EARLY VERSUS ROUTINE HOSPITAL DISCHARGE AFTER UNCOMPLICATED CAESARIAN DELIVERY AT KIJABE HOSPITAL

A DESSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE (MMED) IN OBSTETRICS AND GYNAECOLOGY, SCHOOL OF MEDICINE AT THE UNIVERSITY OF NAIROBI

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DEDICATION

This book is dedicated to my loving husband George, daughter Ariela and parents, Mr. and Mrs. Mameti Shaviya. Your support has been priceless.

ABBREVIATIONS

ACOG   American College of Obstetricians and Gynaecologists

AJOG   American Journal of Obstetrics and Gynaecology

ASA   American Society of Anesthesiologists

BMI   Body Mass Index

CMAJ   Canadian Medical Association Journal

CS   Caesarian Section

DM   Diabetes Mellitus

EAMJ   East African Medical Journal

NHSN   National Healthcare Safety Network

NICE   National Institute of Health and Clinical Excellence

OMH   Omdurman Maternity Hospital

SAJOG South African Journal of Obstetrics and Gynaecology

SSI   Surgical Site Infection

USA   United States of America

VBAC   Vaginal Birth after Caesarian Section

WHO   World Health Organization

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ABSTRACT

EARLY VERSUS ROUTINE HOSPITAL DISCHARGE AFTER UNCOMPLICATED CAESARIAN DELIVERY AT KIJABE HOSPITAL

Background: Caesarian delivery is a major operation in Obstetrics and outcomes and complications are major concerns for the beneficiaries and health providers. The average hospital stay following C/s in most hospitals in Kenya is three to four days, a tradition not supported by any evidence, policy or practice guidelines. Over the years, mainly in high income countries, it's becoming common practice to discharge patients early to satisfy their wishes, reduce cost and also reduce work load in high patient turn-over settings.

Objective: The study was intended to determine if discharge from hospital on day two post-operatively after uncomplicated Caesarian delivery was satisfactory to women and to determine to what extent it was followed by adverse clinical maternal outcomes at Kijabe Hospital.

Study design: This was a randomized clinical trial(unblinded) where the intervention group consisted of patients discharged on day two and the control group as those discharged on routine day three postoperatively after uncomplicated C/s. The primary outcome variables were patient satisfaction, wound infection and maternal readmission rates.

Methods: The study population consisted of patients who had uncomplicated Caesarian delivery at Kijabe Hospital randomized into two groups: day 2 and routine day 3 discharge. Data was extracted from patient records and also from patient interviews by the principal investigator using a structured questionnaire.

Results: From June to October 2014, 171 patients were randomized; 90 to day 2 and 81 to day 3 hospital discharge. The study population encompassed women with a mean age of 29.4 years. Most of them were married, had attained a college level education and were self-employed. The majority were also immuno-competent. We found increased satisfaction among early hospital discharge of the patients (95.6% vs. 71.6%, p=0.001, 95% CI 83.4(78.4-93.6) without increased adverse maternal outcomes: wound infection rate (0.0% vs. 1.2%, p=0.290, 95% CI 0.6(0.0-2.1) or readmission rates (1.1% vs. 0.0%, p=0.341, 95% CI 0.5(0.0-1.7).

Conclusion & Recommendations: Day 2 hospital discharge is associated with significant patient satisfaction and with no significant adverse maternal outcomes. Therefore day 2 hospital discharge is acceptable, feasible, safe, sustainable and likely to be cost-effective. Therefore, early hospital discharge after uncomplicated Caesarian delivery should be considered as an alternative to day 3 discharge.

INTRODUCTION AND LITERATURE REVIEW

Caesarian delivery is a major operation in Obstetrics and outcomes and complications are major concerns for the beneficiaries and health providers. The average hospital stay following C/s in most hospitals in Kenya is three to four days, a tradition not supported by any evidence, policy or practice guidelines. Over the years, mainly in high income countries, it's becoming common practice to discharge patients early to satisfy their wishes, reduce cost and also reduce work load in high patient turn-over settings.

Caesarean delivery rates have grown worldwide from 21 percent of childbirths in 1997 to 33 percent in 2008(1). In Kenya, the rate of caesarian delivery is rising. Among the reasons is that vaginal births after Caesarian delivery (VBAC), which are associated with rare but serious complications including uterine scar rupture (2), have declined and further contributed to the growing number of repeat C-sections performed.

A number of studies have highlighted the maternal benefits of elective caesarian delivery (3), other research indicates that they generally tend to be more costly than vaginal deliveries (4), are associated with higher rates of maternal re-hospitalization, and postpartum medical care utilization (5,6). This is in view of the longer hospital stay and more need for medication (analgesics, antibiotics) as compared to vaginal delivery.

In the United States caesarian deliveries are done in approximately one third of the deliveries with women staying in the hospital for three to four days after the procedure. This compares with one to two days for vaginal deliveries. American College of Obstetricians and Gynaecologists says a shorter hospital stay after C/s is an option if the baby is ready to go home, though

the mother has to meet certain requirements first, for example normal blood pressure, no signs of

infection and adequate pain control (7).

Several studies have been done to assess this with a number citing benefits of early discharge

after caesarian delivery. In Africa, three studies have been conducted to assess the safety and

acceptability of early hospital discharge following uncomplicated caesarian delivery.

In 2000, Fasubaa OB et al carried out a prospective case control study among the Yoruba women

of South Nigeria, aimed at examining issues of reduced hospital stay following caesarian

delivery. This was with a view of making the operation more acceptable and hence offer a

solution to some of the problems faced by women whenever this surgery was indicated. They

concluded that embracing the concept of early home discharge may remove some of the

psychological upsets and economic impediments associated with the operation and make it more

acceptable (8).

A descriptive study was done in Omdurman maternity hospital (OMH)-Sudan, in 2010. The

objective of the study was to assess patient satisfaction and morbidity associated with 24 hours

hospital stay after elective Caesarean delivery. All women admitted for elective Caesarian

delivery were counseled for discharge after 24 hours from surgery. Those with medical or

obstetrical problems necessitating admission for longer time were excluded.

