THE EFFECT OF TIME OF DAY OF UNSCHEDULED CAESERIAN SECTIONS ON PERINATAL AND MATERNAL OUTCOMES IN KENYATTA NATIONAL HOSPITAL, NAIROBI, KENYA

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A Dissertation Submitted in Partial Fulfillment for The Award of Master of Medicine In Obstetrics and Gynecology, College Of Health Sciences University of Nairobi

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DEDICATION

This study is dedicated to my lovely daughter Abby and Son Lee for being an inspiration in my life. God bless you.

To my wonderful parents Peter and Hellen for dedicating all your resources towards supporting my siblings and I through the journey of life, till this far. Your words of wisdom will always be a pillar in my life.

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ABBREVIATIONS

A&E Accident and Emergency

CI Confidence Interval

C/S Caesarian section

CT Computer tomography

DHS Demographic Health Survey

ERC Ethics Review Committee

GA General Anesthesia

GFA Ground Floor ward A

GFB Ground Floor ward B

ICU Intensive Care Unit

IV Intravenous

KNH Kenyatta National Hospital

LSCS Lower Segment Caesarean Section

MD Medical Doctor

MMed Master of medicine

MMR Maternal Mortality Ratio

NBU Newborn Unit

NICU Neonatal Intensive Care Unit

NRFS Non reassuring fetal status

OR Odds Ratio

PNW Postnatal Wards

PACU Post anesthesia care unit

SHO Senior house officer

US Ultra Sound

UON University of Nairobi

1A First floor ward A

DEFINITION OF OPERATIONAL TERMS

Caesarean section: Is a surgical procedure in which one or more incisions are made through

the mother's abdomen and uterus to deliver one or more babies or rarely to remove a dead

fetus.

Unscheduled caesarean section: Surgical procedure to deliver a baby where complications

of pregnancy occur suddenly during the process of labor, and swift action is required to

prevent the deaths of mother, baby (ies) or both.

Postnatal wards: A ward in a hospital where women and their babies are provided with

medical care immediately after the birth of their baby.

Newborn Unit: Is a unit in a hospital that provides expert care for newborn babies who are

ill or are born prematurely. There are different levels of care who need to be in newborn unit:

Neonatal intensive care, High dependency care, Special care

Post Anesthesia Care Unit (PACU): Is the area designed and staffed to monitor and care for

patients who are recovering from the immediate effects of anesthesia and surgery.

Acute Room: A room where a severely ill antenatal and postnatal patient are managed and is

adequately equipped to handle obstetric emergencies.

Senior House Officer: A doctor enrolled in post graduate training in Obstetrics and

Gynaecology.

NICU: An intensive –care unit specializing in the care of ill or premature newborn infants.

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ABSTRACT

Introduction: Large multicenter studies done in teaching hospitals in USA and Europe showed no important differences in maternal and neonatal morbidity after unscheduled cesarean section delivery according to work shift. There were however no studies which had been done at Kenyatta National Hospital (KNH).

Objectives: The objective of the study was to compare the 72 hour post delivery maternal and neonatal outcomes among patients undergoing unscheduled cesarean section during the night and day shifts in KNH.

Study Design: A prospective cohort study in which the exposed group was those patients who had undergone unscheduled cesarean section during the night while the control group was those patients who had undergone unscheduled cesarean section during the day was conducted between February and April 2015 at Kenyatta National Hospital (KNH). The incidence of poor maternal and neonatal outcomes within the first 72 hours post cesarean section was compared between the two groups.

Study Population: This comprised all postnatal mothers who had undergone unscheduled cesarean section at Kenyatta National Hospital and were within 72hours post operation in the postnatal wards, PACU and Intensive Care Unit.

Results: Between the months of February 26th and April 2nd 2015, a total of 240 patients undergoing unscheduled caesarean sections at the Kenyatta National Hospital were recruited into the study including 120(50%) patients who had an operation performed during the night shift and 120(50%) during the day shift. Data was collected prospectively. There was no significant difference in the socio-demographic characteristics of patients according to shifts. Most procedures were conducted under regional anesthesia with no significant differences between day and night surgeries. The leading indications for unscheduled CS during the day and night were: NRFS, obstructed labor and elective CS converted to emergency CS in that order. Conversion of Elective Cesarean section to Emergency CS was significantly more common during the night compared to during daytime. Poor maternal and neonatal outcomes did not show a significant difference depending on time of surgery.

Conclusion: The study showed that there was no significant difference in pregnancy outcomes between unscheduled cesarean section done during the day compared to those done during the night.

Recommendations: Regular clinical audits should be performed and interventions carried out promptly with the aim of reducing poor pregnancy outcomes, patients scheduled for elective cesarean section should be operated on as planned to reduce the high numbers of unscheduled cesarean section done at night due to conversion of these elective cases to emergency cases and that Kenyatta National Hospital should continue with the current schedule in terms of resource provision in both shifts since it has been shown not influence adverse pregnancy outcomes.

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Cesarean section which is the surgical procedure to deliver babies abdominally can either be elective or emergency. Unscheduled cesarean sections are performed in obstetric emergencies where swift action is required to prevent the deaths of mother, baby(ies) or both, and this is normally done when vaginal delivery would put the baby's or mothers' life or health at risk. Therefore the World Health Organization officially withdrew its previous recommendation of a 15% cesarean section rate in 2010 citing that, there was no empirical evidence for optimum percentage. What mattered most was that every woman who needed a cesarean section got it. The global burden now stands at 46% in China, 40% in Italy, 33% in both Europe and Latin America, 25% in Asia and 14% in Nordic countries, Sub- Sahara Africa 6.2% (1)

At The Kenyatta National Hospital, the rates of cesarean sections have been increasing majority being emergencies, in spite of the well documented evidence of increased maternal morbidity and mortality associated with caesarean deliveries worldwide(4). It currently stands at 40% (5) which is higher than the national average. Estimated prevalence 9.7% of adverse maternal outcomes following daytime CS at KNH in April to June 2012 was 9.7% (6). The high cesarean rates have led to high cost of healthcare, increased workload and challenges in ensuring improved quality of care. The recommended decision to delivery time interval for performing emergency cesarean section is 60 minutes locally and 30 minutes internationally a target that has remained elusive(5). Therefore, before any medical strategies can be designed to improve the total quality of unscheduled

Cesarean sections care, the current clinical practice needs to be audited and the optimal institutional mechanisms identified in context of our population characteristics.

