OUTCOMES OF PHARMACOLOGICAL INDUCTION OF LABOUR AT OR NEAR TERM AT KENYATTA NATIONAL HOSPITAL

INVESTIGATOR: DR. ESIROMO AMASE MARIAN

M.MED. OBSTETRICS AND GYNAECOLOGY

UNIVERSITY OF NAIROBI

REG. NO H58 / 71380 / 08

THESIS SUBMITTED AS PART FULFILLMENT FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY AT THE UNIVERSITY OF NAIROBI.

CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Esiromo Amase Marian, MMed student registration number H58/71830/08 in the Obstetrics and Gynaecology Department, College of Health Sciences, University of Nairobi, under the guidance and supervision of Professor Joseph Karanja and Dr. F. Odawa. It has not been presented in any other university for award of a degree.

Signed……. ……

Date……

PROF. KOIGI KAMAU

ASSOCIATE PROFESSOR OF OBSTETRICS/GYNAECOLOGY,

CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST'

CHAIRMAN

DEPARTMENT OF OBSTETRICS/GYNAECOLOGY

UNIVERSITY OF NAIROBI.

DECLARATION

I declare that this is my original work, and it has not been presented or submitted for a reward of a degree in any other university. References to others' work have been clearly indicated.

DR. MARIAN AMASE ESIROMO

MASTER OF MEDICINE STUDENT IN OBSTETRICS AND GYNAECOLOGY

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF NAIROBI.

Signed…….

Date…….

CERTIFICATE OF SUPERVISION

This is to certify that this research work has been done by Dr. Marian Amase Esiromo under my guidance and supervision.

PROFESSOR JOSEPH KARANJA

ASSOCIATE PROFESSOR OF OBSTETRICS/GYNAECOLOGY

DEPARTMENT OF OBSTETRICS/GYNAECOLOGY, SCHOOL OF MEDICINE,

COLLEGE OF HEALTH SCIENCES, UNIVERSITY OF NAIROBI.

Signed……..Date……

DR. F.X.O. ODAWA

LECTURER,

DEPARTMENT OF OBSTETRICS/GYNAECOLOGY, SCHOOL OF MEDICINE,

UNIVERSITY OF NAIROBI.

Signed…….…….Date…….

ACKNOWLEDGEMENT

I thank God for His provision. I thank my lecturers for their guidance and training. I am grateful to my supervisors Professor J Karanja and Dr. F Odawa for their guidance in my research, my research assistants who helped with data collection, and Mr Mwaniki for his contribution in analysis. Special thanks to Dr. Njiru Njeru for his input and tireless support.

I am especially thankful to my family for their continual support and encouragement throughout the duration of the course of this postgraduate programme. May God reward each of you greatly.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ARM- Artificial rupture of membranes

ANC- Antenatal clinic

C/S- Caesarian section

FIGO- International Federation of Obstetrics and Gynaecology

ICU- Intensive Care Unit

KNH- Kenyatta National Hospital

Mcg- micrograms

NBU- Newborn Unit

NRFS- non-reassuring fetal status

PGE1- Prostaglandin E1 (misoprostol)

PGE2- Prostaglandin E2 (dinoprostone)

PPH- Postpartum hemorrhage

PROM- Prelabour Rupture of membranes

WHO- World Health Organization

OPERATIONAL DEFINATIONS

Term- Gestation of 37 completed weeks and above either by last menstrual period, ultrasound estimation or fundal height measurement

Near Term- Gestation of 34 completed weeks up to 37 weeks either by last menstrual period, ultrasound estimation or fundal height assessment

Successful induction- Vaginal delivery following induction of labour

Failed Induction of labour- Failure to deliver vaginally within 24 hours of initiating induction

Induction to delivery interval- Time taken in hours between initiation of Induction and vaginal delivery

Complications of induction- side-effects and other serious adverse medical or obstetric outcomes following pharmacological induction of labour, apart from delivery by caesarian section

ABSTRACT

Background: Induction of labour is artificial initiation of uterine contractions after the period of viability, with the intention of accomplishing delivery prior to onset of spontaneous labor. It is performed when the benefits of expeditious delivery to either mother or fetus outweigh the risk of continuing the pregnancy. The frequency of induction has been increasing, and while it is a beneficial procedure, it is not without risks. At Kenyatta National Hospital (KNH) currently prostaglandin E2, prostaglandin E1 and oxytocin are used for pharmacological labour induction of viable pregnancies at or near term. There have been no recent studies in our setup to evaluate risks and fetal and maternal outcomes following pharmacological induction of labour.

Objective: To describe maternal and fetal outcomes associated with labour induction at or near term at Kenyatta National Hospital.

Study design: This was a cross-sectional descriptive study

Study Setting: The setting was in labor ward and post-natal wards**,** Kenyatta National Hospital.

Sample: 262 pregnant women at gestation age of ≥34 completed weeks, with a live fetus, scheduled for pharmacological induction of labor, during the study period.

Methods: Mothers undergoing induction of labour during the study period were recruited into the study consecutively. A questionnaire was used to obtain data about socio-demographics, obstetric characteristics, methods used for induction, duration of the procedure, and maternal and fetal outcomes.

Results: Most of the participants (64.9%) were aged between 20 to 29 years, 85.9% were married and half of the participants had attained at least secondary level of education. Majority of the women were primigravidas (58%), and the mean gestational age was 39.9 weeks. The pharmacological methods used for induction of labour included oxytocin infusion alone (8.8%), prostaglandin (either misoprostol or dinoprostone) alone (38.5% and 4.2% respectively) or in combination with artificial rupture of membranes and oxytocin infusion. The commonest indication for induction was post-datism (50.8%) followed by hypertensive disease (16%). The average duration from induction to delivery was 19.1 hours. The success rate of induction among

study participants was 74%. The commonest indication for caesarian section was a diagnosis of failed induction of labour (51.5%) which was defined as failure to achieve vaginal delivery within 24 hours of initiating induction. Most women (94.7%) delivered without any other side-effects or complications, while genital tract tears was the most common complication (2.7%). Meconium staining of liquor was noted in 9.9% of cases, and 3.4% had fetal heart rate abnormality intrapartum. Majority (94.6%) of newborns had an Apgar score of seven and above. 18 (6.9%) of newborns were admitted to the newborn unit with the commonest diagnosis (66.7%) being birth asphyxia. There were two cases of fresh stillborn fetuses.

Conclusions: Pharmacological induction of labour resulted in high rate of success, with good maternal and neonatal outcome. However, the induction to delivery time is prolonged, with many patients taking up to 24 hours, which may pose risks to both the mother and fetus. Patients with a diagnosis of post-datism are the majority who undergo the procedure of induction of labour.

Recommendations: Although this study suggests that misoprostol is effective, well designed trials should be conducted to compare the safety and effectiveness of vaginal misoprostol with dinoprostone and oxytocin in our setting. Measures such as routine sweeping of membranes at term should be considered in order to reduce the incidence of prolonged pregnancy. There is also need to review protocols concerning the logistics of antenatal and labour drug administration during the procedure because transfer of patients to and from wards for review may be the reason for delays and prolonging of the induction process.

CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

Induction of labour is the iatrogenic stimulation of uterine contractions before the onset of spontaneous labour, to accomplish vaginal delivery [1]. It is undertaken when the benefits of expeditious delivery to either the mother or fetus outweigh the risk of continuing the pregnancy [1].

Indications and Incidence

Indications for induction of labour may be clinical or social (mother's or clinician's convenience). Clinical indications include post-term pregnancy, hypertensive disorders of pregnancy, prelabour (premature) rupture of membranes, chorioamnionitis, diabetes, isoimmunisation, intra-uterine fetal death, intra-uterine growth restriction, gross fetal anomalies and other maternal conditions [2]. Elective induction may be motivated by a variety of reasons. For example, pregnant women may wish to end their pregnancy because of physical discomfort; concern that rapidly progressing labor would preclude timely arrival at the hospital or epidural placement; scheduling issues; or ongoing concerns for maternal, fetal, or neonatal complications [2].Contraindications to induction include cephalopelvic disproportion, placenta praevia or vasa praevia, abnormal fetal lie, cord presentation/prolapse, previous classical caesarian section scar, prior myomectomy with breach of uterine endometrium, pelvic structure anomalies, invasive carcinoma of the cervix and active genital herpes simplex infection.

Induction of labour is a relatively common procedure. The rate of induction of labour may differ depending on the availability of resources and population. Worldwide, the prevalence of labour induction varies greatly between countries and even between different regions of the same country. In general, however, it is higher in developed countries (at around 20%) than in developing countries [1, 3].

In the Western world, frequency of labour induction has been increasing, with reasons given including the availability of better cervical ripening agents, patient and clinicians desire to arrange a convenient time of delivery, and more relaxed attitudes toward marginal indications for

induction [4]. Patient or provider concerns about the risk of fetal demise with expectant management near term or post-term have also contributed to the increased rate of induction [5].
In the US, between 1990 and 2006, the frequency of labor induction approximately doubled, rising from 9.5 to 22.5 percent [3]. In Finland, Javerlin et al studied various hospitals and found that the overall induction rate in Finland was 19.5% with hypertensive disease being the most common indication [6]. Guerra et al in Latin America studied 120 large hospitals and found a rate of 11.4%, with PROM as the commonest indication [7].

In our setting, Mati et al in 1983 Nairobi Birth Survey reported an overall induction rate of 5.7% [8]. Khisa in 1999 found an induction rate of 14% at Aga Khan hospital Nairobi [9]. Onyambu in 2001, in the same hospital found a rate of 8.04% [10], while Kaguta in 1984 found a rate of 5.6% at Kenyatta National Hospital [11]. In a prospective descriptive cross sectional study done at KNH in 2002, Njagi J,M, [12] found an induction rate of 12.7%. The indications for induction were mainly premature rupture of membranes, prolonged gestation, fetal demise and hypertensive conditions.

Pre-induction assessment

A thorough evaluation of the maternal and fetal condition is important prior to undertaking labor induction to make sure there are no contraindications to labor or vaginal delivery and to assess the likelihood of successful induction. At a minimum, this includes assessing the gestational age and fetal size, determining presentation, performing a cervical examination, and reviewing the patient's pregnancy and medical history. The indications for and alternatives to the procedure, techniques for cervical ripening and labor induction, and the possibility of cesarean delivery or induction over several days should be reviewed with the patient [1].

The magnitude of risk of induction of labour is influenced by factors such as gestational age, presence/absence of fetal lung maturity, severity of the clinical condition, and cervical status. Cervical status is one of the most important factors for predicting the likelihood of successfully inducing labor [13]. In observational studies, other characteristics associated with successful induction include multiparity, tall stature (over 5 feet 5 inches), increasing gestational age, non-obese maternal weight or body mass index, and infant birth weight less than 3.5 kg [14, 15]. However, these characteristics are predictive of success even in spontaneous labors, which

suggests they are more predictive of the route of delivery than the likelihood the patient will reach the active phase of labor [15].

The modified Bishop score is used to assess the cervix. This system tabulates a score based upon the station of the presenting part and four characteristics of the cervix: dilatation, effacement, consistency, and position (Appendix 2). If the Bishop score is high (variously defined as ≥5 or ≥8), the likelihood of vaginal delivery is similar whether labor is spontaneous or induced [13] . In contrast, a low Bishop score is predictive that induction will fail to result in vaginal delivery. These relationships are particularly strong in nulliparous women who undergo induction [13]. The relationship between a low Bishop score and failed induction, prolonged labor, and a high cesarean birth rate was first described prior to widespread use of cervical ripening agents [16]. However, this relationship has persisted even after the introduction of these ripening agents [17].