Women who refused to be discharged were included as control after an informed consent. All

women were operated on by trained registrars or consultants under similar conditions & were

followed till discharge from hospital. The conclusion of the study was that short hospital stay

after elective caesarian delivery was associated with more patients' satisfaction, without increase

in maternal mortality or morbidity, compared to control(9).

A cohort study conducted in 2011 in South Africa by Eckhart Johannes to assess if prolonged hospital stay after uncomplicated caesarian delivery was necessary concluded that discharge on postoperative day 2 was safe and acceptable whereby 89.8% of the patients would choose early discharge again (10).

The National Institute of Health and Clinical Excellence (NICE) also recommends early discharge after 24 hours if the patient and baby are stable as this is not associated with more infant or maternal readmissions. Several studies have concluded the same (11, 12, 13, 14, 15, 16, 17, and 18).

It is known that Caesarian delivery is associated with more morbidity compared with vaginal delivery, hence the Caesarian delivery rate should not exceed 10-15% according to the World Health Organization (19).

It is associated with higher rates of wound sepsis, hemorrhage, higher rates of repeat surgery and adhesions among others. However, in the past few years, the Caesarian rate has markedly increased worldwide, hence associated increased inpatient stay. Among the reasons for this increase is that women are having fewer children, thus a greater percentage of births are among nulliparous who're at increased risk of caesarian delivery. The average maternal age is also rising, and older women especially nulliparous, are at increased risk of Caesarian delivery.

The widespread use of electronic fetal monitoring has increased over time. This technique is

associated with increased C/s rate compared with intermittent fetal heart rate

auscultation. Malpresentation is a common cause of Caesarian delivery, with a vast majority of

fetuses presenting as breech being delivered via this way (20).

The incidence of mid-pelvic forceps and vacuum deliveries has decreased over the years. This

has been substituted with caesarian delivery of infants who might have required instrumental

delivery.

The prevalence of obesity has also risen dramatically, with increased rate of Caesarian delivery.

Rates of induction of labour continue to rise and induced labour especially among nulliparous,

increases the risk of Caesarian delivery.

There has been a rising concern for malpractice litigation and this has contributed significantly to

the present Caesarian rate to avoid adverse neonatal neurological outcome/cerebral palsy. In the

United States, in 2001, a brain-damaged infant was the claim responsible for 40% of all medico-

legal indemnity paid by Obstetricians-Gynaecologists (21). This is despite well-documented lack

of association between Caesarian delivery and any reduction in childhood neurological

problems. According to Foley et al (2002), neither the incidence of neonatal seizures nor of

cerebral palsy diminished as the rate of Caesarian delivery increased (21, 22, and 23).

 Some elective Caesarian deliveries are performed due to concern over pelvic floor injury

associated with vaginal delivery (24).

The rise in Caesarian delivery is associated with more morbidity as compared with vaginal

delivery. Among the main morbidities is puerperal infection. It increases the

infectious morbidity by about 5-20 %(25). Given that Caesarian deliveries continue to

 represent a significant proportion of all births in Kenya, the overall health and

socio-economic burden of these infections is substantial (26).

The main risk factors for puerperal infection include emergency Caesarian delivery, labour

presence, prolonged rupture of membranes (>18 hours), obesity (Body Mass Index >30),

number of vaginal examinations exceeding seven, absence of antibiotic prophylaxis, length

of surgery>60 minutes, ASA Score>III and Diabetes mellitus.

The main types of infectious morbidity after C/s are surgical site infection and endometritis.The

overall surgical site infection and endometritis rates after Caesarian delivery are 4.8% and 3.1%

consecutively. The rates might be lower when considering the risk category with the low risk

surgical case classified as NHSN- Category 0(27).

Certain preventive strategies have been put in place to reduce infectious morbidity and are

 routinely carried out in all facilities. This include cleaning the surgical site with povidone-iodine

or chlorhexidine and antibiotic prophylaxis within sixty minutes of start of surgery (28).

Intraoperative considerations include delivery of placenta by fundal massage and umbilical cord

traction as compared with manual removal. This has been shown to lower rates of postpartum

endometritis (29).

CONCEPTUAL FRAMEWORK

The exposure variable in this study was the prescribed duration of hospital stay; post-operative day 2 or day 3. The outcome variables were patient satisfaction and adverse outcomes. The focus in on the early hospital discharge(day 2), with the goal to determine if patients will be more satisfied with early hospital discharge and how soon this will be followed by any adverse outcome, for example, wound infection, readmission.

There were variables in the causal pathway which include participant's confidence in the discharge plan, which may have influenced whether one consented to be in the study. The health costs incurred may also have influenced the choice to be in the study with eligible candidates desiring to be randomly assigned to early discharge. The clinical status of the participants may also have determined the final discharge plan, with those who were clinically stable going home at the allocated time while those who were not stable having delayed discharge. This was likely to impact the results interpretation. Family support may also have influenced the outcome in that participants who had good support may have been inclined towards early hospital discharge as compared to those who were assigned to routine day 3 hospital discharge.

Confounding variables in this study included age of the participants, their marital status, socioeconomic status and parity. Older participants, married ones or the multiparous and of low socioeconomic status may have been more satisfied with early hospital discharge as compared to the younger, single or primigravidae ones. This may have been due to more experience or better support from their partners.

CONCEPTUAL FRAMEWORK DIAGRAM
Variables in the causal pathway

-Confidence in discharge plan

-clinical status

-family support

Exposure variables   **Outcome variables** (Satisfaction, adverse outcome)

-prescribed hospital stay

Post-operatively (2 or 3 days)