Health workers should be cognizant of the indications of cesarean sections for this intervention to impact on reducing maternal and neonatal mortality/ morbidity by offering it in a timely manner. Indications for cesarean section include; dystocia, fetal distress, cord prolapse, uterine rupture, placental disorders, hypertension in pregnancy, abnormal presentation, abnormal placentation, failed induction of labor, failed assisted delivery, macrosomia, multiple births, bad obstetric history, extensive genital warts, previous classical cesarean sections and more than one previous cesarean sections(7).

Though cesarean sections are considered relatively safe, they pose a higher risk of some complications as compared to vaginal deliveries. The most common complications to the mother and baby are; infections, heavy blood loss with subsequent transfusion, thromboembolic disease, post spinal anesthesia headache, paralytic ileus, constipation, maternal deaths (very rare, rates higher in emergency cesarean sections- 18 in 100,000), intra operative surgical complications(approximately 12%), hysterectomy, admission to intensive care unit (ICU), injury to the baby during delivery, need for neonatal intensive care unit (NICU) and prematurity. These complications can be prevented if quality obstetrical care is provided including timely cesarean section when indicated.

Due to this fact, different studies have been conducted among pregnant women to ascertain their knowledge, attitude and practices towards unscheduled cesarean sections to help reduce maternal and neonatal mortalities/ morbidities and it was found that at least 12.1% of women would not accept cesarean section under any circumstances (8, 13).

Studies suggest that sleep deprivation among health caregivers has been shown to adversely affect performance by impairing neurobehavioral activities (9). However, very few studies have measured its effect on medical errors. The belief that physicians are affected by sleep deprivation is increasingly moving from anecdotal opinion to evidence based knowledge. Multiple studies have shown that judgment suffers and errors increase when physicians lack sleep (10). There are few data regarding surgical performance and sleep deprivation. Studies on actual surgical performance and sleep deprivation have been from small centers. It has been found that cesarean section rates were higher during the day compared to those at night and that appar scores of newborns delivered during the morning where higher compared to those delivered during the night shift. This indicated a marked diurnal variation in urgent operative deliveries.

CONCEPTUAL FRAMEWORK

Figure 1: Conceptual Framework

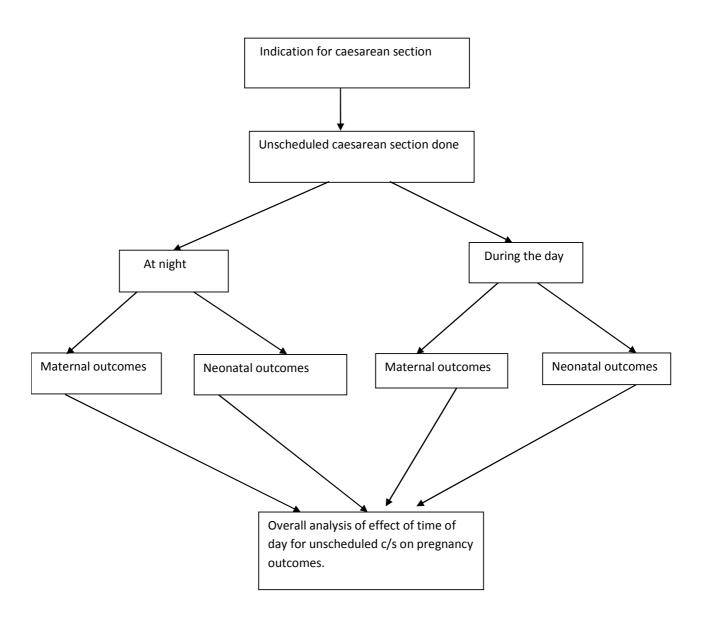


Figure 1: Conceptual Framework

1.1 Narrative for Conceptual Framework

Pregnancy outcomes depend on various factors which interplay together and especially to achieve desired pregnancy outcomes both maternal and neonatal. These factors include: patient factors like age, parity, co-morbidities: Health system factors like health workforce: Structures and Processes: Community factors and political factors. This study is aimed at looking at the processes that influence pregnancy outcomes, exploring if time of day affects outcomes of unscheduled cesarean sections.

1.2 Justification

Good maternal and perinatal outcomes can be ensured through essential obstetric and newborn care provided by skilled attendants during pregnancy and child birth. In many resource- poor settings, access to skilled care and crucial interventions is limited. Cesarean delivery is a marker for the availability and use of obstetric services in these situations.

Although lifesaving, cesarean section delivery increases maternal and newborn risks and costs. Delays in seeking, accessing, and receiving quality care in facilities also contribute to lower cesarean delivery rates and increase risks of adverse pregnancy outcomes.

Some studies have shown an increased rise of maternal morbidity in cesarean sections done at night (1), with others suggesting that sleep deprivation has been shown to adversely affect performance by impairing neurobehavioral activities (9). However, very few studies have measured its effect on medical errors. The belief that physicians are affected by sleep deprivation is increasingly moving from anecdotal opinion to evidence based knowledge. Multiple studies have shown that judgment suffers and errors increase when physicians lack sleep. There are fewer data regarding surgical performance and sleep deprivation. Studies on actual surgical performance and sleep deprivation have been from small centers.