Methods for induction of labour

Synthetic oxytocin administration is a proven method of induction of labour [18]. Oxytocin administration produces periodic uterine contractions, with increasing responsiveness with advancing gestational age. However, it is less successful for labour induction when used in women with uneffaced and undilated cervices [18]. In order to improve cervical score and induce myometrial contractility, cervical ripening is done [19]. Ripening of the cervix can be achieved by either mechanical (physical) interventions (such as disruption of fetal membranes or insertion of dilators or balloon catheter; or by pharmacological methods (application of cervical ripening agents). The choice of method used for induction should take into account the cost of drug, storage, accessibility, administration and supervision during induction. There is continual research for better agents and methods to induce labour [20, 21].

Prostaglandins are a series of closely related 20-carbon unsaturated fatty acids containing a cyclopentane ring, derived from essential fatty acids and arachidonic acid. They have been shown to have a role in cervical ripening and are produced by the cervix in increasing amounts at term [2]. Administration of synthetic prostaglandins results in dissolution of collagen bundles and an increase in the submucosal water content of the cervix. These changes result in a cervical state that is associated with greater success upon labor induction [22]. Prostaglandins also cause

the uterus to contract, and their efficacy has been demonstrated [22]. The optimal route, frequency, and dose of prostaglandins have not been determined. There are various classes and preparations.

Dinoprostone (prostaglandin E2) has been found to be effective, safe and widely recommended as the gold standard [2].It is available as vaginal insert as well as a gel. An advantage of the vaginal pessary over the gel formulation is that the vaginal insert can be removed in case of side effects [23, 24]. Prostaglandin E2 however is expensive and requires cold temperatures for storage.

Misoprostol, a synthetic prostaglandin E1 (15-deoxy-16-hydroxy-16-methyl PGE1) was developed in 1973, for the prevention and treatment of peptic ulcers because of its mucosal protective properties, but was later found to have uterotonic and cervical priming action. It is an effective uterine myometrial stimulant and binds selectively to EP-2/EP-3 prostanoid receptors. It is thus used off-label in most countries for obstetric and gynaecological indications of medical abortion, medical evacuation of miscarriages, induction of labour, management of postpartum haemorrhage and cervical priming before surgical procedure [25].

Its advantages include being widely available, cheap, and stable at room temperature, compared to other prostaglandin analogues. In addition to oral route, it can also be used through vaginal, sublingual, buccal and rectal routes, depending on its indication. It is not suitable for parenteral use because of its rapid degradation in the blood [26].

In pregnant women with intact membranes and an unfavourable cervix meta-analyses have found misoprostol to be more effective than placebo and oxytocin, more effective than other prostaglandins given vaginally for labor induction; caesarian section rates were comparable with other prostaglandins, although there was a higher rate of uterine tachysystole [27, 28].

In local studies, vaginal misoprostol was found to be more effective than dinoprostone for cervical ripening and labour induction in studies carried out by Itsura at Pumwani [29], Ole Kurrarru in Kajiado [30] and Osewe at Kenyatta [31] hospitals. At St. Mary's hospital, Gakara found vaginal misoprostol to be more effective than oxytocin for labour induction in prelabour rupture of membranes at term [32]. In a randomized clinical trial comparing the efficacy and

safety of oral misoprostol solution and intravenous oxytocin in term PROM at Kenyatta National Hospital, Mbaluka found oral misoprostol solution to be as efficacious and as safe as oxytocin for labour induction in patients with PROM at term [33].

Other methods used for labor induction include;

1) Membrane stripping — Involves inserting the examiner's finger beyond the internal cervical os and then rotating the finger circumferentially along the lower uterine segment to detach the fetal membranes. Membrane stripping is typically performed during an office visit in women with a partially dilated cervix who wish to hasten the onset of spontaneous labor. The efficacy of membrane sweeping was demonstrated in a meta-analysis in which sweeping of membranes was associated with reduced frequency of pregnancy continuing beyond 41 weeks and reduced frequency of formal induction [34].
2) Amniotomy –This refers to artificial rupture of the fetal membranes. It is an effective method of labour induction, but can only be performed in women with partially dilated and effaced cervices. A Cochrane review of randomized trials found the combination of amniotomy and intravenous oxytocin to be more effective than amniotomy alone [35].
3) Other –There is limited data regarding the efficacy of breast stimulation, castor oil, hyaluronidase, or sexual intercourse for cervical ripening. Porcine relaxin has been shown to be effective in cervical ripening in some trials. Mifepristone (RU-486) an antiprogesterone steroid has also been shown to be effective in some cases. Laminaria digitata may be used to mechanically dilate the cervix, but it is associated with increased risk of infection. Extra-amniotic saline infusion has also been described as effective in inducing labour [2].

<u>Complications of Induction of labour</u>

Induction of labour is not without risks.

The main aim of inducing labour is culmination in vaginal delivery. Women whose induction of labour does not lead to delivery are typically offered caesarian birth. Caesarian birth in turn is

associated with a host of risks (morbidity and mortality), with risks extending to future pregnancies [2].

There are insufficient data to support a policy of routine elective induction of labor at term. The major concerns associated with elective induction of labor at term are the potential for increased rates of cesarean delivery, iatrogenic prematurity, and cost. Another concern is that maternal-fetal medical benefits, such as reduction in stillbirth, have not been proven. Nevertheless, there are potential advantages to scheduled induction of labor, such as avoiding the risk of delivery en route to the hospital if labor is rapid or the patient lives far away and avoiding sudden disruption of the patient's (and provider's) work and non work-related responsibilities. In a matched cohort study of nulliparous women, Cammu et al [36] demonstrated that elective induction appears to double the risk of operative delivery. This has been supported by similar studies [37-39]. However, other studies have reported that women with favourable cervices were not at increased risk of caesarian birth [40, 41]. Dublin et al found that overall caesarian delivery rate was similar for induced and spontaneous labors in low-risk multiparous women [42].

Even when inductions for medical indications are included, multiparas with induced labour have a relatively low rate of cesarean delivery [42].

In his study at KNH, Njagi [12] found the Caesarian section rate among induced patients was 21.6%. The general maternal outcome was good although one case of maternal mortality due to anesthetic complications was reported.

There are no universal standards as to what constitutes a failed induction. It is important to allow adequate time for cervical ripening and development of an active labor pattern before determining that an induction has failed [43-45]. Rouse et al reported a minimum requirement of 12 hours of oxytocin administration after membrane rupture before diagnosing failed labor induction, with 75% success rate in nulliparas using this criteria, and eliminated failed labor induction as an indication for caesarian birth in parous women. Lin et al [45] proposed that failed induction be defined as the inability to achieve cervical dilatation of 4 cm and 80 percent effacement or 5 cm (regardless of effacement) after a minimum of 12 to 18 hours of both oxytocin administration and membrane rupture. They also specified that uterine contractile

activity should reach 5 contractions/10 minutes or 250 Montevideo units, which is the minimum level achieved by most women whose labor is progressing normally.

Another risk of induction is uterine hyperstimulation with or without fetal heart rate changes. This refers to uterine tachysystole (>5 contractions in 10 minutes for at least 30 minutes) or uterine hypersystole/hypertonus (a contraction lasting at least two minutes) with a normal fetal heart rate. Uterine hyperstimulation with fetal heart rate change denotes uterine hyperstimulation with fetal heart rate changes such as persistent decelerations, tachycardia, or decreased short term variability. These occur more frequently when higher doses of oxytocin, prostaglandin E2, or misoprostol are used [27]. Prostaglandin E2 preparations have a 5% risk of uterine tachysystole, which is usually well-tolerated. Prostaglandin E1 in low doses has been found to have hyperstimulation rates similar to that of E2 [27]. Concurrent administration of oxytocin and a prostaglandin is believed to increase the risk of tachysystole since both drugs carry a risk of this complication.

Hyperstimulation may also result in tumultuous labour, with abrupt placenta, uterine rupture and laceration of cervix. Though a rare occurrence, the authors of the latest Cochrane review recommend against its use in women with previous caesarian sections.

Oxytocin administration in large quantities may cause hyponatremia with water intoxication, and rapid intravenous injection may cause hypotension.

Other major risks of induction to the mother include psychological upset especially with failed induction, tendency of prolonged labour due to abnormal uterine action, increased need of analgesia during labour, increased operative interference, postpartum haemorrhage, intrauterine infections and amniotic fluid embolism. [2]. In a study carried out in Benin, Nigeria among induced patients and their husbands, major objections and unacceptability of the procedure was attributed to pain associated with amniotomy, painful oxytocin contraction and need for infusions and monitoring machines thus preventing ambulation during labour [46]. In a study at KNH, although most patients thought the procedure was more painful than natural labour, 85.2% of them had a positive attitude towards repeat induction in a future pregnancy [12].

To the fetus, induction may result in iatrogenic prematurity, hypoxia (due to disordered uterine action) cord prolapse and physical injuries following precipitate delivery. Neonatal respiratory problems are the major pediatric concerns with elective delivery. Respiratory problems can result from inadvertent delivery of a premature infant or transient tachypnea related to cesarean delivery after failed induction. In a three years comparative retrospective study, Duff and Sinclair found that infants of women who were induced had significantly lower apgar score than those with spontaneous labour [47]. Khisa [9] at Aga Khan hospital reported similar findings, with eight-fold risk of low apgar score at 5 minutes in infants of induced mothers, compared to those mothers undergoing spontaneous labour.

Meconium passage has been shown to be more common in women given misoprostol than those given dinoprostone [48]. Oxytocin use has been associated with hyperbilirubinemia in the neonate in some studies, but not in others [18].

1.1 RATIONALE

The Kenyatta National Hospital is the main referral hospital in Kenya, receiving many high risk referrals as well as many booked patients in the clinics and wards. The rate of induction has been shown to be increasing from 5.6% [11]in 1984 to 12.7% in 2002 [12]. The Caesarian section rate has also been increasing, with failed induction contributing to about 4% of the emergency indications from review of maternity records. It is however not known whether other complications from induction process (such as fetal distress or hyperstimulation) are further contributing to the high caesarian section rate.

While the main purpose of inducing labour is culmination in vaginal delivery, there are potential risks to the fetus. Therefore any benefits realized from reduction of caesarian section rate will be precluded if there is associated significant neonatal morbidity or mortality resulting from induction of labour in women with a viable fetus at or near term.

There have been no recent studies done in our set-up to evaluate whether induction of labour, , carries increased risk for operative delivery or increased risk for other maternal complications or poor fetal outcomes.

Although it is important to evaluate induction of labour in non-viable pregnancies e.g. intra-uterine death and gross fetal anomalies, the issues related to induction for a non-viable fetus are somewhat different when compared with those with a live fetus. Once a pregnancy is near term (34 weeks and above) decision for mode of delivery must bear in mind both maternal and fetal wellbeing. Therefore, there is need to evaluate outcome of pregnancies with viable fetuses to determine if the procedure is really effective and worthwhile.