Confounding variables

         -age

         -marital status

         -socioeconomic status

         -education level

         -parity
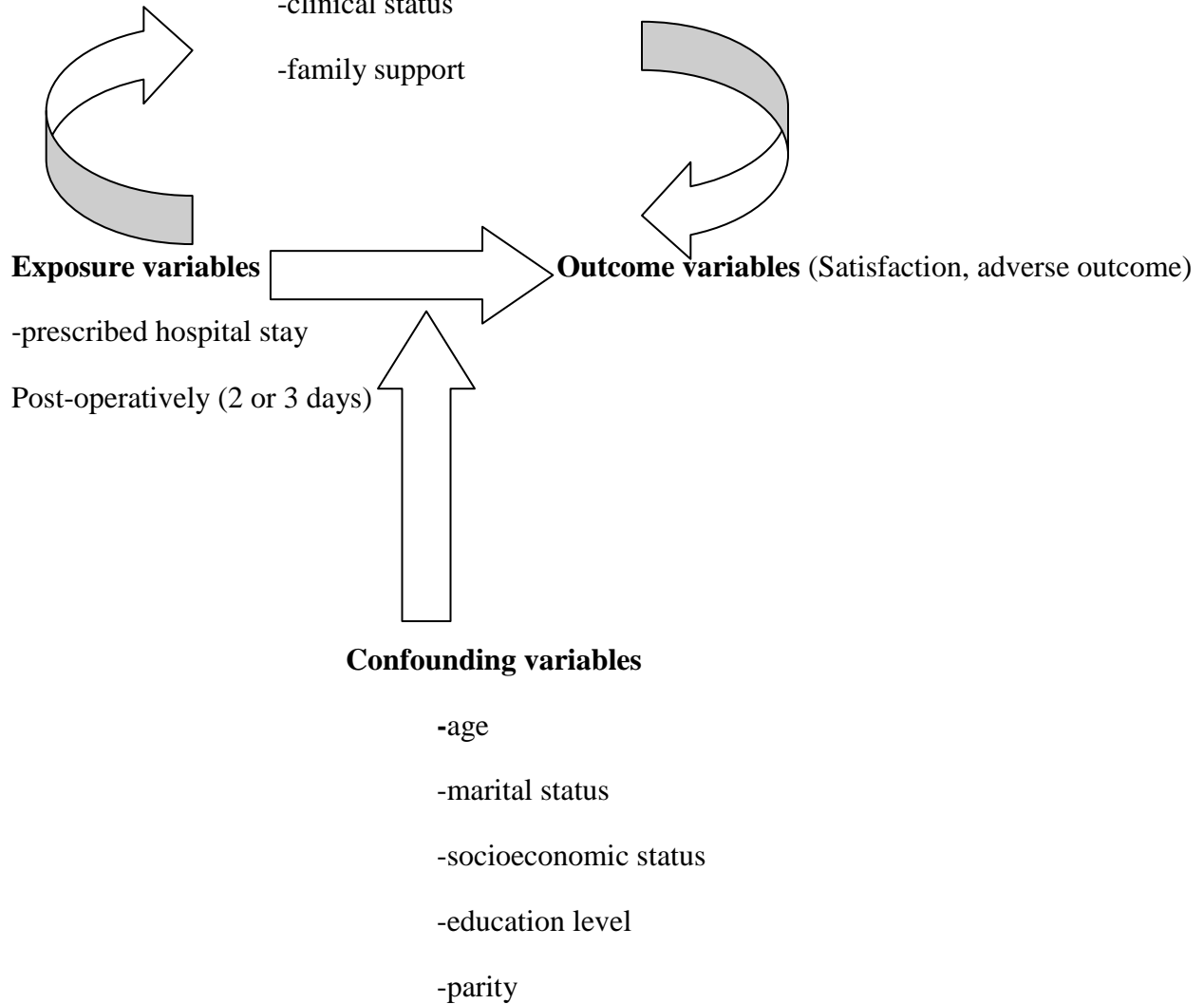
JUSTIFICATION

This study was intended to determine if earlier hospital discharge (on day two) after uncomplicated Caesarian delivery compared to the standard hospital discharge on day three was as satisfactory to women. It also intended to establish if this was associated with increased adverse clinical outcomes.

This study is very practical and applicable in hospitals where the turn-over of patients for Caesarian delivery is very high. Since in Kenya current practice is hospital discharge on day 3-4 it was important to determine if this could be reduced further by comparing day 2 and 3.

Application of the results of this study was to aid in promoting patient satisfaction and also concurrently reduce the cost of inpatient care for uncomplicated caesarian section patients in the Kijabe Hospital and in other facilities especially those with high patient turn-over in the maternity wings. It was also intended to reduce the work load on staff, hence promoting better quality health care for the patients, especially those requiring more attention, considering the heavy work load already being experienced at some facilities.

Three studies done in Africa have shown that early discharge is acceptable, safe and associated with higher patient satisfaction, less hospital costs and no significant difference in complications (8, 9, and 10).

STUDY QUESTION

What are the maternal outcomes on hospital discharge after day 2(>24-48hrs) versus after routine

day 3 (>48-72hrs) following uncomplicated C/s?

BROAD OBJECTIVE

To determine whether hospital discharge on the second post-operative day after uncomplicated

caesarian delivery is satisfactory to women and associated with adverse clinical outcomes.

SPECIFIC OBJECTIVES

1. To establish if hospital discharge on day two following uncomplicated Caesarian delivery is

associated with higher patient satisfaction.

2. To assess rates of wound infection associated with earlier (day two) hospital discharge after

uncomplicated Caesarian delivery.

3. To determine rates of maternal readmission following early hospital discharge after

uncomplicated Caesarian delivery.

MATERIALS AND METHODS

Study design

This was a hospital-based unblinded randomized clinical trial. Patients were randomized to hospital discharge post-operative day 2 intervention group or on postoperative day 3 as the standard of care control group. They were given sealed envelopes containing computer-generated random numbers representing the discharge arm, and opened at time of recruitment. The second post-operative day was defined as day 2 on the postnatal morning round, from date of delivery. This corresponded to surgery to hospital discharge interval of >24-48 hours for day 2 and >48-72 hours for day 3.

Study Site

The study was conducted in the maternity ward of Kijabe Hospital, a teaching and referral hospital in Kiambu county. It is situated 65 km from Nairobi, 4 km off the Nairobi-Nakuru highway. It serves patients from within its environs including Nairobi and Nakuru but also gets referrals from other hospitals in the country and a number of the East African countries. It serves patients in the low to middle-income classes.

It has a bed capacity of 365, approximately 70 of which make up the maternity ward. On a given day, the maternity ward serves an average of 30 patients, 3-4 who undergo caesarian delivery in a 24-hour period. Every month an average of 70-80 caesarian sections are carried out at the facility, a significant number being uncomplicated cases. Hence the study was planned to run for approximately four months.