This study therefore aimed to determine if time of day caesarean section was performed affected pregnancy outcomes and the requisite interventions thereof at Kenyatta National Hospital. This includes coming up with policies in terms of staffing and work shifts for the different cadres of staff especially if a difference is found in poor pregnancy outcomes between the two shifts and are attributed to time factor.

1.3 Research Question

Is there a difference between the incidence of pregnancy outcomes among patients undergoing unscheduled caesarian section during the night (exposed group) compared to those during the day (unexposed group) within the first 72 hours post delivery in KNH?

1.4 Null Hypothesis

There is no difference between the incidence of immediate pregnancy outcomes among patients undergoing unscheduled cesarean section during the night (exposed group) compared to those during the day (unexposed group) within the first 72 hours post delivery in KNH.

1.5 Broad Objective

To determine the difference between the incidence of immediate pregnancy outcomes among patients undergoing unscheduled cesarean section during the night (exposed group) compared to those during the day (unexposed group) within the first 72 hours post delivery in KNH.

1.6 Specific Objectives

Among patients undergoing unscheduled cesarean section during the night compared to those during the day in KNH within the first 72 hours post delivery, to determine and compare the:

- 1. Difference in the incidence of immediate maternal outcomes.
- 2. Difference in the incidence of immediate neonatal outcomes.
- 3. Factors associated with maternal and neonatal outcomes.

CHAPTER 2: METHODOLOGY

2.1 Study Design

Data for this study was collected prospectively from the time of exit from theatre and thereafter at 24 hour intervals until 72hours post surgery. The exposure of interest was the time of day when cesarean section was carried out. The exposed group were those patients who had undergone unscheduled cesarean section during the night while the unexposed group were those patients who had undergone unscheduled cesarean section during the day. The incidence of maternal and neonatal outcomes within the first 72 hours post cesarean section and the difference between the exposed and unexposed groups were determined. Factors associated with poor maternal and neonatal outcomes were also explored. The study was carried out over a period of three months from the 26th of February to the 2nd of April 2015 following approval from the KNH/UON-ERC on the 12th of February2015. Approval was also obtained from the hospital with the ward staff being informed of the study.

2.2 Study Site and Setting

The study was conducted in the post-natal wards and other units where the patients would have been transferred for the necessary post natal care of Kenyatta National Hospital. Kenyatta National Hospital is located in Upper Hill, Nairobi, the capital of Kenya. It is the major referral hospital for the whole country with a bed capacity of about 2500 patients. It is the largest hospital in East and Central Africa and serves as the teaching hospital for the University Of Nairobi School Of Medicine and the Kenya Medical Training College.

Labour ward has an acute room where severely ill antenatal and post-natal patients are managed and it is adequately equipped to handle obstetric emergencies. Adjacent to labour ward are two maternity theatres, where most emergency and elective obstetric operations take place. Antenatal and post-natal admissions are handled in wards GFA, GFB and 1A.

The labour ward is staffed by Resident Senior House Officers(SHO) enrolled in post-graduate training in Obstetrics and Gynecology 24 hours every day, Medical officer interns, Clinical officer interns, Clinical officers undergoing post-graduate diploma course in obstetrics and gynecology and highly trained midwives. Twelve hourly ward rounds are conducted by Senior Registrars and on-call Consultants. Acutely ill patients are reviewed on need basis with consultations with other specialties as required.

Postnatal clinics are conducted every Friday. These clinics are run by a team of Consultants, Registrars and highly trained Nursing Officers. There is also an outpatient gynecology consultation room at A&E department where obstetric and gynecologic emergencies are reviewed, stabilized and admitted as per need on a 24 hour basis. Patients are admitted to postnatal wards directly or through these clinics. Monthly MMR at KNH ranges between 787/100000 to 1001/100000 live births almost double the national average of 488/100,000 live births while the monthly perinatal mortality rate ranges between 120/1000 to 151/1000. (KNH monthly mortality meetings records)(11).

At Kenyatta National Hospital where the cesarean section rate stands at 40% (11), the leading causes of emergency cesarean deliveries are; non- reassuring fetal status, failed vaginal birth after cesarean delivery, malpresentatioin/malposition, 2 previous scar in labor, pre-eclampsia/eclampsia, in order of occurrence. On average, 10 to 20 emergency cesarean deliveries are conducted in a day with approximately equal distribution between day and night.

2.3 Study Population

The study population comprised all postnatal mothers who had undergone unscheduled cesarean section at Kenyatta National Hospital and were within 72 hours post operation in the postnatal wards, PACU and Intensive care unit.

2.3.1 Inclusion Criteria

 All postnatal mothers who had consented and had undergone unscheduled cesarean section at Kenyatta National Hospital and were within 72 hours post operation in the postnatal wards, PACU and intensive care units. Women admitted to PACU and intensive care units and whose next of kin/ guardians had consented were included in the study.

2.3.2 Exclusion Criteria

- 1. Non-consenting postnatal mothers who had undergone emergency C/S.
- 2. All postnatal mothers who were within 72 hours post cesarean section but whose surgeries were done outside KNH.

2.4 Sample Size

The sample size required in each group (patients sectioned at night and those sectioned during the day) was calculated using the formula for comparison of two proportions (6)

$$n = \frac{2 \times (Z_{\alpha} + Z_{\beta})^2 \bar{p} (1 - \bar{p})}{p_1 - p_2}$$

 p_1 = Estimated prevalence (9.7%) of adverse maternal outcomes following daytime CS at KNH in April to June 2012 (5)

 p_2 = Expected proportion of adverse outcomes at night, calculated using the formula for comparison of two proportions.

 \bar{p} = Average of p_1 and p_2

 $Z_{\alpha/2}$ = Type I error rate (1.96)

 $Z_{(1-\beta)} = Power(0.84)$

$$n = \frac{2 \times (1.96 + 0.84)^2 \cdot 0.169 (1 - 0.169)}{0.097 - 0.24}$$

n = 120 cesarean sections per shift.