While dinoprostone has been recognized as the gold-standard for cervical ripening, it is expensive and thus not readily accessible by majority of patients in our set-up. This may result in delays in administration of drug. Misoprostol has therefore been recently re-introduced in the unit as an alternative drug for pharmacological induction of labour according to national guidelines because it is cheaper and does not require refrigeration. Accordingly, fetal and maternal outcomes with use of this drug needs to be evaluated.

This study sought to identify the common indications for induction, the rate of success, maternal complications and neonatal outcomes of pregnancies with viable fetuses after pharmacological induction. The study will thus contribute towards review of induction protocols at the hospital.

1.2 RESEARCH QUESTION

What are the maternal and fetal outcomes among women at or near term undergoing pharmacological induction of labour at KNH?

1.3CONCEPTUAL FRAMEWORK

In women with live fetus at or near term, the aim of induction of labour is to accomplish a successful vaginal delivery with good neonatal outcome. Pharmacological induction of labour may be successful or may result in caesarean section or other maternal and fetal side effects.

This was a cross-sectional study with descriptive research design that sought to describe success of induction (vaginal delivery) and any maternal side-effects/complications experienced, and neonatal outcome. The women included in this study were those who had a singleton, live intrauterine fetus in cephalic presentation at 34 weeks gestational age and above.

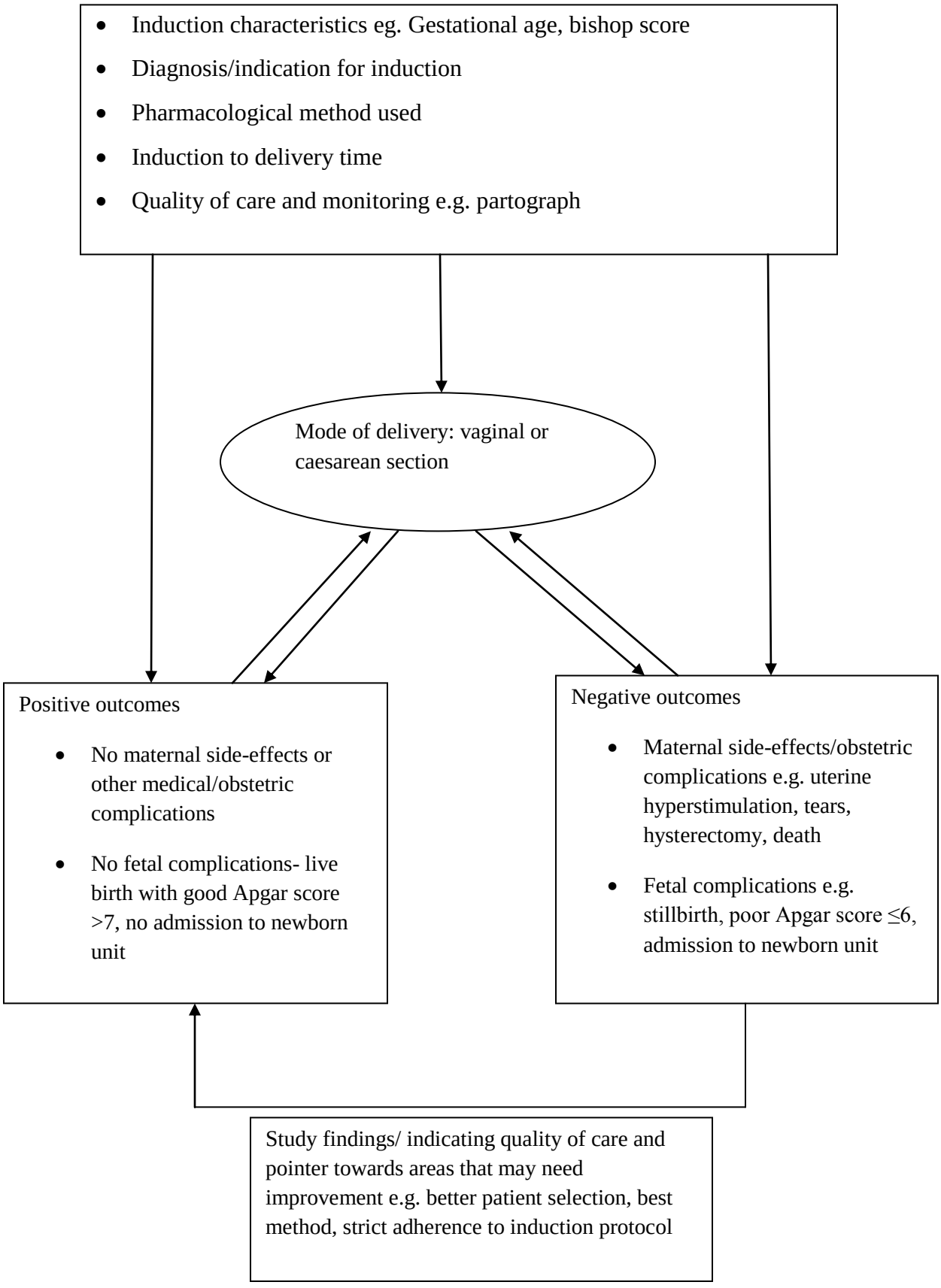
This study sought to review outcomes of induction and thus contribute to induction protocols followed at the hospital e.g. patient selection, adherence to protocols, monitoring of patients undergoing induction, and suitability of pharmacological methods used.

Study participants were recruited from postnatal/labour wards immediately after delivery. Once consent was obtained, the participants were interviewed and information obtained was entered into a structured questionnaire. Labour and delivery records, infant notes and operating theatre notes were then reviewed, and any missing information was obtained from the primary care giver in the labour ward. This information was entered into a structured questionnaire.

Outcome variables measured were:

1) Maternal
    - Induction to delivery interval
    - Mode of delivery- vaginal or caesarean section
    - Other complications/side-effects- tachysystole, hypertonus, vomiting, fever, ruptured uterus, PPH, blood transfusion needed, hysterectomy, maternal death.
2) Fetal
    - Intrapartum complications- FHR changes (bradycardia, tachycardia), meconium-stained liquor
    - Birth weight
    - Apgar score at 5 minutes
    - Admission to Newborn unit
    - Neonatal death

1.4 SCHEMATIC CONCEPTUAL FRAMEWORK



1.5 BROAD OBJECTIVE

To describe methods used for pharmacological induction of labour and the maternal and fetal outcomes in pregnancies at or near term, at Kenyatta National Hospital.

1.6 SPECIFIC OBJECTIVES

1) To describe the pharmacological methods used for induction of labour at or near term at KNH

2) To estimate the duration of time taken from induction to delivery among women at or near term undergoing pharmacological induction of labour at KNH

3) To determine the success rate of labour induction among women at or near term undergoing pharmacological induction of labour at KNH

4) To describe maternal and fetal complications following induction of labour among pregnant women at or near term at KNH

CHAPTER TWO

2.0 METHODOLOGY

2.1 STUDY DESIGN

This was a cross sectional descriptive study done at KNH. This design was suitable for the study because it sought to observe and describe the maternal and fetal outcomes following induction of labour without intervening in any way. It was thus a review of procedures already followed in the unit, in order to give a feedback on what is already practiced. The participants were recruited from postnatal or labour ward immediately after delivery, thus it was a cross-sectional study. Once consent was obtained, the participants were interviewed, labour and delivery records were studied, and the primary care giver interviewed. The information was entered into a structured questionnaire.

2.2 STUDY SETTING

The study took three months and was conducted at Kenyatta National Hospital. It is the largest hospital in Kenya with a bed capacity of approximately 2000. It is situated in Nairobi,

approximately 4km from the City centre along Ngong Road. It serves as a national referral hospital that receives high risk, self-referrals and many un-booked patients from Nairobi and its environs as well as from neighboring hospitals. It also serves as a teaching hospital for the under-graduate and post-graduate students from the University of Nairobi Faculty of Medicine and for the students from the Kenya Medical Training College, Nairobi. The maternity unit caters for about 8000-10000 deliveries annually, offering comprehensive obstetric care. There is also a neonatal unit manned by pediatric department. The site was thus suitable for this study. The Obstetric unit is managed as a collaboration of Department of Obstetrics/Gynaecology of University and the Department of Kenyatta National Hospital. The Obstetrics unit consists of an antenatal clinic, three antenatal/postnatal wards, a labour ward and a maternity operating theatre. For ease of operations, the staff, who are led by consultants, are divided into three firms who each have weekly running of the labour ward and antenatal clinic days on alternate days of the week.

At the Kenyatta National Hospital, patients are induced only for medical indications; elective inductions at mother's request are not done. Post-term pregnancy is induced beyond 41 weeks; PROM beyond 34 weeks is induced with oxytocin. Other indication such as diabetes, hypertensive disease, and rhesus negative mothers are induced at 38 weeks if they have been otherwise stable. Patients with breech presentation and previous uterine scars are not induced. The patient is counseled about the procedure and indication, and consent is obtained. The patient is admitted to antenatal or labour ward depending on the severity of her condition. Physical examination is done and Bishop score of the cervix is noted. If the score is 6 or less, cervical ripening is done with prostaglandin pessary; a score of 7 and above is managed by ARM and oxytocin.

If PGE2 (dinoprostone) is used, 3mg tablet is administered every 6-8 hours inserted at the posterior fornix, to a maximum of 3 doses.

When misoprostol is used, it is administered as 25mcg inserted to the posterior fornix every 4-6 hours to a maximum of 6 doses according to hospital protocol. Once the mother experiences contractions or vaginal exam confirms favorable Bishop score, she is transferred to labour ward, ARM is done and oxytocin infusion started. If the mother has not gone into labour4 hours after the 6^{th} dose, critically reappraisal is done. If Bishop's score remains poor she may be allowed to

rest for 24hrs then induction started again, or caesarean section delivery depending on the indication of induction and urgency for delivery.

Oxytocin infusion rates for induction of labour are administered as per WHO protocol starting with 5IU in 500mls of normal saline at 10 drops/minute, increased at 10 drops ½ hourly to a maximum of 60 drops/min or 3 strong contractions in 10 minutes.

Fetal wellbeing is established by continuous electronic monitoring or intermittent monitoring depending on severity of condition or any complications. In case of uterine hyperstimulation, drug is removed from the vagina and oxytocin infusion stopped. Tocolysis is given if indicated. Fetal heart rate abnormality is managed by immediate delivery via caesarian. After successful delivery of the baby and stabilization of mother, the patient is observed for 12 hours within the Labour Ward and then transferred to the postnatal wards for postnatal care after review by the doctor.

2.3 STUDY POPULATION

This comprised of patients with a singleton fetus in cephalic presentation at a gestation of 34 weeks and above who had been admitted for induction of labour.

2.4 ELIGIBILITY CRITERIA

2.4.1 Inclusion criteria:

The participants included were mothers for induction of labour with:

- Singleton, live gestation in cephalic presentation
- Gestation age 34 weeks and above
- Willing to participate and given a signed informed consent

2.4.2 Exclusion criteria:

The participants excluded were those who:

- Refused to participate
- Contraindications to induction (relative and absolute) e.g. previous uterine scar, breech presentation

- Contraindications to vaginal delivery e.g. contracted pelvis, placenta praevia
- Multiple gestation

2.5 SAMPLE SIZE

A sample size of 262 mothers was sufficient to estimate the outcomes of induction at KNH with 95% confidence and error margin of ± 5%. From previous literature[12], the proportion of successful deliveries after induction (78.4%) was used to calculate the sample size using the formula below. Although sample size calculation was carried out for other outcome criteria, success of induction was chosen because it was the main outcome measure and it gave the largest sample size.