Study population

The study population consisted of consenting women aged 18 years and above who had had uncomplicated Caesarian delivery at term in the antenatal ward at the Kijabe Hospital. Additionally they had to have available telephone contact for follow-up. In this study, uncomplicated Caesarian delivery was defined as elective or emergency Caesarian delivery with no significant intra-operative complications (Significant intra-operative complications included the following: intra-partum hemorrhage, hemorrhage requiring interventions like blood transfusion, ballon tamponade or visceral injury).

Excluded from the study were patients with any of the following   present: 1)medical conditions e.g. hypertension, cardiac disease, diabetes mellitus, anemia <10g/dl, 2)high risk for post-operative infection (that is prolonged rupture of membranes, labour of more than 20 hours, obstructed labour and pyrexia in labour).

Sample size calculation and sampling procedure

We used patient satisfaction as the main outcome measure to be considered. Using proportions from the South African Study by Eckhart Johannes in 2011 based on the unmatched prospective cohort using patient satisfaction for early hospital discharge at 89.8% (P0=89.8%) and the unsatisfied patient rate for early hospital discharge at 10.2% (P1=10.2%).

For a randomized control trial with two comparison groups with the same size of subjects; sample size calculation depends on the type of primary outcome measures.

$$n_1 = n_2 = (z_{1-\alpha} + z_{1-\beta})^2 \ [p_1(1-p_1)(p_2(1-p_2)]/(p_1-p_2)^2$$

Where;

 n = is the required sample size;

$z_{1-\alpha}$ = Significance α-level set at 5% (95% Confidence interval) = 1.96

$z_{1-\beta}$ = Power of the study β-level set at 80%; = 2.56

P_1 = prevalence of the cases set at 89.8%;

 P_2 = prevalence of the controls (expected to be 10% lower in satisfaction due to late discharge) set at 78.9%;

Substituting the value in the equation above we get;

 n1= n2= 89.8656

= 90 study cases(day 2 discharge) and 90 standard cases(day 3 discharge).

Sources and methods of enrolment

The principal investigator or research assistant counselled all potential candidates within the first 12hours after uncomplicated Caesarian delivery. She explained the study and its associated procedures to the potential subject prior to conducting any study procedure verbally in English or Kiswahili. The explanation provided included purpose of the study, procedures, risks and benefits of the study. The patient was informed that if she consented to participate, she would be randomly assigned to one arm of the study- either to day 2 discharge or to day 3 discharge. Following the verbal explanation, the patient was provided with a written consent form to go through.   The patient was provided with an opportunity to ask questions and also educated on their rights as participants in the study.

Once the patient's questions were answered to her satisfaction and she had agreed to participate in the study, she signed and dated the consent form. The principal investigator or research assistant also signed. A copy of the consent was provided to the patient together with an information sheet with phone numbers to call if she had any problems or questions. A person who could speak and understand English or Kiswahili, but could not read and write, could be enrolled in the study by making their mark with their left thumbprint on the English consent document.

A consecutive sampling method was utilized for all with successive Caesarean delivery who fulfilled the eligibility criteria.

Randomization

The women had an equal probability of assignment in the day 2 intervention and day 3 routine hospital discharge groups. The randomization code was developed using a computer random number generator to select random permuted blocks of ten till a total of 180 was reached and the codes sealed in envelopes. This was done by the statistician then given to the principal investigator. The researchers enrolling and following up the patients allocated the next available number on entry into the trial. This was done in the maternity ward within the first 12 hours after the surgery. The nature of this study made it an un-blinded randomized clinical trial in that the code was revealed to the patient after recruitment.

Allocation concealment

The interventions were sealed in sequentially numbered identical opaque envelopes according to the allocation sequence. We ensured that the envelopes were opened sequentially and only after the participant's name and details were written on the appropriate envelope.

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Follow-up and Data Collection

Data was collected by the principal researcher or the research assistants using a pretested structured questionnaire, which was administered verbally to the study subjects after recruitment in the maternity ward. The interviews were conducted in maternity ward upon recruitment of the patient. The information obtained was entered into the questionnaire by the principal investigator or her research assistants. A final telephone interview was done at day 14.

Patients who had been enrolled in the study were followed up daily till discharge. They all received standard care as per the hospital protocols; pre-operative intravenous cefazolin 1g, post-operative parenteral analgesia and intravenous fluids. At hospital discharge, they were examined by the principal investigator or her assistants and educated on identification of symptoms and signs of complications and taken through an exit oral interview. This was followed by a telephone interview at day 14. Those participants who had delayed hospital discharge or crossed over to day two were still followed up and analyzed for outcomes under the initial allocation arm.

A structured questionnaire was completed at day 14 by asking them some questions concerning their experience and any complications detected. Symptoms included fever or chills that develop within two weeks of caesarian section, severe pain in the lower abdomen, abnormal vaginal discharge, purulent discharge from the surgical site, gapping of the surgical site and readmission of the patient at the same or another facility.

The study investigator was available by phone 24 hours a day should a study subject develop any complications and require clarification about it. All adverse effects occurring in the course of the study were collected and reported to the principal investigator.

The primary outcome variable needed for analysis was maternal satisfaction. Secondary variables were puerperal infection and maternal readmission.

Two medical officers working in the maternity ward were trained as research assistants. They were trained on the study protocol including history taking, consenting procedure, using the inclusion and exclusion criteria to enroll participants, and client assessment post-operatively for enrolment into the study. They were also taught on how to administer and fill in the questionnaire. Standard definitions of terminologies were given and diagnostic criteria for some conditions were outlined. The medical officer interns, nurses working in the maternity ward and other staff who were involved in the study were trained on the study protocol in a one-day workshop at the Kijabe Hospital.

Pre-testing of the questionnaire was done prior to the study. This was followed by weekly review of the study process by the principal investigator and the research assistants to ensure high quality data collection and results.

The questionnaire comprised of four sections: the Sociodemographic characteristics, reproductive history, current pregnancy dating and outcome details and the follow-up interview (check annex).