2n = 240 cesarean sections (total sample size)

CHAPTER 3: STUDY PROCEDURES.

3.1 Approach

Post cesarean section mothers were approached after exiting theatre and the nature of the study explained to them. They were voluntarily recruited to the study after signing an informed written consent form.

3.2Recruitment

All consenting mothers were recruited to the study.

3.3 Consenting

Postnatal mothers, who had undergone unscheduled cesarean section at KNH, were recruited into the study through their own consent.

3.4 Interview/Data abstraction

Mothers were directly interviewed by the principal investigator on a daily basis at 24hour intervals in the morning during or after the daily ward rounds, history taken, examined physically and a questionnaire filled during the interview. Further information was retrieved from theatre notes, nurses cardex, laboratory and radiology test results.

3.5 Follow up

The inclusion criterion was all postnatal mothers who had consented and had undergone emergency cesarean section and were within 72 hours post operation at Kenyatta National hospital.

The principal investigator recruited the patient from theatre recovery and followed the patient on a daily basis, presenting the questionnaire every 24hours for 72 hours after the procedure. The outcomes of the procedures were documented in a questionnaire.

3.6 Data Collection and Management

Data was collected by the principal investigator and research assistants. Data was coded entered into an excel data base, validation and cleaning was performed and analysis as per the study objectives conducted.

3.7 Data Analysis

Data obtained was coded and entered in preformed Excel data sheet and analyzed using Statistical Package for social sciences (SPSS) version 17.0. For sample descriptive results were presented in prose as well as numbers, percentages, medians and ranges, and in the form of bar charts, tables and pie charts as appropriate. The primary outcome was calculated as percentage of mothers and neonates with adverse outcomes following caesarean delivery. The common adverse maternal outcomes comprised hemorrhage (within 6 hrs), early post operative wound infection and surgical trauma. Maternal and neonatal adverse outcome data was analyzed according to the work shift during which the patient entered theatre (day shift 0700-1859 and night shift 1900-0659). T-tests and one way analysis of variance (ANOVA) with post-hoc analysis was used to compare continuous variables between good and poor maternal outcome groups. Chi-square was used for categorical variables to test for association between these variables and good or poor maternal outcomes. Similar analyses were also conducted comparing good neonatal outcome group to the poor outcome group. Logistic regression analysis was used to determine whether time of the day during which CS is conducted is an independent risk factor for maternal or neonatal adverse outcome controlling for potential confounding factors including maternal age, parity and antenatal profile, gestational age and indication for CS.

3.8 Ethical considerations

The study was undertaken after approval by the KNH/ University of Nairobi Ethics Review and Committee (KNH/UON ERC) and permission was sort from the Department of Reproductive Health, KNH. The nature of the study was explained to the participants in full. The study was undertaken after informed consent had been obtained from the participant. The consent explanation was thorough and had contacts of the principal investigator, his supervisors and that of KNH/UON-ERC. It was also made clear to the respondents that they could contact any of the above contacts for questions or clarifications during the period of study or even thereafter. Participation in the study was on a voluntary basis.

Confidentiality was maintained at all times. No patient identifiers were collected or analyzed, electronic data is password protected and accessible to the Investigators and paper based data will be kept in lockable cabinets. Results of the study will be availed to the Ethics Committee of the Kenyatta National Hospital and University of Nairobi. The study was

undertaken after approval by the KNH/UON Ethics and Research committee. The nature of the study was explained to the participants in full. The study was undertaken after informed consent was obtained from the participant. The consent explanation was thorough and had contacts of the principal investigator, his supervisor and that of KNH/UON-ERC. It was also made clear to the respondents that they could contact any of the above contacts for questions or clarifications during the period of study or even thereafter. Participation in the study was on a voluntary basis. Confidentiality was maintained at all times. Results of the study were to be availed to the KNH/ERC Ethics. Appendix 3 outlines the consent.

Post surgical care was given to all participants according to the normal standard guidelines. Participants were taken through all the probable complications that may arise from the procedure(s). They were informed to report to the nurses of any complication that would arise for the necessary doctor to be called and the primary investigator would be informed too so that appropriate interventions would be taken according to the hospitals standard guidelines.

3.9 Study Limitations

There was a challenge during data collection due to the differences in surgical techniques used by different surgeons in their respective firms since there were no standard operating guidelines for caesarean section. The nature of each operation may have also been influenced by the reason for the emergency, which was beyond the scope of this study.

CHAPTER 4: RESULTS

A total of 240 patients undergoing unscheduled caesarean sections were recruited into the study between the months of February and April 2015 including 120 (50%) patients who had an operation performed at night and 120 (50%) daytime procedures. There were a total of 1435 deliveries during the study period of which 574 (41%) were cesarean sections while 861 (59%) were vaginal deliveries. Of the 574 cesarean section deliveries 537 (93%) were unscheduled while 37 (7%) were scheduled .Two hundred and sixty four 264 (55%) of the unscheduled CS were carried out during the day while 243 (45%) were done at night. This trend was also similar in other studies done in Sub- Sahara Africa (16, 17, 19).

The comparisons of the demographic characteristics of the participants according to timing of surgery are presented in Table 1. Most patients undergoing surgery either during the day or night surgery groups were married (91.7% and 88.3%) and reported that they were Christians (98.0% and 96.7%). There were no significant differences in parity, or employment status of the mothers who underwent surgery during the day and those operated at night.