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

Where:

n = required sample size

Z = Z statistic for a 95% level of confidence (1.96)

P = Proportion of the outcome of induction that has the highest value (78.4%)

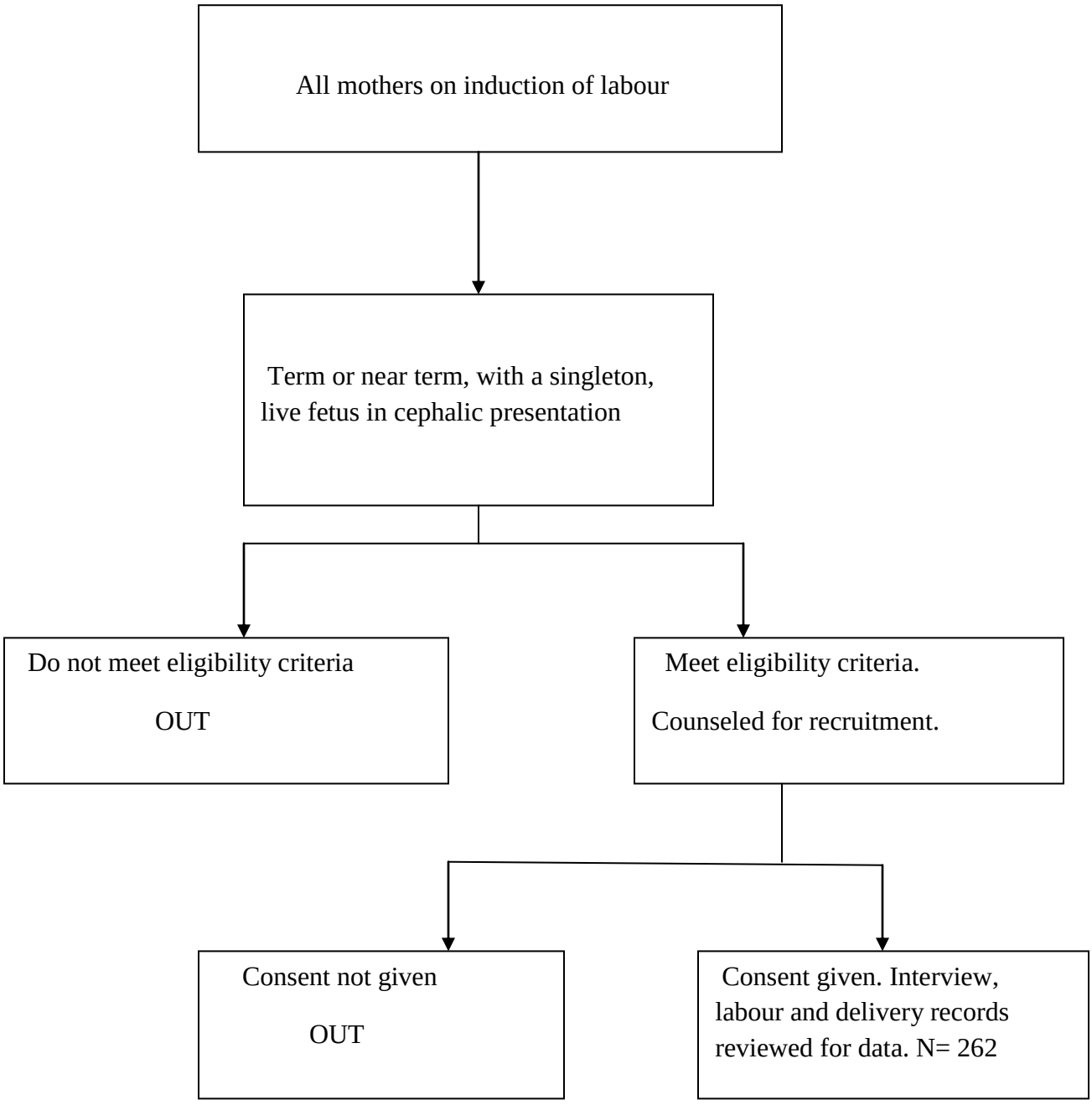
d = Margin of error of ±0.05.

Substituting for the variables:

$$n = \frac{1.96^2 \times 0.784(1-0.784)}{0.05^2}$$

n = 262 participants.

2.6 STUDY FLOW CHART



2.7 STUDY INSTRUMENT AND PROCEDURE

Data was collected using a structured questionnaire (Appendix 1) designed to contain questions on socio-demographic characteristics, obstetric history, indications for induction, induction method used and the outcome measures. The questionnaire was pretested in the labour ward and postnatal wards of KNH by the principal investigator a few weeks before the study to establish the reliability of the study questions and to ensure that any errors or ambiguities were corrected before data collection began. Three registered nurse-midwives were recruited as research assistants. The principal investigator trained them on recruitment, obtaining consent and data collection before the study commenced.

All women in labour and post-natal wards who met the eligibility criteria were recruited to participate in the study and explanation about the purpose and procedure of the study given.. Those who consented were consecutively enrolled to reach the targeted sample size. The women and primary care givers were interviewed for socio-demographic and obstetric data., and other information such as method used, duration of induction to delivery, mode of delivery, neonatal outcome and any side effects recorded was obtained from labour and delivery records and filled into the questionnaires.

2.8 STUDY VARIABLES

2.8.1 Independent variables

- Socio-demographic characteristics e.g. age, marital status, occupation
- Obstetric characteristics e.g. parity, gestational age
- Indication for induction

2.8.2 Outcome variables

The following maternal outcomes were observed:

- Mode of delivery –caesarian section, vaginal
- Induction to delivery interval
- Intra-partum complications of tachysystole, hypertonus, hypertonus, vomiting, fever, shivering, diarrhoea, ruptured uterus, hysterectomy, or any other

- Postpartum complications- uterine atony, genital tract tears, need for blood transfusion
- Death

The following fetal outcomes were observed:

- Intra-partum- bradycardia or tachycardia (NRFS)
- Meconium-stained liquor
- Birth-weight
- Apgar score at 5 minutes
- Admission to NBU
- Neonatal death

CHAPTER THREE

3.0 DATA MANAGEMENT AND CONTROL

Data was collected using a structured questionnaire (Appendix 1). The questionnaires were coded to make the data entry easy. All raw data was reviewed by the principal investigator and cross-checked to ensure completeness; any clarifications to be made were sought out immediately. The filled questionnaires were kept in a safe and confidential place that was accessible only to the principal investigator, ready for the data entry.

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

3.1 DATA ANALYSIS

Analysis of data involved descriptive statistics i.e. frequency distribution, means, standard deviations, proportions and cross tabulations. Data was presented in tables and graphs. Cross tabulation was done for method used for induction and the success in vaginal delivery.

3.2 ETHICAL CONSIDERATIONS

The principal investigator instituted all measures to ensure that the ethical rights of the study participants were safeguarded. The following measures were put into place:

1. Approval was obtained from Ethics and Research Committee of The Kenyatta National Hospital and from the Department of Obstetrics/Gynecology before carrying out the study.

2. The participants were counseled about the study in a language that they understood .Participation was entirely voluntary.

3. To ensure confidentiality, the questionnaires did not bear any patient's name or other personal and identifying information, but were numbered serially.

4. No form of inducement or coercion was given to participants to force them to participate..

5. Women who were not willing to participate in the study were not victimized and were not denied care. They received the same quality of care as those who agreed to participate.

3.3 STUDY LIMITATIONS

1. Monitoring of women during labour and administration of drug may not have been consistent, therefore appropriate interventions such as timely decision to deliver by caesarean section may have been delayed in some cases, with consequent poor fetal outcome.

2. Sample size calculation was based on success of induction (vaginal delivery rate) alone. However, this was the main outcome measure, and gave the largest sample size calculation.

CHAPTER FOUR

4.0 STUDY RESULTS

Between the months of August and October 2011, 262 pregnant women at a gestational age at 34 weeks gestation and above undergoing pharmacological induction of labour were recruited..

4.1 Socio-demographic characteristics of women undergoing pharmacological induction of labour at or near term at KNH

Table 1: Socio-Demographic Characteristics of women undergoing pharmacological induction of labour at or near term, at KNH (N = 262)

Characteristics	Frequency(n)	Percent (%)
Age (in years)		
< 20	8	3.1
20 – 29	170	64.9
30 – 39	81	30.9
40+	3	1.1
Marital status		
Single	37	14.1
Married	225	85.9
Education level		
No formal education	3	1.1
Primary	33	12.6
Secondary	131	50.0
College	95	36.3
Occupation		
Student	11	4.2
Unemployed	86	32.8
Formal employment	67	25.6
Self-employed	83	31.7
Casual worker	15	5.7

Table 1 shows the majority of participants were aged between 20-29 years (64.9%) and 85.9% were married and half of the participants had attained secondary level of education. Other socio-demographic characteristics were as shown in table 1. Majority of participants (32.8%) were unemployed

Table 2: Obstetric Characteristics of women undergoing pharmacological induction of labour at or near term at KNH (N= 262)

Characteristics	Frequency	Percent (%)
Parity		
Zero	152	58.0
1	60	22.9
2 – 4	50	19.1
Gestation		
<38	17	6.5
38-41	210	80.2
>41	35	13.4

As shown in table 2 above, majority of the patients (58%) were primigravidas, while 19% were multiparas. Majority (80.2%) of participants were between 38 to 41 weeks gestational age. The mean gestational age was 39.9 weeks.

Table 3: Methods used for pharmacological induction of labour at or near term at KNH (N= 262)

Induction method	frequency	Percentage (%)
Prostaglandin E2	11	4.2
PGE2 + ARM + Oxytocin	21	8.0
Prostaglandin E1	101	38.5
PGE1 + ARM + Oxytocin	106	40.5
Oxytocin	23	8.8

. The commonest method used for induction was prostaglandin E1 in combination with artificial rupture of membranes and oxytocin, 106 (40.5%), followed by prostaglandin E1 alone. 23 (8.8%) of patients were induced with oxytocin infusion alone, while the least common method was prostaglandin E2 alone (4.2%).

