetric history.

Table 8 : Delivery outcomes in women who had cerclage in KNH

Outcome	Frequency (N=168)	Percent (%)
Gestation age at delivery/ loss of pregnancy		
< 20 weeks	10	6
20-28 weeks	26	15.5
29-36 weeks	37	22
37-40 weeks	85	50.6
41 weeks and above	10	6
Mode of delivery		
Spontaneous vertex delivery	97	61.4
Emergency CS	38	24.1
Elective CS	15	9.5
Assisted vaginal delivery	2	1.3
Breech delivery	6	3.8

Out of the 168 women who had cerclage 56.6% carried the pregnancy to term (37weeks and above) with a delivery rate at between 37-40 weeks being 50.6% and at 41 weeks and above being 6%.

Pregnancy loss below 20 weeks was at 6% with losses between 20-28weeks being 15.5%. Preterm deliveries at 29-36 weeks of gestation were 22%.

On mode of delivery 61.4% of women had spontaneous vertex deliveries while 24.1% and 9.5% were by emergency and elective caesarean sections respectively.

Table 9: Neonatal outcomes in women who had cerclage at KNH.

outcome	Frequency(N)	Percent (%)
Pregnancy outcome (N=158)		
Live birth	144	85.7
Still birth	14	8.3
Birth weight (N=146)		
< 1000 g	12	8.2
1000-1500 g	9	6.2
1501-2000 g	22	15.1
2001-2500 g	18	12.3
2501-3000 g	40	27.4
3001-3500 g	38	26
3501-4000g	5	3.4
>4000g	2	1.4
Apgar score at 5 minutes (N=146)		
< 4	6	4.1
4-6	11	7.5
7-10	129	88.4
NBU admission (N=146)		
Yes	34	23.3
Indication for NBU admission (N=34)		
Prematurity	21	61.8
Respiratory distress syndrome	6	17.6
Neonatal sepsis	5	14.7
Meconium aspiration syndrome	1	2.9
Neonatal jaundice	1	2.9

Live birth rate was 85.7%. There were 2 pairs of twins among the live births. More than half of the neonates had a birth weight of 2500g. There were 34 admissions to newborn units with prematurity accounting for 61.8% of these admissions. 58.2% had a birth weight of more than 2500g.

Bivariate analysis

Bivariate analysis was done to test any association between the variables and gestation at delivery /pregnancy loss after cerclage as outcome of interest.

Table 10: Socio-demographic characteristics and gestational age at delivery/ pregnancy loss after cerclage insertion

characteristic	> 37	<37	Odds			
	weeks	weeks	ratio	95% CI	p	
Age in years						
21-25	23(24.2)	15(20.5)	1.0 (Ref)			
26-30	41(43.2)	32(43.8)	1.2	0.54	2.66	0.659
31-35	19(20.0)	16(21.9)	1.29	0.51	3.27	0.59
36-40	9(9.5)	6(8.2)	1.02	0.3	3.46	0.972
41-47	3(3.2)	2(2.7)	1.02	0.15	6.86	0.982
Education Level:						
Primary	23(24.2)	14(19.2)	1.0 (Ref)			
Secondary	41(43.2)	33(45.2)	1.32	0.59	2.96	0.498
College & University	31(32.6)	23(31.5)	1.22	0.52	2.87	0.65
None	0(0.0)	3(4.1)	NA			
Marital Status:						
Single	7(7.4)	2(2.7)	1.0 (Ref)			
Married	88(92.6)	71(97.3)	2.82	0.57	14.02	0.204
Occupation :						
Formal employment	26(27.4)	25(34.2)	1.0 (Ref)			
Self-employment	36(37.9)	23(31.5)	0.66	0.31	1.42	0.291
Unemployed	33(34.7)	25(34.2)	0.79	0.37	1.68	0.536

The gestational age at delivery or pregnancy loss did not show significant associations with the maternal socio-demographic characteristics including: age, level of formal education, marital status and occupation.