Table 1: Socio-demographic characteristics of mothers undergoing unscheduled caesarean section in KNH

	Time of day (CS conducted		
	Night	Day	OR(95% CI)	P value
	No. (%)	No. (%)		
Education				
Primary	40(33.0)	32(26.7)	1.00	
Secondary	39(32.5)	65(54.2)	0.48(0.25-0.92)	0.018
College	41(34.7)	23(19.2)	1.42(0.68-3.02)	0.313
Marital status				
Married	110(91.7)	106(88.3)	1.00	
Single	10(8.3)	14(11.7)	0.69(0.26-1.75)	0.389
Parity				
Para 0+0	49(40.8)	52(39.1)	1.00	
Para 1+0	33(27.5)	48(39.8)	0.73(0.39-0.17)	0.295
Para 2+0	20(16.7)	16(16.4)	1.32(0.58-3.08)	0.468
Others	18(15.0)	4(4.7)	4.78(14.2-20.5)	0.005
Religion				
Christian	114(95.0)	116(96.7)	1.00	
Islam	6(5.0)	4(3.3)	1.52(0.35-7.54)	0.518
Employment				
Self employed	31(25.8)	32(26.7)	1.00	
Formal employment	20(16.7)	34(28.3)	0.61(0.27-1.36)	0.186
No employment	69(57.5)	54(45.0)	1.31(0.69-2.54)	0.372

As shown in Table 2, significant differences were observed in the intra operative procedures in surgeries conducted during the day compared to surgeries done at night. Out of all the night surgeries 72 (60.0%) were first order surgeries while 76 (63.3%) daytime surgeries were also first order surgeries. Third order surgeries were more likely to be performed during day time (OR = 2.96, 95%CI 1.0-10.9; p = 0.04) compared to first order surgeries. Most procedures were conducted under regional anesthesia with no significant differences between day (97.5%) and night (100%) surgeries.

Table 2: Intra operative information of surgery in mothers undergoing unscheduled caesarean section in KNH according to time of the day for procedure

	Time of day CS			
	Night	Day	OR(95% CI)	P value
	No. (%)	No. (%)		
Order of surgery				
First	72(60.0)	76(63.3)	1.00	
Second	34(28.3)	39(32.5)	0.92(0.5-1.68)	0.771
Third	14(11.7)	5(4.2)	2.96(1.0-10.9)	0.04
Anesthesia				
General	0(0.0)	3(2.5)	1.00	
Regional	120(100.0)	117(97.5)	NA	NA

The indications for unscheduled caesarean sections are shown in table 3, according to the time of the day for the procedure. The leading indications for unscheduled CS during the day and night were: NRFS (40.3 and 35.8%), obstructed labor (35.0 and 28.3 %) and elective CS converted to emergency CS (8.3 and 25.0%). Conversion of Elective Cesarean section to Emergency cesarean section as an indication for unscheduled caesarean section was significantly more common during the night compared to during daytime (Table 3). Conversion of elective to emergency CS was more common at night OR = 3.04(95% CI, 1.33-7.42).

 $\begin{tabular}{ll} Table 3: Indications unscheduled caesarean section in KNH according to time of the day for procedure \end{tabular}$

	Time of day CS conducted			
	Night	Day	OR(95% CI)	P
	No. (%)	No. (%)		value
NRFS				
No	77(64.2)	71(59.7)	1.00	
Yes	43(35.8)	49(40.3)	0.81(0.46-1.41)	0.426
Placenta previa				
No	115(95.8)	116(96.9)	1.00	
Yes	5(4.2)	6(3.1)	0.85(0.1-3.41)	0.779
Placenta abruption				
No	120(100.0)	117(97.5)	1.00	
Yes	0(0.0)	3(2.5)	NA	NA
High blood pressure				
No	111(92.5)	109(90.8)	1.00	
Yes	9(7.5)	11(9.1)	0.80(0.28-2.23)	0.640
Obstructed labor				
No	86(71.7)	78(65.0)	1.00	
Yes	34(28.3)	42(35.0)	0.73(0.41-1.31)	0.267
Elective CS converted to emergency CS				
No	94(75.0)	110(91.7)	1.00	
Yes	26(25.0)	10(8.3)	3.04(1.33-7.42)	0.004

The patients undergoing surgery during the day did not differ significantly from those operated on at nights with regard to labor onset of preexisting moribund status (Table 4). The proportion of patients in a moribund state prior to the procedure during daytime and the night were 17.5% and 15.0%. Duration of labor onset prior to procedure did not vary significantly among patients operated for during the day and night (Table 3).

Table 4: Labor onset and patient condition prior to unscheduled caesarean section in KNH according to time of the day for procedure

	Time of day CS conducted			
	Night	Day	OR(95% CI)	P value
	No. (%)	No. (%)		
Labor onset				
Labored at home <1 hr	11(10.2)	14(12.7)	1.00	
Labored at home 1-3 hrs	29(26.9)	35(31.8)	1.05(0.38-3.0)	0.911
Labored at home >3-6 hrs	49(45.3)	44(40.0)	1.41(0.53-3.84)	0.441
Labored at home >6 hrs	19(17.6)	17(18.7)	1.42(0.45-4.5)	0.500
Prior moribund state				
Yes	18(15)	21(17.5)	1.00	
No	102(85.0)	99(82.5)	1.20(0.57-2.59)	0.600

The maternal outcomes of the patients undergoing unscheduled caesarean sections are shown in Table 5. Maternal outcomes did not show a significant difference depending on time of surgery. Pain was the most common outcome in both groups of patients in the postoperative period (15.0% and 18.3%) for daytime and night surgeries, respectively). The remaining outcomes namely; hemorrhage; hysterectomy, wound infection, surgical trauma and dialysis were rare in both groups affecting less than 5% of patients (Table 5). No maternal deaths occurred in the study.