4.2 Indications for induction of labour among women undergoing pharmacological induction at or near term at KNH

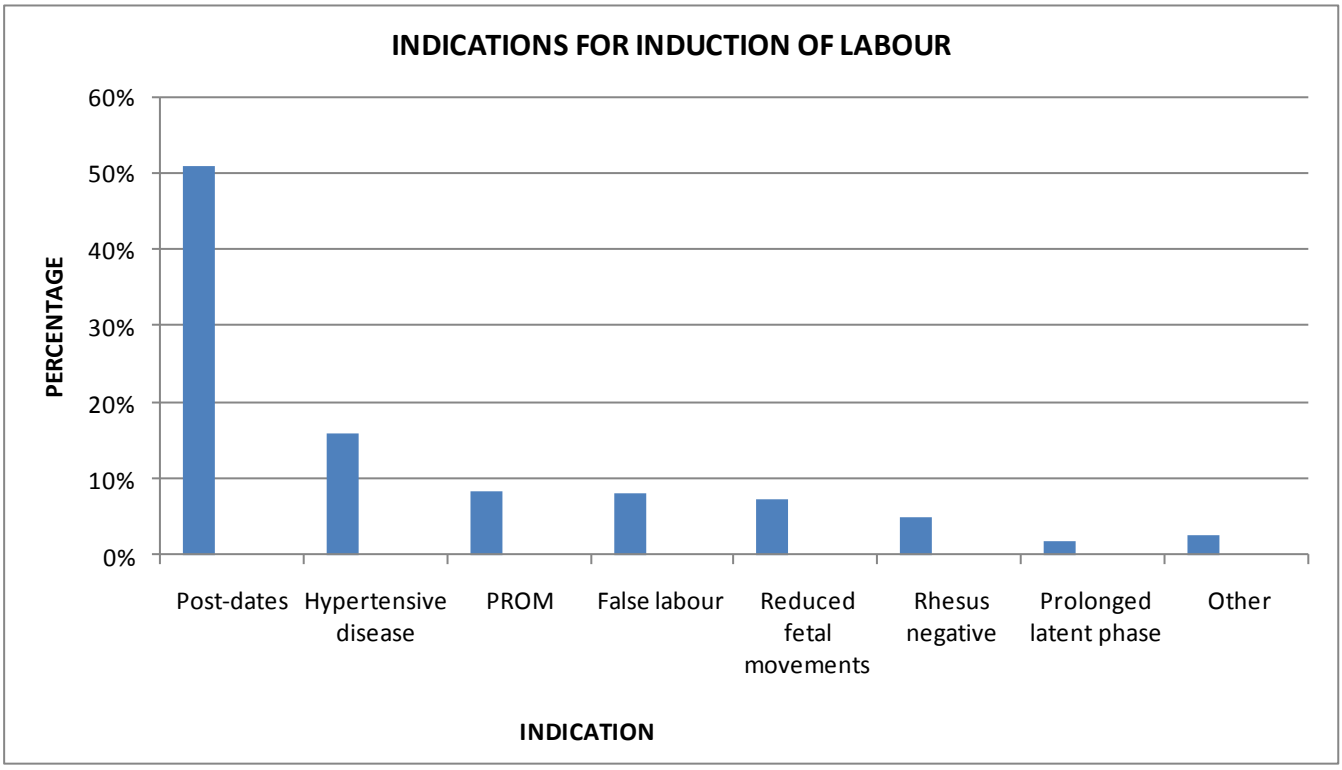


Figure 1: Common indications among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

As shown in figure 1 above, the commonest indication for induction of labour was post-datism 133 (50.8%), followed by hypertensive disease 42 (16%), followed by premature rupture of membranes 22 (8.4%).The other indications were as depicted in figure 1.

4.3 Induction to delivery time taken among women undergoing pharmacological induction of labour at or near term at KNH

Table 4: Induction to delivery time among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

Characteristic	Frequency	Percent (%)
Induction to delivery time (minutes)		
≤ 720 (≤12 hours)	26	13.1
721 – 1,440	138	69.7
≥1,441 (≥24 hours)	34	17.2

Table 3 shows the time taken from induction to delivery. The mean induction to delivery time among induced patients was 19.1 hours. Majority of participants 138 (69.7%) had an induction to delivery time of between 12-24 hours; 13.1% had induction to delivery time of less than 12 hours, and 17.2% had an induction to delivery time of more than 24 hours.

4.4 Success rate among women undergoing pharmacological induction of labour at or near term at KNH

Table 5: Success rate among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

Characteristics	Frequency	Percent (%)
Mode of delivery		
Vaginal	194	74.0
CS	68	26.0
Indication for CS		
Failed Induction	35	51.5
Non-reassuring fetal status	18	26.5
CPD	11	16.2
Other	4	5.9

The success rate for induction of labour (vaginal deliveries) was 74%. The commonest indication for caesarian section was failed induction (51.5%), followed by 'non-reassuring fetal status' (26.5%).

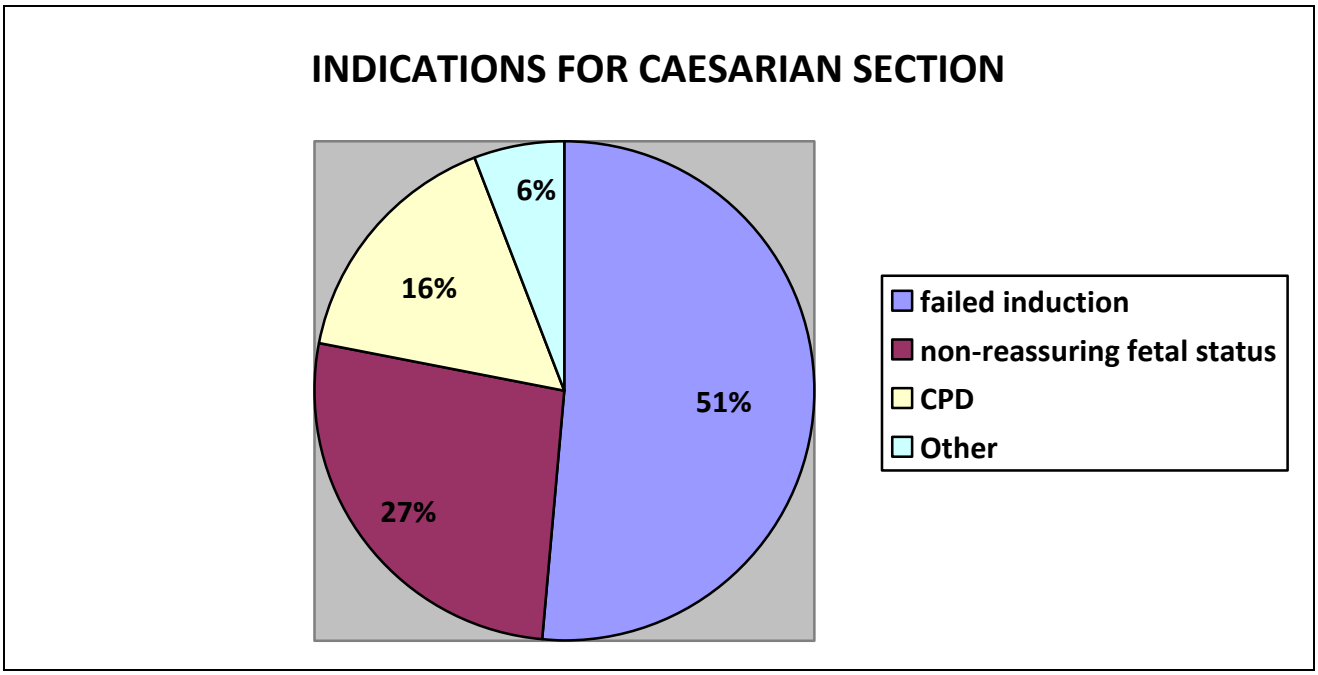


Figure 2: Indications for caesarian section among women undergoing pharmacological induction of labour at or near term at KNH (N= 262)

The commonest indication for caesarian section delivery was failed induction of labour (51%).

4.5 Other Maternal and fetal complications among women undergoing pharmacological induction of labour at or near term at KNH

Table 6: Other specific medical and obstetric complications among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

Characteristics (Complications)	Frequency (n)	Percent (%)
Tachysystole	1	0.4
Hypertonus	1	0.4
Hyper stimulation	1	0.4
Vomiting	2	0.8
Uterine atony	4	0.8
Genital tract tears	7	2.7
Delivery without complication	248	94.7

Table 6 shows that majority of participants delivered without any other medical or obstetric complications, 248 (94.7%). 14 patients experienced at least one complication. The most common complication was genital tract tears (2.7% of all participants). There were no reports of post-partum haemorrhage, no hysterectomies, no maternal deaths or any other complications.

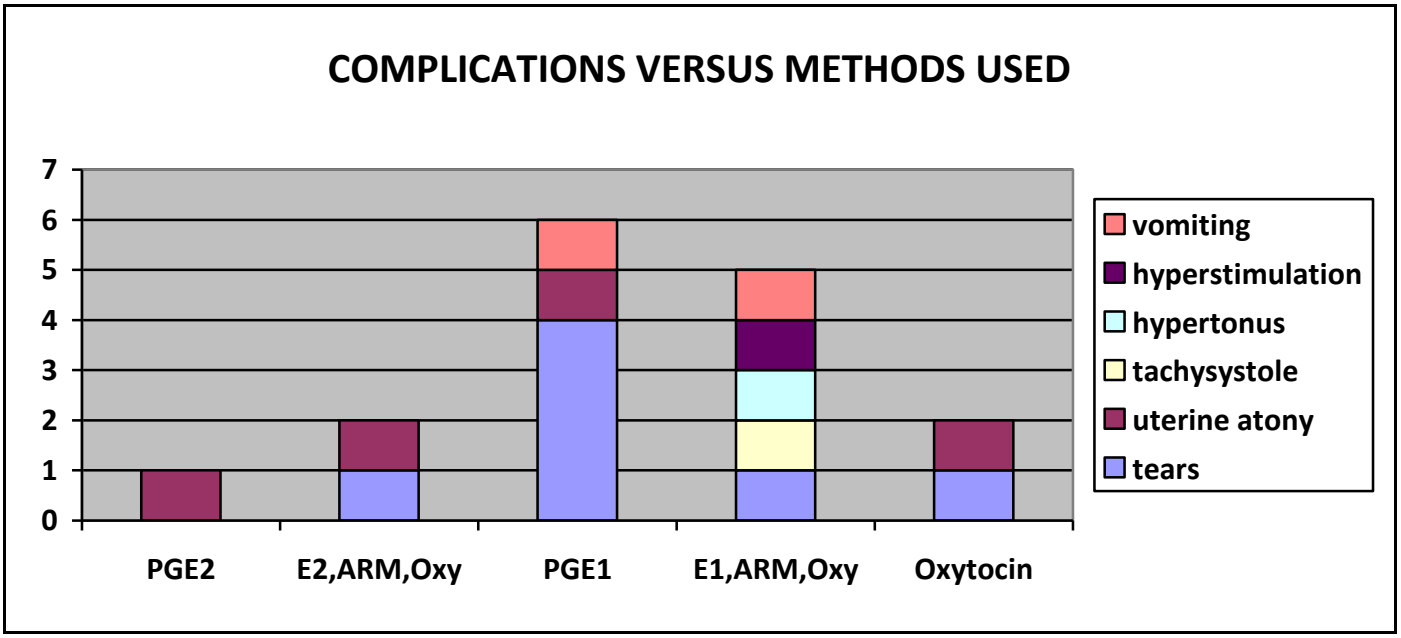


Figure 3: Specific medical and obstetric complications versus method used, among women undergoing pharmacological induction of labour at or near term at KNH (N= 262)

The most common complication was genital tract tears which was mostly (57%) experienced in women who were induced with PGE1 alone. The least complications were noted in participants who were induced with prostaglandin E2 .

Table 7: Fetal outcomes among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

Characteristics	Frequency	Percent (%)
Intrapartum complications		
FHR abnormality	9	3.4
Meconium	26	9.9
No abnormality	227	86.7
Fetal outcome		
live birth	260	99.2
fresh still birth	2	0.8
Apgar score (5 minutes)		
0 - 3	2	0.8
4 - 6	12	4.6
7 – 10	248	94.6
Admission NBU		
Yes	18	6.9
No	244	93.1

Meconium staining of liquor was noted in 26 (9.9%) of participants, whereas 9 (3.4%) experienced fetal heart rate abnormalities intrapartum.