Data management and analysis

Data cleaning and entry

Completed questionnaires were checked for completeness, consistency and accuracy, coded and sorted out .Data collected was entered into a password protected Microsoft Excel Database in consultation with the statistician. The hard copy data forms were stored in a lockable cabinet in

the Principal Investigator's office. Upon completion of data entry, hard copy forms were compared with the entered data to identify errors and corrections made appropriately before analysis.

Data analysis

All data analysis was carried out according to a pre-established analysis plan. Descriptive statistics were carried out where discrete variables as marital status, education level, employment, religion and HIV status were summarized with frequencies and percentages. Continuous variables such as age, number of previous pregnancies, number of previous abortions, number of living children and gestation age were summarized using measures of central tendency such as mean, median, mode and standard deviation.

Patient satisfaction, acceptability and uptake of day two and day three discharge protocols as well as associated adverse outcomes were estimated using simple proportions. Categorical factors associated with acceptability of the two discharge protocols such as marital status, education level, employment and religion were identified using Chi-squared tests and Fisher's exact tests for nominal variables such as age, number of previous pregnancies, number of previous Caesarian sections, number of living children and gestation age and t-tests for continuous variables.

Ethical considerations

Ethical clearance was sought from the University of Nairobi Obstetrics and Gynaecology department, Kenyatta National Hospital/University of Nairobi and Kijabe Hospital Ethics and Research Committees. A written consent was obtained before participating in the study. Potential participants were informed that participation was voluntary and that standard care would be

provided to all women regardless of whether they consented or declined to participate in the study. The patients' records were coded and patient's name was not used to maintain confidentiality. The information obtained remained confidential and was not used for any other purposes other than the study. The interview was conducted in a private environment to ensure confidentiality.

RESULTS

FIGURE 1: ENROLMENT FLOW-CHART

Enrolment

Assessment for Eligibility
(n=337)

Ineligible
(n=157)

Allocation

Randomization (n=180)

Day 2(n=90)   Day 3(n=90)

Discharged
(n=85)

Deferred (n=5)

Cross-over
(n=9)

Discharged
(n=81)

LFU (n=0)

LFU (n=9)

Follow up

Analyzed
(n=90)

Analyzed
(n=81)

Analysis
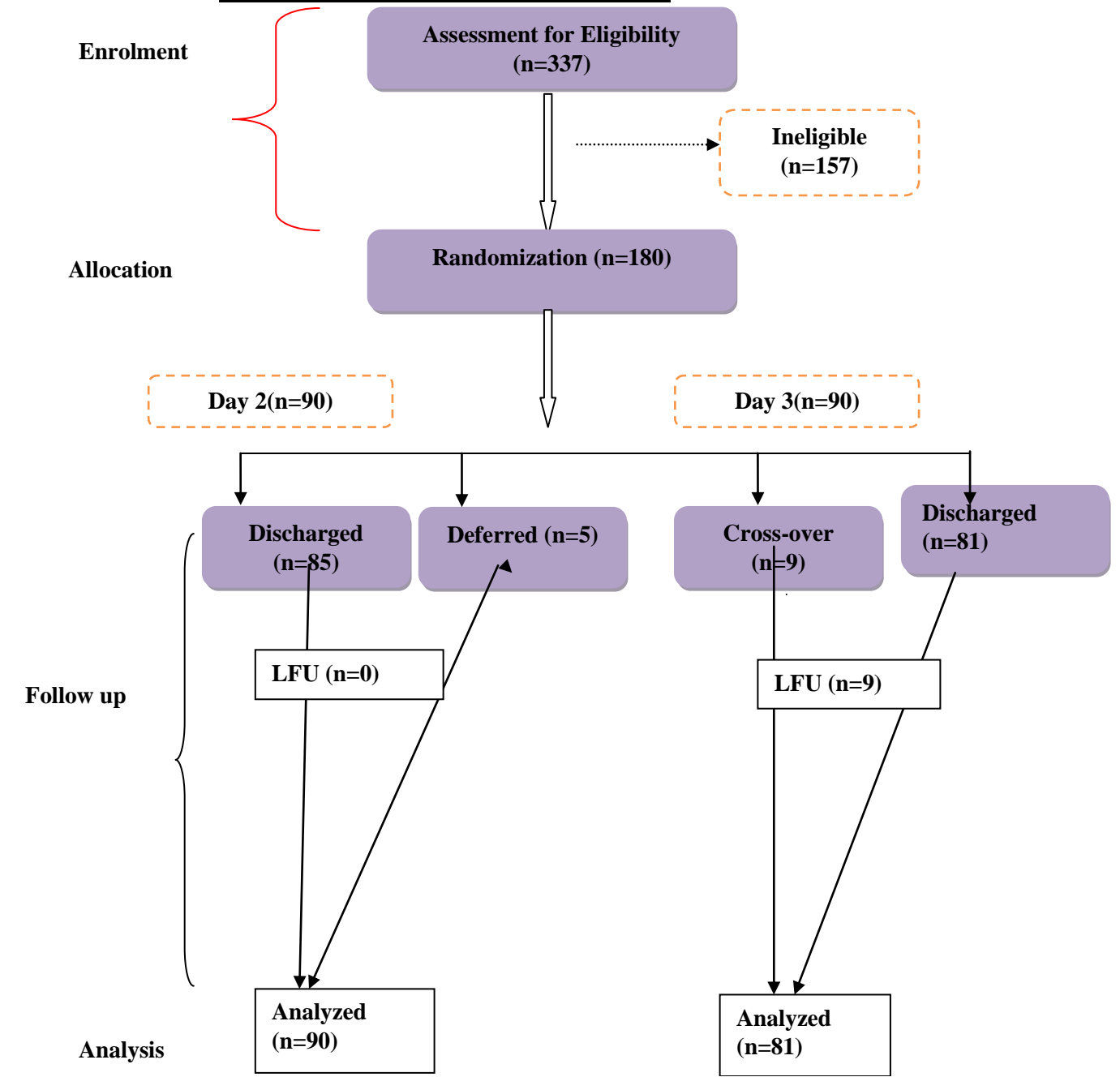
RESULTS

This was an unblinded randomized clinical trial to determine outcomes of early versus routine hospital discharge after uncomplicated Caesarian delivery at Kijabe Hospital.