Table 5: Poor maternal outcomes following unscheduled caesarean section in KNH according to time of the day for procedure

	Time of day CS	S conducted		
	Night	Day	OD/OFO/ CI	n .1 .
	No. (%)	No. (%)	OR(95% CI)	P value
Hemorrhage				
No	115(95.8)	116(96.7)	1.00	
Yes	5(4.2)	4(3.3)	1.26(0.26-6.51)	0.734
Wound infection				
No	120(100.0)	119(99.2)	1.00	
Yes	0(0.0)	1(0.8)	NA	NA
Hysterectomy				
No	119(99)	119(99)	1.00	
Yes	1(1.0)	1(1.0)	1.0(0.01-79.1)	1.000
Pain				
No	98(81.7)	102(85.0)	1.00	
Yes	22(18.3)	18(15.0)	1.27(0.61-2.68)	0.488
Organ injury				
No	118(98.3)	117(97.5)	1.00	
Yes	2(1.7)	3(2.5)	0.66(0.05-5.89)	0.651
	ĺ			

Table 6 presents the neonatal outcomes in unscheduled caesarean sections conducted in KNH at night and during the day. The rate of complications was not significantly different depending on the time of surgery. The most prevalent neonatal outcome in both night and day surgeries was respiratory difficulties (20.8 and 19.2%). There were 8 (6.7%) neonatal deaths during night surgeries and 4 (3.3%) deaths during the day, OR2.1 (95% CI, 0.54-9.64). Trauma and neonatal sepsis were rare affecting less than 3% of neonates delivered during both day and night surgeries (Table 6).

Table 6: Outcomes of neonates delivered by mothers undergoing unscheduled caesarean section in KNH according to time of the day for procedure

	Time of day CS	conducted		
	Night	Day	OD (050/ CI)	D l
	No. (%)	No. (%)	OR(95% CI)	P value
Neonatal death				
No	112(93.3)	116(96.7)	1.00	
Yes	8(6.7)	4(3.3)	2.1(0.54-9.64)	0.236
Respiratory difficulties				
No	95(79.2)	97(80.8)	1.00	
Yes	25(20.8)	23(19.2)	1.11(0.56-2.2)	0.747
Trauma				
No	117(97.5)	117(97.7)	1.00	
Yes	3(2.5)	3(2.3)	1.0(0.13-7.62)	1.000
Neonatal sepsis				
No	119(100.0)	118(99.2)	1.00	
Yes	0(0.0)	2(0.8)	NA	NA

4.1 Discussion and conclusion

The objective of this study was to find out if there is a difference in incidence of immediate poor pregnancy outcomes among patients undergoing unscheduled cesarean section during the night compared to those during the day within the first 72 hours post delivery in Kenyatta National Hospital.

The main finding of this study was that there was no significant difference in poor pregnancy outcomes between unscheduled cesarean sections done during the day as compared to those done during the night. This was similar with large multicenter studies done in teaching hospitals in USA and Europe which showed no important differences in maternal and neonatal morbidity after unscheduled cesarean section delivery according to work shift(2) although some have shown increased risk of maternal but not neonatal morbidity in cesarean sections done at night. (1). This was however the first study to be done at the Kenyatta National Hospital (KNH).

This study found that there were no significant differences in parity, or employment status of mothers who underwent surgery during the day and those during the night, though it has been shown that pregnancy outcomes depend on various factors which interplay together and especially to achieve desired pregnancy outcomes both maternal and neonatal. These factors include: patient factors like age, parity, co-morbidities: Health system factors like health workforce: Structures and Processes: Community factors and political factors as explored by the study.

The study also showed significant differences in intra operative procedures in surgeries conducted during the day compared to surgeries done at night. Out of all the night surgeries 60.0% were first order surgeries while 63.3% daytime surgeries were also first order surgeries. Third order surgeries were more likely to be performed during day time compared to first order surgeries. This was significantly different in other studies done in Europe where first order surgeries were significantly low (14,15). Most procedures were conducted under regional anesthesia with no significant differences between day (97.5%) and night (100%) surgeries.

Our findings for the leading indications for unscheduled cesarean section during the day and night were; Non reassuring fetal status (40.3 and 35.8%), obstructed labor (35.0 and 28.3 %) and elective CS converted to emergency CS (8.3 and 25.0%) in that order. Conversion of Elective Cesarean section to Emergency cesarean section as an indication for unscheduled

caesarean section was significantly more common during the night compared to during daytime. This was probably attributed to patients scheduled for elective surgeries missing theatre during the day and developing complaints at night which necessitated intervening immediately. This was in line with a study done at the Kenyatta National Hospital in 2006(4) which showed that the leading indication for unscheduled cesarean section was Non reassuring fetal status(27.3%) followed by failed VBAC(16.1) and Dystocia(13.1%) in that order. Other studies done in southern Africa also demonstrated the same trend. (18)

We also found that patients undergoing surgery during the day did not differ significantly from those operated on at night with regard to labor onset of preexisting moribund status. The proportion of patients in a moribund state prior to the procedure during daytime and the night were 17.5% and 15.0% respectively. Duration of labor onset prior to procedure did not vary significantly among patients operated for during the day and night.

Adverse maternal outcomes did not show a significant difference depending on time of surgery. Pain was the most common outcome in both groups of patients in the postoperative period (15.0% and 18.3%) for daytime and night surgeries, respectively. The remaining outcomes namely hemorrhage; hysterectomy, wound infection, surgical trauma and dialysis were rare in both groups affecting less than 5% of patients. This was discrepant with a study done at The Kenyatta National Hospital in 2011(5) which showed that postpartum hemorrhage was the leading maternal complication. This would probably be attributed to pain not being considered as a complication of unscheduled cesarean section.

The study showed that the rate of neonatal complications was not significantly different depending on the time of surgery. The most prevalent neonatal outcome in both night and day surgeries was respiratory difficulties (20.8 and 19.2%). There were 6.7% neonatal deaths during night surgeries and 3.3% deaths during the day, which was consistent with the 2011(5) retrospective study which was carried out at the Kenyatta National Hospital which placed the perinatal mortality rate at 6.3%. Trauma and neonatal sepsis were rare affecting less than 3% of neonates delivered during both day and night surgeries. Fewer studies have however been done to compare emergency caesarean section and their effect on neonatal outcomes. Some have reported increased neonatal mortality rates (20), while some have shown no significant differences in neonatal outcomes (21).