Majority 260 (99.2%) had live births, 2 patients delivered fresh stillbirths.

Majority of the newborns (94.6%) had apgar score of 7 and above, while 12(4.6%) had a score of 4-6. 18 (6.9%) of newborns were admitted to the newborn unit for various indications.

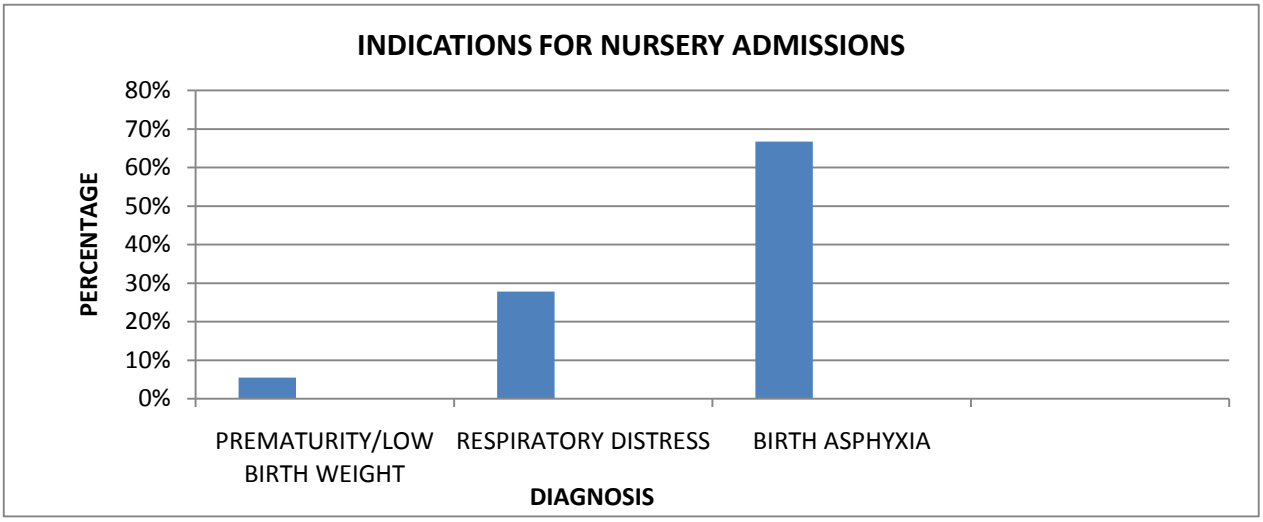
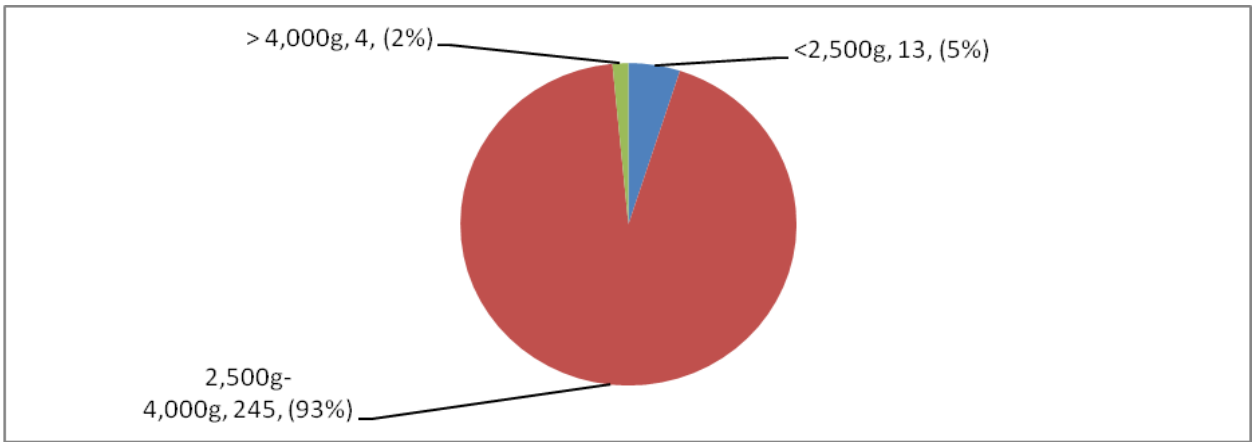


Figure 4: Indications for newborn admission to NBU following pharmacological induction of labour at or near term at KNH (n=18)

As shown in figure 2 above, a total of 18 newborns were admitted to the newborn unit. The most common diagnosis for admission was birth asphyxia 12 (66.7%), followed by respiratory distress 5 (27.7), and prematurity/low birth weight 1 (5.5%).

Figure 5: Birth weight infants delivered to women undergoing pharmacological induction of labour at or near term at KNH (n=262)



Majority 245(93%) of newborns weighed between 2500 grams and 4000 grams. 13% of the newborns had a low birth weight of less than 2500 grams, while 5% weighed greater than 4000 grams.

4.6 Correlation between pharmacological method used and mode of delivery

Table 8: Association between Induction Method used and Mode of delivery among women undergoing pharmacological induction of labour at or near term at KNH (N=262)

	Mode of delivery			
Induction method	**Vaginal (n)**	**CS (n)**	**OR (95% CI)**	**p-value**
Prostaglandins E2	4 (36.4)	6 (54.6)	ref.	-
PGE2 + ARM + Oxytocin	20 (95.2)	1 (4.7)	0.0 (0.0 - 0.4)	0.001
Prostaglandin E1	58 (57.4)	43 (42.6)	0.5 (0.1 - 2.2)	0.332
PGE1 + ARM + Oxytocin	95 (89.6)	11 (10.4)	0.1 (0.0 - 0.4)	0.006
Oxytocin	16 (69.6)	7 (30.4)	0.3 (0.1 - 1.7)	0.139

Patients induced with prostaglandin E2 followed by artificial rupture of membranes and oxytocin; and those induced with prostaglandin E1 with artificial rupture of membranes and oxytocin were more likely to have a successful induction than those on prostaglandin alone or oxytocin alone (p=0.001 and 0.006 respectively, with 95% confidence interval).

CHAPTER FIVE

5.0 DISCUSSION

The study evaluated 262 women (with singleton live fetus above 34 weeks gestation) who had induction of labour at the Kenyatta National Hospital Maternity unit over a period of three months (August 2011 to October 2011).

The mean age of patients undergoing induction of labour in this study was 27.6 years, with the majority (64.9%) being of age between 20-29 years. This is comparable to the age of patients undergoing induction in a study done by Njagi [12] at Kenyatta National Hospital where the mean age of patients was 26.8 years, but differs from a similar study done in more affluent population at the Aga Khan Hospital[9, 10] where the mean age was higher (31.2 years). The ages range in this study was 18-43 years and from audit reports, it was comparable to the age range of women admitted to the maternity ward in KNH during the study period. .

Other socio-demographic characteristics such as education level, marital status and occupation were comparable to a previous study [12] in Kenyatta National hospital which reviewed a total of 185 women who underwent induction of labour and found that the majority (81%) of women were married, 41.1% had attained secondary level of education, and 64.3% were unemployed. This indicates a population of lower socio-economic status which benefits from the use of misoprostol which is less expensive than dinoprostone.

The mean parity of women undergoing induction during the study period was 0.7, with the majority (58%) of women being primigravidas. The mean gestational age for the study population was 39.9 weeks. This is comparable to the study in Aga Khan [10] where the mean gestational age was 39.7 weeks, but differs from the KNH study which had a mean gestational age of 36.6 weeks [10]. However, this difference could be due to the fact that these other studies included women with gestation age from 28 weeks.

The magnitude of risk of induction of labour is influenced by factors such as parity, gestational age, fetal lung maturity, severity of maternal condition and cervical status. In observational studies, Crane [15] in Canada and Pevzner [14] in California reported that characteristics associated with successful induction included cervical status (cervical dilatation), multiparity, tall

stature (over 5 feet 5 inches), increasing gestational age, non-obese body mass index, and infant birth weight less than 3.5 kg. In this study, women of parity upto 4 were induced, with gestational age from 34 weeks and beyond. All the women induced were those who had already been determined to have a cervical bishop score of below 7; therefore cervical status was not assessed. Majority (92%) had normal infant birth weight of between 2500 to 4000 grams.

The commonest indication for induction of labour was post-date pregnancy (58%) followed by hypertensive disease (16%). Likewise, Duff Sinclair [47] in a review of Ireland maternity hospitals, Lydon in France [3] and Abdul in Nigeria [49] described prolonged pregnancy as the most common reason for induction of labour. This may be attributed to increased awareness about risk of stillbirth in prolonged pregnancies. In other settings in the Western world, indications for induction of labour differ due to patients' and clinicians' desire to arrange a convenient time for delivery, and more relaxed attitudes toward marginal indications for induction [4]. In a retrospective analysis of 4541 women who had labour induced in various hospitals in Washington, it was noted that 15% of inductions were not clinically indicated according to standard protocols. In our study, the diagnoses and reasons for inducing labour were found to be well documented, and all indications were according to hospital protocol.

Prostaglandin E1 tablet in combination with artificial rupture of membranes and oxytocin infusion was the most common method used for inducing labour in this study while prostaglandin E2 was the least common. At the Aga Khan hospital [10], prostaglandin E2 is the most common method used because it is the gold-standard and more accessible to this population of higher socio-economic status. Oxytocin infusion alone was used only in patients who had a diagnosis of premature rupture of membranes (8.4%) according to hospital protocol. Likewise, in his review, Njagi [12] found that oxytocin infusion was used mainly in patients with premature rupture of membranes. In Nigeria [49], the most common method used is prostaglandin E1 for cervical ripening in combination with rupture of membranes and oxytocin infusion and this has been associated with high rates of induction success (92%).

When analysis was done for method of induction used against success of induction, the use of either PGE1 or PGE2 in combination with ARM and oxytocin infusion was more likely to result in a successful vaginal delivery than prostaglandin alone ($p=0.001$ and 0.006 respectively, 95% CI). Similarly Balci [19]illustrated that vaginal prostaglandin with oxytocin infusion was more

effective for labour induction than oxytocin alone in patients with a Bishop score less than 6. However, Guerra et al [7] in their review described a high rate of successful induction regardless of method used.

Achieving vaginal delivery within 24 hours is the benchmark used to measure efficacy of a chosen induction method, beyond which there is increased risk to mother and fetus. In a prospective study of 397 women at term undergoing induction of labour, Simon et al [44] found that a latent phase of 18 hours during induction of labour in nulliparous women allowed the majority of them to achieve a vaginal delivery without being subject to increased risk of significant maternal or neonatal morbidity. Similarly, Rouse et al [43] illustrated that if membranes are ruptured and at least 12 hours of oxytocin is administered before a diagnosis of failed induction is made, then many more women will progress to successful vaginal deliveries.. However, in other studies [16], a long latent phase of more than 18 hours has been found to be associated with a higher rate of caesarean section deliveries and poor fetal outcomes. The mean induction to delivery time in our study was 19.1 hours with 17.2% of patients requiring more than 24 hours. . Thus, although the patients were allowed enough time to progress before a diagnosis of failed induction was made, this duration is long and may result in side effects such as fetal distress, maternal exhaustion, infections. This long duration may have been attributable to delays in drug administration because the patients had to be transferred from antenatal wards where they were admitted to labour ward where drug was administered, and this resulted in delays and longer intervals between dosages. Njagi [12], when analyzing labour in the same setting found the majority of patients (86.9%) had a duration of up to 12 hours between induction and delivery.