Table 11: Reproductive history and gestational age at delivery/ pregnancy loss after cerclage insertion

History	> 37 weeks	<37 weeks	Odds ratio	95% CI		p
Number previous pregnancy losses						
< = 3	84(88.4)	50(68.5)	1.0 (Ref)			
> 3	11(11.6)	23(31.5)	3.51	1.58	7.81	0.002
Number of previous term deliveries						
None	49(51.6)	46(63.0)	1.0 (Ref)			
1 or more	46(48.4)	27(37.0)	0.63	0.34	1.17	0.139
Previous cerclage insertion						
yes	27(28.4)	25(34.2)	1.0 (Ref)			
No	68(71.6)	48(65.8)	0.76	0.39	1.47	0.419
Cervical tear						
Yes	0(0.0)	2(2.7)	N/A			
No	95(100.0)	71(97.3)	N/A			
D & C						
Yes	14(14.7)	11(15.1)	1.0 (Ref)			
No	81(85.3)	62(84.9)	0.97	0.41	2.29	0.952

There was a significant association between number of previous pregnancy losses and age at delivery or pregnancy loss in the index pregnancy ($p = 0.002$). The risk of delivery or pregnancy loss before term was 3.5-fold greater in mothers who had previously lost more than 3 pregnancies (OR = 3.51, 95% CI 1.58-7.81).

There was no significant association between prior cerclage procedures and early delivery or loss of pregnancy for the index pregnancy. Previous cerclage insertion was not associated with early delivery during ($p = 0.419$), neither was D&C during previous cerclage ($p = 0.952$).

**Table 12: Current cerclage procedure and gestational age at delivery/
pregnancy loss after cerclage insertion**

Procedure	> 37 weeks	<37 weeks	Odds ratio	95% CI		p
Gestation at insertion of cerclage						
			1.0 (Ref)			
9-12 weeks	12(12.6)	6(8.2)	(Ref)			
13-16 weeks	61(64.2)	47(64.4)	1.54	0.54	4.41	0.42
17-20 weeks	18(18.9)	15(20.5)	1.67	0.5	5.51	0.402
21-24 weeks	4(4.2)	5(6.8)	2.5	0.49	12.89	0.273
Length of cervix in mm						
			1.0 (Ref)			
<25 mm	8(8.4)	3(4.1)	(Ref)			
26-35 mm	20(21.1)	16(21.9)	2.13	0.49	9.38	0.316
36-45 mm	11(11.6)	13(17.8)	3.15	0.67	14.86	0.147
46 mm and above	14(14.7)	11(15.1)	2.1	0.45	9.81	0.348
Medical / Obstetric Complications post cerclage insertion						
APH						
			1.0 (Ref)			
Yes	4(4.2)	1(1.4)	(Ref)			
No	91(95.8)	72(98.6)	3.16	0.35	28.94	0.308
Diabetes						
			1.0 (Ref)			
Yes	1(1.1)	1(1.4)	(Ref)			
No	94(98.9)	72(98.6)	0.77	0.05	12.46	0.851
PPH						
			1.0 (Ref)			
Yes	3(3.2)	1(1.4)	(Ref)			
No	92(96.8)	72(98.6)	2.35	0.24	23.05	0.464
Preeclampsia						
			1.0 (Ref)			
Yes	5(5.3)	12(16.4)	(Ref)			
No	90(94.7)	61(83.6)	0.28	0.09	0.84	0.023

The development of preeclampsia was associated with early delivery or loss of pregnancy (p =0.023).

Discussion

The objective of this study was to describe the diagnostic criteria for cervical insufficiency at KNH and the pregnancy outcomes following cerclage. Gaps and inconsistencies were noted in the diagnosis of insufficiency with no clear criteria in selection of patients for cerclage. Significant adverse occurrence following cerclage noted with PROM and preterm labour being the commonest at 23.2% and 29.2%. 2 cases of iatrogenic rupture of membranes at cerclage and 3 cases of chorioamnionitis were reported. The overall rate of term delivery was 56.6% with a mean birth weight of 2704g, prematurity was the leading indication for NBU admissions.