The study took place from June, 2014 to October, 2014. Over the course of the study, 785 patients were delivered from June to October, 2014. Of these, 337 underwent Caesarian section (both emergency and elective). 180 were eligible for the study with 90 on each arm. However, we had an attrition of 9, all from the day 3 discharge arm. We could not establish telephone follow-up with no response at 4 calls, 3 out-of-service numbers and 2 wrong numbers.

There was protocol deviation in both groups. In the day 2 intervention group, five women had their discharge deferred; four due to poor milk let-down and one due to significant surgical site pain. In the routine day 3 group, nine patients crossed over to day two discharge after requesting the examining doctor to be allowed home earlier. However, this did not affect the final analysis as it was by intention-to-treat principle with analysis done according to group assignment.

We had 171 patients for analysis due to failure to attain follow-up for the 9 patients. Therefore we had 90 on the intervention arm (day 2 discharge) and 81 on the control arm (day 3 discharge).The mean age of the population was 29.3 in the intervention group and 29.6 in the control group.

Baseline characteristics are shown in table 1. The baseline age, educational level, marital status, HIV status, parity and type of C/s were all similar in the two groups with no significant difference. Most of the population was aged between 20-39 years; majority had attained college education, married, immuno-competent and had a parity of 1-4. The type of Caesarian delivery was similar in both groups with no significant difference in the elective or emergency deliveries.

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Table 1: Baseline characteristics of the participants

Baseline Characteristics		Intervention group n (%)	Routine discharge group n (%)	P value
Age	20-29	47(52.2)	47(58.0)	
	30-39	41(45.6)	34(42.0)	0.433
	40+	2(2.2)	0(0.0)	
Marital status	Married	84(93.3)	69(85.2)	0.596
	Single	6(6.7)	12(14.8)	
Education level	Primary	6(6.7)	10(12.3)	0.505
	Secondary	22(24.4)	22(27.2)	
	College	62(68.9)	48(60.5)	
Employment	Self	42(42.7)	31(38.3)	
	Salaried	32(35.6)	29(35.8)	0.106
	Unemployed	16(17.8)	21(25.8)	
Religion	Catholic	21(23.3)	12(14.8)	
	Protestant	69(76.7)	66(81.5)	0.069
	Muslim	0(0.0)	3(3.7)	
C/s type	Emergency	43(47.8)	40(49.4)	0.412
	Elective	47(42.2)	41(50.6)	
HIV status	Negative	87(96.7)	80(98.8)	0.138
	Positive	3(3.3)	1(1.2)	
Living children	1	31(34.4)	40(49.4)	
	2	23(27.8)	22(27.2)	
	3	26(28.9)	16(19.8)	0.075
	4	7(7.8)	3(3.7)	
	5+	1(1.1)	0(0.0)	

As shown in tables 2 and 3, there was a statistically significant difference in the satisfaction rate between those patients discharged early and those discharged on routine day 3(95.6% versus 71.6%, p-0.001). However there was no statistically significant difference in the adverse maternal outcomes in both groups, with no puerperal infection reported in the intervention group

and a 1.2% in the control group (p- 0.290). The intervention group had a low readmission rate of 1.1% with no readmission reported in the control group (p- 0.341).

Table 2: Primary outcomes of study participants at time of hospital discharge

Outcome		Intervention day 2 discharge n (%)	Routine day 3 discharge n (%)	P value
Satisfied with discharge	Yes	81 (95.6)	58(71.6)	
	No	9 (4.4)	23(28.4)	<0.001
Wound infection	Yes	-	-	-
	No	90(100.0)	81(100.0)	

Table 3: Secondary outcomes of study participants at day 14

Outcomes		Intervention day 2 discharge n (%)	Routine day 3 discharge n (%)	P value	95% CI
Satisfied with discharge	Yes	81(95.6)	58(71.6)	<0.001 83.4(78.4-	
	No	9(4.4)	23(28.4)		93.6)
Wound infection	Yes	-	1(1.2)	0.290	0.6(0.0-
	No	90(100.0)	80(98.8)	2.1)	
Maternal readmission	Yes	1(1.1	-	0.341	0.5(0.0-1.7)
	No	89(98.9))	81(100.0)		