The success rate of induction of labour in this study was 74%, with 26% delivering via emergency caesarian section. This was comparable to a similar study in the same setting where Njagi [12] found that successful vaginal delivery was achieved in 75.1% of induced patients and Onyambu in Aga Khan hospital reported a rate of 78.5%. This success rate is comparable to that of 70.4% and 72% described in other settings in Latin America [7] and USA [14] respectively. The commonest indication for caesarian delivery was failed induction of labour (51.5%).

Fourteen patients experienced at least one complication or side-effect during induction of labour, with some experiencing more than one complication. A major concern with use of prostaglandins in combination with oxytocin is the risk of uterine hyperstimulation and uterine rupture. There were no cases of uterine rupture and no maternal deaths recorded in our study. The most common complication was genital tract tears (in 2.7% of all mothers). In his review in KNH, Njagi [12] reported one maternal death and found that genital tract tears was the most common complication (in 8.8% of participants) among induced patients. Elsewhere in Nigeria, in a similar teaching and referral hospital using vaginal misoprostol for induction of labour, a review of 151 cases reported the commonest complication of induction of labour to be uterine hyperstimulation in 5% of participants [50]. However, the dose of misoprostol used was higher (50 micrograms) than that used in this study.

In our study, at least 9.9% of patients were noted to have meconium-staining of liquor of various degrees intrapartum. This was less than that reported by Onyambu's [10] in Aga Khan hospital (38.2%) in patients who were induced with prostaglandin E2 tablets. Intrapartum abnormalities of fetal heart rate pattern was reported in 3.4% of women. Majority (96.9%) of babies delivered had a good Apgar score of above seven at five minutes. Majority (93%) of babies had birth weight of between 2500grams to 4000 grams. This neonatal outcome was comparable to other studies [3, 7, 10].

Two cases of fresh stillbirths were reported; one was due to delayed second stage with cord tightly around neck, and the second was due to fetal distress.

5.1 CONCLUSIONS

1) The methods used for pharmacological induction of labour at KNH are effective with a success rate of 74%, attesting to the effectiveness of vaginal misoprostol which has recently been introduced for use in the unit. It is comparable to success rates in other settings worldwide.

2) Post-dated pregnancy accounts for the majority of indications for induction of labour at term at KNH.

3) The average induction to delivery time is long (19.1 hours) and this may be associated with side-effects that may result in poorer maternal and fetal outcomes. Delays in administration of drug may be the cause of prolongation of the induction process, especially since the ward where patients are admitted is not the same ward where the drug is administered.

5.2 RECOMMENDATIONS

1) There is need to consider measures that may help reduce incidence of prolonged pregnancy e.g. routine stripping of membranes at term. This may help in reducing the incidence of prolonged pregnancy, and thus reduce the number of women who will have induction of labour.

2) Well-designed randomized controlled trials should be done to compare the safety and effectiveness of misoprostol with dinoprostone and oxytocin in our population in order to determine the most suitable method.

3) There is need to review the protocols of administration of prostaglandins in the antenatal and labour wards because the movement of patients to and from the wards in between drug administration may be the cause of delays and incorrect dosaging intervals.

References

[1] ACOG Practice Bulletin No. 107: Induction of labor. *Obstet Gynecol* 2009; **114**:386-397.

[2] Cunningham, F., Grant, N., Levono, K. and al, e. *Williams Obstetrics* twenty first edition ed., 2001.

[3] Lydon-Rochelle, M. T., Cardenas, V., Nelson, J. C., Holt, V. L., Gardella, C. and Easterling, T. R. Induction of labor in the absence of standard medical indications: incidence and correlates. *Med Care* 2007; **45**:505-512.

[4] Rayburn, W. F. and Zhang, J. Rising rates of labor induction: present concerns and future strategies. *Obstet Gynecol* 2002; **100**:164-167.

[5] Gulmezoglu, A. M., Crowther, C. A. and Middleton, P. Induction of labour for improving birth outcomes for women at or beyond term. *Cochrane Database Syst Rev* 2006; CD004945.

[6] Jarvelin, M. R., Hartikainen-Sorri, A. L. and Rantakallio, P. Labour induction policy in hospitals of different levels of specialisation. *Br J Obstet Gynaecol* 1993; **100**:310-315.

[7] Guerra, G. V., Cecatti, J. G., Souza, J. P., Faundes, A., Morais, S. S., Gulmezoglu, A. M., Parpinelli, M. A., Passini, R., Jr. and Carroli, G. Factors and outcomes associated with the induction of labour in Latin America. *Bjog* 2009; **116**:1762-1772.

[8] Mati, J. K., Aggarwal, V. P., Sanghvi, H. C., Lucas, S. and Corkhill, R. The Nairobi birth survey. II. Antenatal care in Nairobi. *J Obstet Gynaecol East Cent Africa* 1983; **2**:1-11.

[9] Khisa, W. Review of risk factors associated with induction of labour at Aga Khan Hospital Nairobi. *M. Med Thesis U.O.N* 1999.

[10] Onyambu B Induction of labour with prostaglandin E2 pessaries at the Aga Khan University Hospital [M.Med Thesis]. In: University of Nairobi, 2001.

[11] Kaguta, T. K. Review of induction of labour at Kenyatta National Hospital. *M. Med Thesis U.O.N* 1984.

[12] Njagi JM Indications and pregnancy outcomes of induction at Kenyatta National Hospital [M.Med Thesis]. In: University of Nairobi, 2002.

[13] Bishop, E. H. Pelvic Scoring for Elective Induction. *Obstet Gynecol* 1964; **24**:266-268.

[14] Pevzner, L., Rayburn, W. F., Rumney, P. and Wing, D. A. Factors predicting successful labor induction with dinoprostone and misoprostol vaginal inserts. *Obstet Gynecol* 2009; **114**:261-267.

[15] Crane, J. M. Factors predicting labor induction success: a critical analysis. *Clin Obstet Gynecol* 2006; **49**:573-584.

[16] Arulkumaran, S., Gibb, D. M., TambyRaja, R. L., Heng, S. H. and Ratnam, S. S. Failed induction of labour. *Aust N Z J Obstet Gynaecol* 1985; **25**:190-193.

[17] Xenakis, E. M., Piper, J. M., Conway, D. L. and Langer, O. Induction of labor in the nineties: conquering the unfavorable cervix. *Obstet Gynecol* 1997; **90**:235-239.

[18] Kelly, A. J. and Tan, B. Intravenous oxytocin alone for cervical ripening and induction of labour. *Cochrane Database Syst Rev* 2001; CD003246.

[19] Balci, O., Mahmoud, A. S., Ozdemir, S. and Acar, A. Induction of labor with vaginal misoprostol plus oxytocin versus oxytocin alone. *Int J Gynaecol Obstet* 2010; **110**:64-67.

[20] Dowswell, T., Kelly, A. J., Livio, S., Norman, J. E. and Alfirevic, Z. Different methods for the induction of labour in outpatient settings. *Cochrane Database Syst Rev* 2010; CD007701.

[21] Mealing, N. M., Roberts, C. L., Ford, J. B., Simpson, J. M. and Morris, J. M. Trends in induction of labour, 1998-2007: a population-based study. *Aust N Z J Obstet Gynaecol* 2009; **49**:599-605.

[22] Kelly, A. J., Kavanagh, J. and Thomas, J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. *Cochrane Database Syst Rev* 2003; CD003101.

[23] Smith, C. V., Rayburn, W. F. and Miller, A. M. Intravaginal prostaglandin E2 for cervical ripening and initiation of labor. Comparison of a multidose gel and single, controlled-release pessary. *J Reprod Med* 1994; **39**:381-384.

[24] Witter, F. R., Rocco, L. E. and Johnson, T. R. A randomized trial of prostaglandin E2 in a controlled-release vaginal pessary for cervical ripening at term. *Am J Obstet Gynecol* 1992; **166**:830-834.

[25] Wing, D. A. and Gaffaney, C. A. Vaginal misoprostol administration for cervical ripening and labor induction. *Clin Obstet Gynecol* 2006; **49**:627-641.

[26] Zieman, M., Fong, S. K., Benowitz, N. L., Banskter, D. and Darney, P. D. Absorption kinetics of misoprostol with oral or vaginal administration. *Obstet Gynecol* 1997; **90**:88-92.

[27] Hofmeyr, G. J. and Gulmezoglu, A. M. Vaginal misoprostol for cervical ripening and induction of labour. *Cochrane Database Syst Rev* 2003; CD000941.

[28] Austin, S. C., Sanchez-Ramos, L. and Adair, C. D. Labor induction with intravaginal misoprostol compared with the dinoprostone vaginal insert: a systematic review and metaanalysis. *Am J Obstet Gynecol* **202**:624 e621-629.

[29] Itsura, M. Comparison between vaginal misoprostol and dinoprostone in cervical ripening and induction of labour at Pumwani In: University of Nairobi, 2004.

[30] Kurrarru, R. Comparison of the efficacy of vaginal misoprostol and vaginal dinoprostone in cervical ripening and induction of labour at Kajiado District Hospital. In: University of Nairobi, 2006.

[31] Osewe, S. Comparison of misoprostol and dinoprostone in induction of labour at KNH. In: University of Nairobi, 2004.

[32] Gakara, J. Comparison of vaginal misoprostol and oxytocin for induction of labour in PROM at term. In: University of Nairobi, 2006.

[33] Mbaluka, C. The effectiveness and safety of oral misoprostol as compared to intravenous oxytocin in labour induction due to PPROM at term: a RCT at KNH. In: University of Nairobi, 2010.

[34] Boulvain, M., Stan, C. and Irion, O. Membrane sweeping for induction of labour. *Cochrane Database Syst Rev* 2005; CD000451.

[35] Howarth, G. R. and Botha, D. J. Amniotomy plus intravenous oxytocin for induction of labour. *Cochrane Database Syst Rev* 2001; CD003250.

[36] Cammu, H., Martens, G., Ruyssinck, G. and Amy, J. J. Outcome after elective labor induction in nulliparous women: a matched cohort study. *Am J Obstet Gynecol* 2002; **186**:240-244.

[37] Osmundson, S., Ou-Yang, R. J. and Grobman, W. A. Elective induction compared with expectant management in nulliparous women with an unfavorable cervix. *Obstet Gynecol* 2010; **117**:583-587.

[38] Vardo, J. H., Thornburg, L. L. and Glantz, J. C. Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. *J Reprod Med* 2011; **56**:25-30.

[39] Selo-Ojeme, D., Rogers, C., Mohanty, A., Zaidi, N., Villar, R. and Shangaris, P. Is induced labour in the nullipara associated with more maternal and perinatal morbidity? *Arch Gynecol Obstet* 2011; **284**:337-341.

[40] Nielsen, P. E., Howard, B. C., Hill, C. C., Larson, P. L., Holland, R. H. and Smith, P. N. Comparison of elective induction of labor with favorable Bishop scores versus expectant management: a randomized clinical trial. *J Matern Fetal Neonatal Med* 2005; **18**:59-64.

[41] Macer, J. A., Macer, C. L. and Chan, L. S. Elective induction versus spontaneous labor: a retrospective study of complications and outcome. *Am J Obstet Gynecol* 1992; **166**:1690-1696; discussion 1696-1697.