The prevalence of cervical insufficiency in the antenatal population at KNH was 1.26%. This compares with the 1% prevalence reported in other populations (7). The mean age of the study population was 29.1 years with a range of 21 to 47 years. All the women had lost a pregnancy at any gestation before term with 87.5% losing one or more pregnancies between 14-36 weeks of gestation and 48.2% having lost at least a pregnancy before 14 weeks of gestation, confirming that this indeed was a high risk group with recurrent pregnancy losses.

RCOG recommends the diagnosis of cervical insufficiency and use of cerclage to manage the same in patients with 3 or more midtrimester or early 3rd trimester losses, patient with atleast 1 or 2 midtrimester or early 3rd trimester losses with a cervical length of 25mm or below measured by a transvaginal ultrasound scan at gestations between 14-24 weeks and use of rescue cerclage in patient with cervical dilation of 4cm and below in absence of labour, per vaginal bleeding and rupture of membranes or infection at gestation less than 24 weeks. It further discourages the

use of cerclage in multiple order pregnancies since its been found to confer no benefit and could actually result in preterm labour and other complications.(15) . There were 2 pairs of multiple order pregnancy pregnancies who had cerclage in this study.

This study demonstrates that even though the diagnosis of cervical insufficiency was mostly by history of previous losses, there was no adherence to any minimum number of losses or gestation at loss. 12.5% had not lost any pregnancy between 14-36 weeks of gestation and so diagnosis in this group of women was mostly reliant on 1st trimester losses which ideally are not considered in assigning diagnosis of incompetence. Only 20.8% had lost 3 or more pregnancies between 14-36 weeks, thus meeting the threshold for diagnosis based on history.

Of the total 168 women, 126 (75%)had ultrasound scan examinations before 24 weeks and out of this only 4(3.2%) were transvaginal scans, the recommended route of scanning in measurement of cervical length. (14). The rest being transabdominal scans. Furthermore 30 out of the 126 ultrasound reports either had no mention of cervical length or described the cervix as short, long or adequate without assigning numerical measurements to the same. 11.5% had a cervical length of 25mm or below with 13.5% having features suggestive of dilatation and funnelling.

From the results of this study ultra sonography as a tool for diagnosis of insufficiency and patient selection for cerclage, though frequently performed(75%) ,seem to only been marginally useful in this set up and therefore its use might only have added to patients care costs without conferring the true benefits that it could have when fully and correctly utilised. Trans abdominal ultra sound scanning has been found to be inaccurate in measurement of cervical length since the full bladder

required during such examination artificially lengthens the cervix. (30) . This was however the modality of choice at 96.8%.

The results demonstrate that cervical cerclage is associated with a number of complications. Iatrogenic rupture of membranes at insertion of cerclage was reported in 2 women. Excessive bleeding was noted in 8.3% of the cases. Similar immediate complications were reported by the study by RCOG/MRC working party cervical cerclage.(17).

Spontaneous preterm premature rupture of membranes and preterm labour were the commonest complications reported after cerclage as the pregnancies advanced occurring in 23.2% and 29.2% necessitating removal of the cerclage. Three case of chorioamnionitis were reported in this study. The rates of PROM and preterm labour were higher than those reported in an Asian population at Aga Khan Teaching Hospital Karachi at 10% and 15.7%. (22).

A single case of partial annular amputation of the cervix requiring examination under anaesthesia and repair occurred in a patient who went into labour at 37 weeks with the stitch in situ.

In the study population obstetric complications unrelated to cerclage with direct impact on the pregnancy outcomes were noted. 15 cases of severe preeclampsia and 2 cases were reported resulting 6 cases of intrauterine foetal demise and requiring premature removal of stitch with induction of labour in the rest of the cases with resultant preterm deliveries. Other complications noted included 5 cases of ante partum haemorrhage, 2 of gestational diabetes. Two cases of ante partum haemorrhage were delivered by emergency caesarean section with outcome of fresh still births.