Figure 2: Rates of patient satisfaction at day 14 follow-up
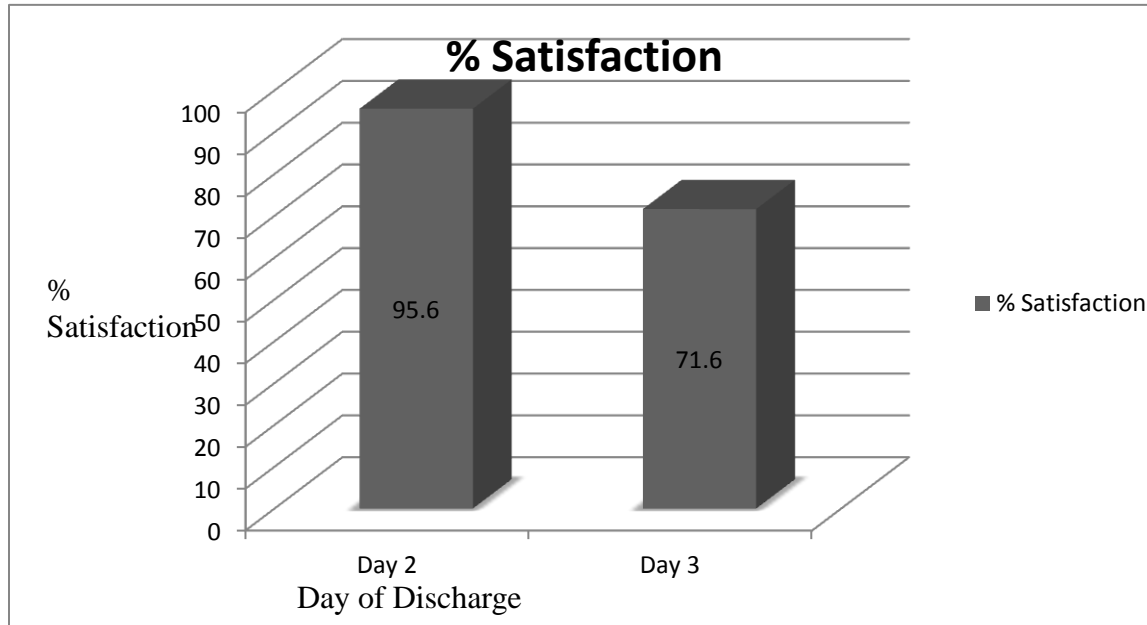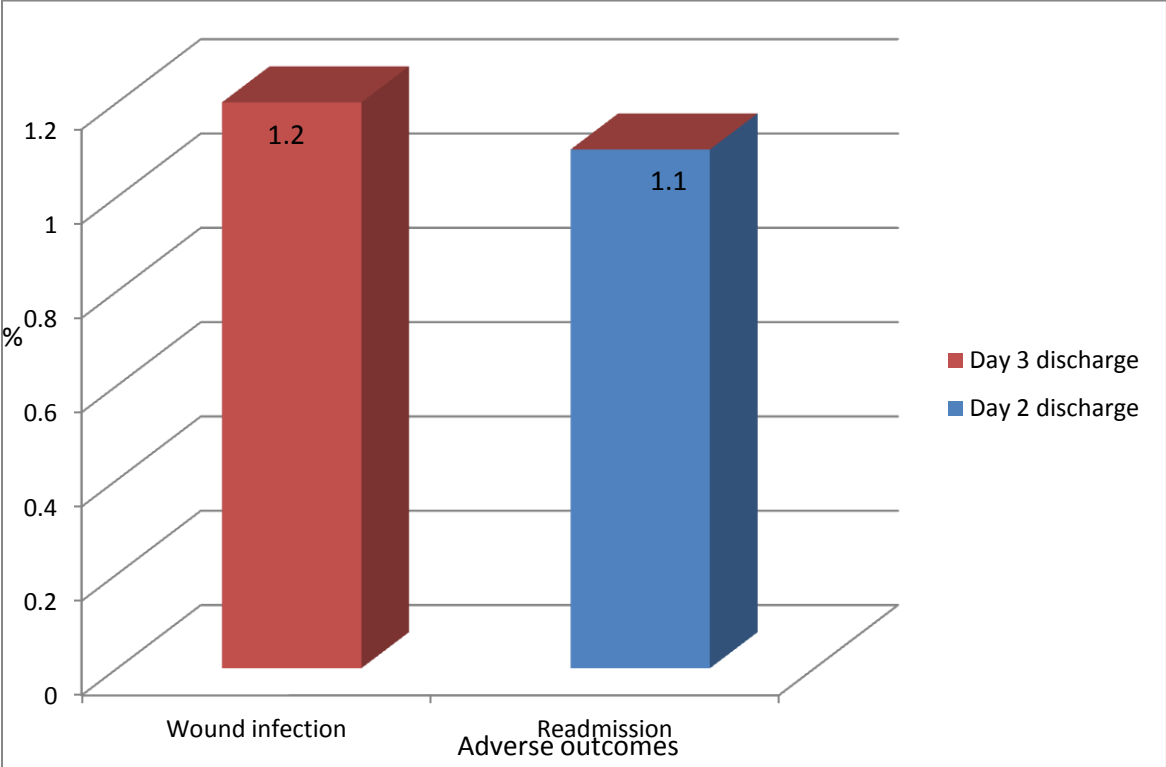
Figure 3: Adverse outcomes among participants at day 14 follow-up

DISCUSSION

The main objective of our study was to determine and compare maternal satisfaction following early discharge after uncomplicated C/s.

In this study most of the participants were young women with an average age of 29.4yrs, most of whom were immuno-competent. Analysis was done using an intention-to-treat approach thus deferrals and cross-over were adequately considered and found not to have a significant net effect on the outcomes.

We found increased satisfaction with day 2 discharge (95.6% vs. 71.6%, p=0.001) without increased wound infection or readmission rate. These results are comparable with previous studies done in Africa. Fasubaa et al (2000) compared discharge after three days versus seven to eight days after uncomplicated C/s and found more satisfaction and less hospital bill in the day 3 group.

Eckhart Johannes et al (2002) in South Africa compared day 2 discharge with routine day 3 following C/s. H e found out that 89.8% of the patients would choose early discharge again.

Umbeli et al (2012) evaluated satisfaction of patients following discharge after 24hrs after elective C/s. 85.6 % satisfaction in study group versus 37.2% in control(p-value-0.0001)).

A Malaysian randomized clinical trial (South East Asia) in 2013 found that 87% of the patients were satisfied with day 1 versus 86% with day 2.

The Africa studies, published before 2013, suggested that early discharge following uncomplicated or elective C/s was associated with more patient satisfaction. However, most were prospective designs and included diverse study populations. In this randomized clinical trial, we found a higher satisfaction rate and comparable adverse maternal outcomes.

Factors attributed to the high satisfaction rate included less hospital stay, less inpatient costs and good services at the facility. Whether early discharge was cost-effective or not was debatable among some patients. However, this was beyond the scope of our study.

According to literature, post-discharge surveillance is still a matter of dispute. An ideal method needs to have a high follow-up rate, high sensitivity and specificity and also cost-effective (29, 30,31, 32). In our study, all the participants owned or had access to a telephone, and the response rate at day 14 was 95% which was high. Therefore, we concluded that this method of a telephone questionnaire was feasible, effective and not very time-consuming. It's also probable that it may have been more acceptable to patients and therefore also contributed to their satisfaction.

There was no significant difference in the rates of wound infection in the intervention and control group.

The overall surgical site infection rate was much lower than rates reported from other studies that have used post-discharge surveillance (1.2% in intervention group). Rates have varied from place to place; 9.6% in Brazil to 17% in Australia (33, 34). Umbeli et al demonstrated similar findings where he found no significant difference in wound infection rates (1.3% in cases vs. 1.7 % in controls) following discharge after 24 hours compared to the routine 48 hours at OMH (9).