4.2 Conclusion

On the whole, the study found out that there was no significant difference in pregnancy outcomes between unscheduled cesarean section done during the day compared to those done during the night.

4.3 Recommendations

- 1. Regular clinical audits should be performed so that factors contributing to poor pregnancy outcomes can be established and interventions carried out promptly with the aim of reducing poor pregnancy outcomes.
- 2. Patients scheduled for elective cesarean section should be operated on as planned to reduce the high numbers of unscheduled cesarean section done at night due to conversion of these elective cases to emergency cases.

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APPENDICES

APPENDIX I: QUESTIONNAIRE

TITLE: THE EFFECT OF TIME OF DAY OF UNSCHEDULED CAESAREAN SECTION ON NEONATAL AND MATERNAL OUTCOMES IN KENYATTA NATIONAL HOSPITAL.

STUDY ID : P702/11/2014.
DATE:
HISTORY
BIODATA
A) Age in years
B) Level of Education(tick where appropriate)
primary
secondary
college
C) Marital status
married
Single
Socio- Demographic Characteristics.
A) Parity(tick where appropriate)
para 0+0
para1+0
para2+0
para3+0
others

B) Religion
Christian
Islam
Hindu
others (specify)
C) Employment
self
formal
no employment
D) Distance from hospital
meters
kilometers
1) Did labour start at home, if yes how long did it take you to reach hospital? (if no,
skip question).
*time in minutes
2). Did you have any prior moribund state?
yesWhich one?
no
MEDICAL RECORDS
Characteristics of clinical attendants.
For this part tick if ay was present
doctor
anesthetist
nurse
1) What was the time of day of the procedure?
Day(8a.m-8p.m)
Night(8p.m-8a.m)

2) What was the order number of the surgery?
1 st
2 nd
3 rd
Other (specify)
4) What was the indication for current cesarean section?(tick where appropriate).
nrfs
placenta praevia
placenta abruption
high bp's
obstructed labour
elective c/s converted to emergency c/s
5) Are you a clinic attendant?
yes
no
6) What type of anesthesia was used?
general
regional