Controversy still surrounds the true benefit of cervical cerclage.(7,13,25). In this study 56.6% of women carried their pregnancy to term (37 weeks and beyond) after cerclage. 6% of the pregnancies ended at less than 20 weeks gestation while a significant number of pregnancies (15.6%) ended between 20-28 weeks of gestation. Preterm deliveries at between 29-36 weeks were 22%. And this clearly demonstrates that even with cerclage a large proportion of pregnancies still end prematurely,this reality should be taken into consideration during patients counselling for cerclage and planning for subsequent antenatal follow up and eventual neonatal care.

The live birth rate is 85.7%, the birth weights closely mirrors the gestation at delivery with 58.2% of neonates weighing 2500g. The mean birth weight was 2704g. In a Nigerian population 68.8% of the women carried pregnancy to term with a mean birth weight of 2900g (23). While in an Asian population, Karachi, Pakistan the delivery rate at term after cerclage was 62.8%.(22)

Prematurity was the commonest indication for NBU admissions at 61.8% of the total 34 documented NBU admissions. Patient counselling on possibility of this outcome and the clinicians preparedness in dealing with this eventuality should be an integral part in managing women with cervical insufficiency. It's important to note that information on the neonates status was scanty in some files and absent in most cases and so there was chances of underreporting of NBU admissions.

On mode of delivery there was increased rate of elective caesarean delivery and breech vaginal delivery at 9.5% and 3.8% respectively compared to 4-6% rate of elective caesarean delivery and less than 1% in the general hospital population.(31).

The increased rates may be attributed to the decision to have patients with recurrent

losses undergo elective caesarean delivery with bad obstetric history as the indication as was observed in this study. The increased number of breech delivery was mostly due to the pregnancies that ended preterm.

The 14 stillbirths were mostly due to obstetric complications including preeclampsia/eclampsia, ante partum haemorrhage and 1 case reported in a patient with chorioamnionitis. The development of preeclampsia was associated with early delivery or loss of pregnancy ($p=0.023$). The obstetric complications were confounders. A single case of maternal mortality was reported in this study intra operatively at emergency caesarean section due to anaesthetic complications with a pre operative diagnosis of delayed 2nd stage.

There was no association between the socio demographic characteristics and gestation at delivery or end of pregnancy. Association between previous 3 or more preterm pregnancy losses and preterm delivery/ loss in index pregnancy after cerclage was observed, ($p=0.002$). This is unlike what has been observed in other studies in which cervical cerclage reduces subsequent loss in patients who have had 3 or more losses due to cervical incompetence.(18) . This observation is possibly a reflection the very liberal usage of cerclage as demonstrated in this study with absence of a clear criteria for selection of women with insufficiency and thus possible inclusion of patients with recurrent losses which are not necessarily due to cervical insufficiency with increased risk of subsequent loss despite cerclage.

The major limitation of this study was missing files and partially missing information due to poor documentation. The other limitation was because of the reliance on the files it was not possible to characterise the nature and possible aetiology of the previous losses since apart from the gestation at loss any extra information on the

losses were either scanty or nonexistent. This study however documented the diagnostic criteria at KNH noting the weaknesses and inconsistencies in the same. It also clearly described the outcomes after cerclage. And files with no documentation on delivery outcomes were excluded from the final analysis.

Conclusion

From the results of this study the following conclusions were drawn:

1. There is no standardised diagnostic criteria for cervical insufficiency at KNH.
2. Ultrasonography as a tool for evaluation of cervical insufficiency was not fully and correctly utilised.
3. Despite the intervention of cervical cerclage premature end of pregnancy remained a challenge with 6% of the pregnancies ending as abortions and 37.5% ending as preterm deliveries before 37 weeks gestation with attendant neonatal morbidity and NBU admissions.
4. Cerclage being an invasive surgical procedure had attendant risks of complications and this should inform patient counselling and selection.
5. Increased rates of elective caesarean delivery noted in the study population.