[42] Dublin, S., Lydon-Rochelle, M., Kaplan, R. C., Watts, D. H. and Critchlow, C. W. Maternal and neonatal outcomes after induction of labor without an identified indication. *Am J Obstet Gynecol* 2000; **183**:986-994.

[43] Rouse, D. J., Owen, J. and Hauth, J. C. Criteria for failed labor induction: prospective evaluation of a standardized protocol. *Obstet Gynecol* 2000; **96**:671-677.

[44] Simon, C. E. and Grobman, W. A. When has an induction failed? *Obstet Gynecol* 2005; **105**:705-709.

[45] Lin, M. G. and Rouse, D. J. What is a failed labor induction? *Clin Obstet Gynecol* 2006; **49**:585-593.

[46] Orhue, A. A. Induction of labour at term in primigravidae with low Bishop's score: a comparison of three methods. *Eur J Obstet Gynecol Reprod Biol* 1995; **58**:119-125.

[47] Duff, C. and Sinclair, M. Exploring the risks associated with induction of labour: a retrospective study using the NIMATS database. Northern Ireland Maternity System. *J Adv Nurs* 2000; **31**:410-417.

[48] Wing, D. A., Ortiz-Omphroy, G. and Paul, R. H. A comparison of intermittent vaginal administration of misoprostol with continuous dinoprostone for cervical ripening and labor induction. *Am J Obstet Gynecol* 1997; **177**:612-618.

[49] Abdul, M. A., Ibrahim, U. N., Yusuf, M. D. and Musa, H. Efficacy and safety of misoprostol in induction of labour in a Nigerian tertiary hospital. *West Afr J Med* 2007; **26**:213-216.

[50] Ekele, B. A., Nnadi, D. C., Gana, M. A., Shehu, C. E., Ahmed, Y. and Nwobodo, E. I. Misoprostol use for cervical ripening and induction of labour in a Nigerian teaching hospital. *Niger J Clin Pract* 2007; **10**:234-237.

APPENDIX 1: QUESTIONNAIRE

Number……

Date of admission…….time(am/pm)…….

A. Socio-demographic data:

1. Age……

2. Marital status (a) single [ ] (c) divorced/separated [ ]

(b) married [ ] (d) widowed [ ]

3. Education level attained (a) no formal education [ ]

(b) primary [ ]

(c) secondary [ ]

(d) college [ ]

4. Occupation (a) student [ ] (b) unemployed [ ]

(c) formal employment [ ] (d) self-employed [ ]

(e) casual worker [ ]

B. Obstetric Data

1. LMP……..EDD……Gestation by Dates……..

2. Diagnosis……

C. Induction Data

1. Pre-induction Bishop score…….

2. Method used (i) prostaglandin E2 (dinoprostone [Prostin®]) [ ]

(ii) PGE2 + ARM + Oxytocin [ ]

(iii) Prostaglandin E1 (misoprostol [Vagiprost®]) [ ]

(iv) PGE1 + ARM + Oxytocin [ ]

(v) oxytocin [ ]

3. (a) If prostaglandin is used,

- Time of 1st dose(am/pm).....2nd dose……..3rd dose……4th dose……..…5th dose……6th dose…….

- Total number of doses administered…….

(b) If oxytocin used, Rate of infusion……Total volume of fluid infused……..

4. Time in active labour……. Induction to active labour (hours)…….

5. Time in second stage of labour…….... Induction to second stage(hrs)……..

6. Time of delivery……. Induction to delivery time…….

D. Induction success

1. Mode of delivery (a) vaginal [ ]

(b) caesarian section [ ]

(c) vacuum [ ]

2. Indication for Caesarian section (a) failed induction [ ] (b) non-reassuring fetal status [ ]

(c) CPD [ ] (d) other(specify)……..……

E. Maternal outcomes

1. Tachysystole (5 or more contractions in 10 minutes) experienced (a) yes [ ] (b) no [ ]

2. Hypertonus (a contraction lasting at least 2 minutes) experienced (a) yes [ ] (b) no [ ]

3. Hyperstimulation (tachysystole or hypertonus resulting in fetal heart changes necessitating intervention) experienced (a) yes [ ] (b) (no) [ ]

4. Other side effects experienced (a) vomiting [ ] (b) diarrhea [ ] (c) shivering [ ] (d) fever [ ]

(e) other (specify)…… (f) none [ ]

5. APH/PPH (a) ruptured uterus [ ] (b) uterine atony [ ] (c) tears (cervical/vaginal/perineal) [ ]

(d) retained placenta [ ] (e) other(specify) …….. (f) none [ ]

6. Final maternal outcome (a) delivery without complications [ ]

(b) delivery with complications [ ]

(c) maternal death [ ] Cause of maternal death……..

F. Neonatal Outcomes

1. Fetal heart-rate abnormality requiring treatment (a) yes [ ] (b) no [ ]

2. Meconium passed (a) yes [ ] What grade(I, II, or III)……

(b) no [ ]

3. Fetal outcome (a) live birth [ ] (b) fresh stillbirth [ ]

(c) macerated stillbirth [ ]

- Cause of stillbirth (i) fetal distress [ ] (ii) ruptured uterus [ ] (iii) other…….

4. Birth weight (grams)……

5. Apgar score in 1 minute……..5minutes……10 minutes……

6. Admitted to nursery/NBU (a) yes [ ] (b) no [ ]

7. Reason for nursery admission (a) birth asphyxia [ ] (b) prematurity [ ] (c) other…….

APPENDIX 2: BISHOP SCORING

	Score			
Factor	0	1	2	3
Dilatation (cms)	0	1-2	3-4	5-6
Length (cms)	3	2	1	0
Station (-3 to 3)	-3	-2	-1 or 0	+1 or +2
Consistency	Firm	medium	Soft	
Position	Posterior	middle	anterior	

APPENDIX 3: PATIENT INFORMATION AND CONSENT FORM

MATERNAL AND FETAL OUTCOMES AMONG WOMEN UNDERGOING PHARMACOLOGICAL INDUCTION OF LABOUR AT KENYATTA NATIONAL HOSPITAL

This document is to be read by or read to each prospective participant in a language she understands.

Principal investigator: Dr. Esiromo Marian

Supervisors:

1. Professor J.G. Karanja, Associate Professor of Obstetrics/Gynaecology, University of Nairobi
2. Dr. F.X. Odawa, Lecturer in department of Obstetrics/Gynaecology, University of Nairobi.

I am a resident doctor specializing in obstetrics and gynaecology at the University of Nairobi. I am conducting a research on women who are having their labour induced. You are being asked to participate in this study which will include a total of 261 women who will deliver in this hospital. The purpose of this consent form is to provide you with basic information about the research, and to help you decide whether you wish to be included in the study or not. Please read through the form and feel free to ask any questions/ make clarifications or raise any concerns at any point. When you have read through and feel satisfied that your questions have been answered and you agree to participate in the study, you will be asked to sign (or thumb-print) your consent.

Participants Rights

Participation in this research is entirely voluntary, and you have a right to decide whether you would like to participate or not. You have a right to ask any questions at any time. If you decide to enroll, you can drop out of the study at any time, and you will not be denied any care. If you decline to participate in the study, it will not affect your management and you will receive normal care and standard treatment and medication.

Purpose of study

The purpose of this study is to review the outcome of women and their infants when their labour has been induced. The study is being done in order to assess whether women undergoing induction of labour will experience any side effects, whether they will deliver successfully or end up having a caesarian section, and whether their babies will experience any side effects. The information obtained from the study will help us improve on management of women undergoing induction in our maternity unit.

Procedure

If you decide to participate in the study, you will undergo induction as per the attending doctor's instructions. This will involve insertion of the prostaglandin tablet vaginally every 4-6 hours until onset of labour. Once labour sets in, you will be monitored by attending midwife and doctor in the labour ward until the time that you deliver. A caesarian section may be performed if your labour does not progress well, or if there is any indication that your baby is distressed during the labour process. The duration of your labour and any side effects will be recorded by the attending nurse or doctor, as well as your baby's general health upon birth. If you choose not to participate in the study, you will not be penalized or disadvantaged in any way. The same management will be given to you as described above, however, the outcome of your labour will not be used for purposes of this study.

Risks and Discomforts

This study is simply observing your labour and baby's health at birth, and will not include any interference or interventions aside from routine management of women whose labour is being induced.

Benefits and compensation

There will be no financial or material benefit to you if you choose to participate in the study. Your participation will be very helpful and information obtained from the study will help us improve on management of women who are undergoing induction of labour.

Confidentiality

Any information that is collected in this study will be kept strictly confidential. Your full name will not appear on any study document and only the principal investigator will have access to information you provide. No information by which your identity can be revealed will be released or published.

Who to contact

If you wish to ask any questions later, you may contact the responsible doctor caring for you or reach me on number 0722630181 or contact ethical committee secretary on 726300-9 ext. 44102.

Consent

I have read the information sheet (or it has been read to me) concerning this study and I understand what is required of me to participate in the study. My queries have been addressed to my satisfaction. I voluntarily agree to take part in the study.

Patient's signature(or thumb print)……..
Date……

Witness' signature…….
Date……..

HABARI KWA MGONJWA NA CHETI CHA KUKUBALI KUSHIRIKI KATIKA UTAFITI

Mtafiti ni Dr. Esiromo Marian, daktari na mwanafunzi wa maswala yanayohusu uzazi, katika Chuo Kikuu cha Nairobi. Huu ni utafiti wa matumizi ya dawa zinazotumiwa kuleta uchungu wa kuzaa, kwa sababu tofauti katika mimba.

Maelezo ya utafiti

Maana kuu ya hii cheti cha kukubali ni kupasa wewe mshiriki habari kuhusu huu utafiti. Haya maelezo yatakuwezesha kuamua kama utakubali kushiriki au la. Tafadhali yasome maelezo haya kwa utaratibu. Unaweza kuuliza maswali kuhusu maana ya utafiti, yale mambo faida na adhari kwako, haki zako na jambo linguine lolote lingine ungelitaka kujua juu ya huu utafiti. Wakati ambapo tumejibu maswali yako yote, utaamua kushiriki kwenye utafiti au la.

Sababu na manufaa ya huu utafiti

Sababu hasa ya kufanya huu utafiti ni kuchunguza afya na mama na mtoto wanapotumia dawa za kuleta uchungu wa kuzaa kwa wamama wajawazito ambao bado hawajapata huo uchungu. Uchunguzi huu utatatusaidia zaidi kwa kuwatunza wamama ambao wanapatiwa hizi dawa.

Habari tutazopata kwako tutaziweka siri na hakuna mtu mwingine atajulishwa. Jina lako halitatumika wakati utafiti huu utakapochapishwa.

Cheti cha kukubali kushiriki kwenye utafiti

Mimi nimekubali kushiriki katika utafiti wa matumizi ya dawa ya kuleta uchungu wa kuzaa kwa akina mama wajawazito. Nimeelezwa kwamba habari zangu zitawekwa siri, na kwamda matibabu yangu hayataadhiriwa nikikataa kushiriki ama kujiondoa kwenye utafiti. Nimekuwa na nafasi ya kuuliza maswali, na kama nitakuwa na maswali mengine, ninaweza kuuliza watafiti wakati wowote.

Sahihi ya mshiriki…….au

Kidole gumba
(kulia/kushoto)……..tarehe……
…….