PHSYSICAL EXAMINATION

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Maternal outcomes.
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(if no poor maternal outcome, skip this question)
maternal death
thromboembolism
hemorrhage
wound infection
emergency hysterectomies
pain
surgical trauma
admission to icu
dialysis
admission beyond 72hours
```

Poor neonatal outcomes
(if none, skip this question)
neonatal death
respiratory difficulties
trauma
sepsis

APPENDIX II: CONSENT

INFORMED CONSENT FORM

THE EFFECT OF TIME OF DAY ON UNSCHEDULED CESAREAN SECTIONS-

PERINATAL AND MATERNAL OUTCOMES

INVESTIGATOR'S CONTACT

DR. ANCHINGA ARNOLD MAKORI: TEL:0722676650; P.O.BOX 67731 00200

Introduction

I am Dr. Anchinga Arnold Makori, a third year resident in the Master of Medicine in

Obstetrics, Gynecology program at The University of Nairobi. I am conducting a study on the

effects of time of day on unscheduled cesarean sections on maternal and neonatal outcomes

in Kenyatta National Hospital, as part of my post-graduate program requirements. I will

strive to answer any queries that may arise before and during the course of the intended

study.

Purpose of the research

The objective of this survey is to determine the difference between the incidence of

immediate poor maternal and neonatal pregnancy outcomes among patients undergoing

unscheduled cesarean sections during the night as compared to those during the day within

the first 72 hours post cesarean section at KNH.

Research Intervention

This research will provide information to be availed to policy makers at the hospital if any

difference is found to improve on pregnancy outcomes.

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Participant selection

Every postnatal mother who has undergone unscheduled cesarean section at KNH and is

within 72 hours post the procedure will be recruited into the study.

Voluntary Participation

Your participation in this research is entirely voluntary. You are free to withdraw from the

study at any point during the study without any adverse consequences to you.

Duration

The research is intended to take place between December 2013 and February 2014. During

that time questionnaires will be administered to all consenting participants.

Risks

By participating in this research you will not be exposed to any risk.

Benefits

There are no known benefits from the study to the participants recruited into the study.

Confidentiality

The information that I collect from this research project will be kept confidential. Any

information about you will have your initials to which a serial number will be assigned

instead of your name.

Who to Contact

If you have any questions you may ask them now, during the period of the study or even after

the study is over. If you wish to ask questions later, please use the contacts below:

Dr. Anchinga Arnold Makori (Researcher) – 0722676650 arnoldmakori@yahoo.com.

Prof. James Bill Oyieke- Onjua (Supervisor) - Tel. 0722520838

Prof. Patrick Muia Ndavi (Supervisor) Tel. 0720797587

KNH/UON-ERC uonknh_erc@uonbi.ac.ke, www.uonbi.ac.ke/activities/KNHUoN

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STUDY PROCEDURES.

Approach

Post cesarean section mothers were approached after exiting theatre and the nature of the study explained to them. They were voluntarily recruited to the study after signing an informed written consent form.

Recruitment

All consenting mothers were recruited to the study.

Consenting

Postnatal mothers, who had undergone unscheduled cesarean section at KNH, were recruited into the study through their own consent.

Interview/Data abstraction

Mothers were directly interviewed by the principal investigator on a daily basis at 24hour intervals in the morning during or after the daily ward rounds, history taken, examined physically and a questionnaire filled during the interview. Further information was retrieved from theatre notes, nurses cardex, laboratory and radiology test results.

Follow up

The inclusion criterion was all postnatal mothers who had consented and had undergone emergency cesarean section and were within 72 hours post operation at Kenyatta National hospital.

The principal investigator recruited the patient from theatre recovery and followed the patient on a daily basis, presenting the questionnaire every 24hours for 72 hours after the procedure. The outcomes of the procedures were documented in a questionnaire.

Data Collection and Management

Data was collected by the principal investigator and research assistants. Data was coded entered into an excel data base, validation and cleaning was performed and analysis as per the study objectives conducted.

CONSENT DECLARATION

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I hereby consent to participate in this research.

Participant's Name
Participant's Signature.
Serial no. of Participant:
Date:
Statement by the Researcher
I confirm that the participant was given an opportunity to ask questions about the study, and
all the questions asked by the participant have been answered correctly and to the best of my
ability. I confirm that the individual has not been coerced into giving consent, and the consent
has been given freely and voluntarily.
Name of Researcher:
Signature: Date:

APPENDIX III - CONSENT FORM – KISWAHILI

MHUJUMU MKUU: Dr. Anchinga Arnold Makori.

Kwa majina naitwa **Dr. Anchinga Arnold Makori** kutoka chuo kikuu cha Nairobi,idara ya

wamama.Hili ni ombi kwako ukubali kushiriki katika utafiti.Lengo la fomu hii ya ridhaa ni

kukufahamisha yale utakayohitajika kujua ili kukusaidia kuamua ushiriki wako katika

utafiti.Tafadhali isome fomu hii kwa makini.unaweza kuuliza maswali kuhusu yale nitakayo

hitaji kufanya, athari zozote, manufaa, haki zako kama mshirika.

LENGO NA MANUFAA YA UTAFITI

Utafiti huu utachunguza kama kuna tofauti zozote katika afya ya mama na mtoto wake baada

ya upasuaji wa dharura tukilinganisha wakati wa usiku na mchana.

TARATIBU ZITAKAZO FUATWA

Ukikubali kuhusishwa katika utafiti utaulizwa maswali ambayo utajibu. Maswali yatagusiya

ju ya idadi ya watoto ulionawo,dini yako, unapoishi, kama umewai kupasuliwa mbeleni,

ulipasuliwa kwa sababu gani na kama kuna madhara yoyote uliyopata wewe ama mtoto wako

kutokana na upasuaji wa dharura katika hospitali ya Kenyatta. Nambari maalum itatumika

kukutambulisha wala si majina yako.

MADHARA NA MATATIZO.

Kushiriki kwako katika utafiti huu ni wa hiari.Wakati wowote ukiwa na swali kuhusu utafiti

huu, mhujumu atakusaidia. Unaruhusiwa kutojibu swali/ maswali au kujiondoa kwenye

mjadala /mahojiano wakati wowote bila kuhujumiwa.

SIRI

Habari zozote wakati wa mahojiano zitahifadhiwa vyema. Majina hayatawekwa wakati wa

mahojiano.Mahojiano yatafanywa kwa chumba pekee ukiwa peke yako. Kila juhudi itatiwa

kuhakikisha kuwa yale utakayo yasema yamehifadhiwa kwa siri,Jina lako halitatokea katika

ripoti yeyeote itakayo andaliwa baada ya utafiti isipokua namba ya kutambulisha walio

husika katika utafiti. Fomu zitahifadhiwa katika sehemu maalum. Mtafiti pekee ndiye atakaye

kua na kibali.

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GHARAMA

Hutohitajika kulipa chochote cha ziada ili kushiriki katika utafiti huu isipokua wakati wak	. 111 KUSHITIKI KALIKA ULAHU HUU ISIDOKUA WAKAU WAKO.
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MimiNimekubali kuhusika na utafiti kuhusiana na
ulinganishi wa adhari zinzoweza kutokana na upasuaji wa dharura kwa mama na motto wake
ama wote ukilinganisha wakati wa siku. Nimefahamu ya kwamba kujihusisha ni kwa
hiyari.Ninauwezo wakujitoa katika utafiti huu wakati wowote bila kushurutishwa.Kuhusika
ni bure. Nimehakikishiwa kwamba mchango wangu utahifadhiwa na kutumiwa kwa utafiti
kwa manufaa ya jamiii.
SAHIHI (ya mama)
SAHIHI
Mimi ninadhibitisha ya kwamba nimemueleza kwa uwazi na
umakini bwana/bibikuhusiana na uteketaji wa wanawake na
huduma za afya kwa hawa wanawake wakiwa waja wazito.
SAHIHI ————
Kwa maswala yeyote kuhusiana na utafiti unaweza kuwasiliana na Dr.Anchinga Arnold
Makori nambari 0722676650.

Unaweza kuwasiliana na Komitii ya uadilifu kwa utafiti: KNH/UoN/ERC-0735-274288/0721-665077.

APPENDIX IV: KNH/UON-ERC LETTER OF APPROVAL



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

Ref: KNH-ERC/A/54

Dr. Anchinga Arnold Makori Dept. of Obs/Gynae School of Medicine University of Nairobi

Dear Dr. Anchinga

Stall and and

KNH/UON-ERC Email: uonknh_erc@uonbi.ac.ke Website: www.uonbi.ac.ke

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

12th February, 2015

Research Proposal: The effect of time of day of unscheduled caesarean sections on perinatal and maternal outcomes in Kenyatta National Hospital (702/11/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and <u>approved</u> your above proposal. The approval periods are 12th February 2015 to 11th February 2016.

This approval is subject to compliance with the following requirements:

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

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

Protect to discover

Yours sincerely

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH/UON-ERC
The Dean, School of Medicine, UoN
The Chairman, Dept. of Obs/Gynae, UoN
Supervisors: Prof. B.O. Oyieke, Prof. Patrick M. Ndavi

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