Recommendations

1. KNH being a Teaching and National referral hospital needs to have Standard Operating Procedure/Protocol for diagnosis of cervical incompetence, patient selection and counselling for cervical cerclage, timing of procedure and subsequent antenatal follow up.
2. Further studies to evaluate the effect of a standardised protocol for diagnosis of cervical insufficiency on the ultimate pregnancy outcomes.

Work plan

activity	2014 March	2014 April	2014 May	2014 June	2014 July	2014 August	2014 September	2014 October
Proposal writing	✓	✓	✓					
Proposal presentation				✓				
Presentation to ERC				✓	✓	✓		
Data collection						✓		
Data processing							✓	
Report writing							✓	
Study presentation								✓

Budget

Item	Total cost (kshs)
Biostatistician fee	20, 000
Stationary & printing costs	4,000
Internet hours	2,000
KNH/UON ERC fee	2,000
Miscellaneous	2,000
Research Assistant	20,000
GRAND TOTAL	50,000

Source of funds: Personal savings.

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Appendix 1

Data Abstraction Form

I SOCIODEMOGRAPHIC CHARACTERISTICS

1. Age in completed years

2. Highest level of education attained

Primary

Secondary

College & University

None

3. Marital status

Single

Married

Separated

Divorced

Widowed

4. Occupation

Formal employment

Self employed

Unemployed

II REPRODUCTIVE CHARACTERISTICS

5. Parity

 +

PREGNANCY OUTCOME	ORDER OF PREGNANCY								
	1st	2nd	3rd	4th	5th	6th	7th	8th	9th
Term delivery (37 weeks plus)									
Preterm delivery(28-36weeks)									
IUFD at 37 weeks plus									
IUFD at 28-36 weeks									
Abortion at 14-28weeks									
Abortion at <14weeks									

6. Cerclage in previous pregnancy

yes

No

If yes

Number of cerclage inserted

Gestation at delivery/Loss after previous cerclage

1st

2nd

3rd

7. Previous history of cervical surgical procedure

YES

NO

D&c

Leep

Cone biopsy

Cervical tear/ repair

III INDEX PREGNANCY

8. Diagnostic criteria

History of previous losses/preterm delivery

Yes

No

If yes: number of losses/preterm deliveries

Ultrasonography

yes

No

If yes :

Gestation at scanning in weeks

Length of cervix

Presence of dilatation/funnelling

Yes

No

Foetal anomaly

Digital examination

yes

No

If yes

Cervical dilatation in cm

Membrane prolapsed

yes

No

9. Gestation at cervical cerclage in weeks

10. Cerclage technique

MacDonald	<input type="checkbox"/>
Shirodkar	<input type="checkbox"/>
Transabdominal	<input type="checkbox"/>

11. Cerclage material

Silk	<input type="checkbox"/>
Mersilene tape	<input type="checkbox"/>
Others (specify)

12. Complications following cerclage (if yes specify gestation at occurrence)

	YES	NO	Gestation
Excessive bleeding after cerclage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Persistent per vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Premature rupture of membranes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pyrexia/ chorioamnionitis

Preterm labour

Annular amputation

Cervical scarring

13 .Gestation at removal of cerclage

14. Obstetric complications in index pregnancy

Yes

No

If yes specify

Preeclampsia

Gestational diabetes

Ante partum haemorrhage

Postpartum haemorrhage

Others (specify)

.....

15. Gestation at delivery/pregnancy loss

Onset of labour

spontaneous

induced

16. Mode of delivery

Spontaneous vertex delivery

Caesarean section

Assisted vaginal delivery

Breech delivery

17. Delivery outcome

Alive

Dead

If dead specify

FSB

MSB

Birth weight in grams

Apgar score at 5min

NBU admission

Yes

No

If yes specify indication

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