Generally, surgical site infection rate after C/s is estimated to be 4.1%. It may be lower for low – risk category of patients (NHSN-Category 0). Our study results portray this picture as those enrolled were low risk for any infectious morbidity and did not have other significant co-morbidities. Studies done have suggested that direct observation of surgical sites by trained professionals is the most accurate method to detect SSI (35, 36). In our study, surveillance was

only done by a follow-up telephone call due to human and financial resources allotted to this. This may also be a reason why our infection rate was lower than those from other studies.

In total, only one patient was readmitted from the intervention group due to postpartum deep venous thrombosis with a non-significant difference of readmission between the groups (1.1%). There was no direct relationship between the reason for readmission and early discharge from hospital. This was comparable to Eckhart Johannes et al (3.1% overall readmission rate) and Umbeli et al: (1.1% vs.1.8% in the controls).

This study involved majorly young women within the age group of 20-39 years who had uncomplicated C/s. Hence this may be replicable to individuals with similar characteristics. However, it may not be applicable to women who may be having other co-morbidities, are high risk for infection or those who may have had significant intra-operative complications.

Considering that it was done in a resource-poor setting and serving mostly low to middle income groups, the results can be replicated in a primary, secondary or tertiary level of care. The effect on other related outcomes was not assessed, for example, cost-effectiveness and quality of life assessment which may affect the uptake of early discharge.

Strengths

The main strength of this study was that, as a randomized clinical trial, done in a resource-poor setting, it has prospects of informing policy change and practice to day two discharge thus reducing cost of care.

Unique findings

It can contribute to practices and policy amendments relevant to human resource in health and early hospital discharges to relieve workload and bed occupancy versus personnel issues especially as relates to free maternity health care in Kenya without compromising quality of care.

Secondly, it provides communication opportunity in the postpartum period between the patients and health personnel regarding the danger signs and postpartum messaging, a period when mothers are infrequently provided care.

Limitations

One limitation in this study was that patient influence may have played a role in cross-over of some patients to day two discharge. We also may not have adequately controlled for all confounders of patient satisfaction, for example, individual patient experiences at hospital, parity and previous mode of delivery (whether vaginal or Caesarian delivery). However, the net impact on the final analysis was not significant. We also had a 5% attrition rate which incidentally fell on the routine day 3 discharge arm. However, this was not significant as the response rate was still high enough to power the study.

Conclusion

From this study, day 2 hospital discharge after uncomplicated Caesarian delivery is associated with significant patient satisfaction, and with no significant adverse outcomes. Therefore it is acceptable, feasible, safe, sustainable and likely to be cost-effective.

Recommendations

Early hospital discharge after uncomplicated Caesarian delivery should be considered as an alternative to day 3 hospital discharge. We recommend further analysis or similar but multi-centre studies which will strengthen the evidence established in this study.

TIME LINES

Activity	May 2014	June-Sep 2014	Oct 2014	Oct 2014
Ethical Approval	■			
Data Collection		■		
Data Analysis and report writing			■	
Data Presentation				■

BUDGET

EXPENSE	COST IN KSHS
Training Budget	2,000
Cost of follow-up telephone calls	5,000
Research assistants' fees	20,000
Consent forms and questionnaires	20,000
Printing, photocopying and binding	15,000
Ethics and Research Committee	2,000
Consultancy – biostatistician	20,000
Stationery	1,000
10% contingencies	12,000
TOTAL	97,000

REFERENCES

1. Macdorman M.F., Menacker F., Declercq E. Cesarean birth in the United States: epidemiology, trends, and outcomes. Clinical Perinatology, 2008; 35:2933

2. Guise J., Berlin M., McDonagh M., et al. Safety of vaginal birth after Cesarean: A systematic review. American College of Obstetricians and. Gynecologists, 2004; 103(3):42029.

3. National Institutes of Health. State of the Science Conference Statement. Cesarean delivery on maternal request. Obstetrics and Gynecology, 2006; 107: 1386–97.

4. Zupancic JAF. The economics of elective Cesarean section. Clinical Perinatology, 2008; 35:59199.

5. Lui T., Chen C., Lin H. Does elective Cesarean section increase utilization of postpartum maternal medical care? Medical Care, 2008; 46(4):44043.

6. Declercq E., Barger M., Cabral H.J., et al. Maternal outcomes associated with planned primary Cesarean section births compared with planned vaginal births. Obstetrics and Gynecology, 2007; 109(3):66977.

7. World Health Organization. Appropriate technology for birth. *Lancet* 1985; 2: 436-7

8. Fasubaa OB, Ogunniyi SO, Dare FO, et al. Uncomplicated caesarian section; is prolonged hospital stay necessary? East African Medical Journal, 2000 Aug; 77(8):448-51).

9. Umbeli T, Rabaa Abd Elwahab, Salah Ismail, et al. Assessment of discharge after 24 hours following elective caesarean section in Omdurman Maternity Hospital, Sudan, 2010. Sudan JMS Vol. 7, No.4, December 2012.

10. Eckhart Johannes Buchmann, N.Pillay. Early discharge from hospital after caesarian delivery at Chris Hani Baragwanath Hospital, South Africa. South African Medical Journal of Obstetrics and Gynaecology, Vol.17, No.1 (2011)

11. National Institute of Health and Clinical Excellence (NICE). Clinical guidelines 132: Caesarian Section (2004).Issue-Nov.2011.

12.Liu S, Heaman M.Kramer MS, Demissie K, et al. Length of hospital stay, obstetric condition at childbirth, and maternal readmission: a population-based cohort study.AJOG,2002,Sep;187(3)681-7.

13. Early postpartum discharge at a university hospital, Outcome analysis. Journal of Reproductive Medicine, 2001 Jan; 46(1)39-43.

14. Brown S, Small R, Faber B, et al. Early postnatal discharge from hospital for healthy mothers and term infants. Cochrane Database Systematic Reviews, 2002 ;(3):CD002958.

15. RM Hager, AK Dattreit, D. Hoffoss, et al. Complications of caesarian deliveries: rates and risk factors. American Journal of Obstetrics and Gynaecology.2004; 190:428-34.

16. JC Rageth, C.Juzi, H.Grossenbacher. Delivery after previous caesarian: a risk evaluation. Obstetrics and Gynaecology. 1999; 332-7.

17. JU Hilbard, MA Ismail, Y Wang, et al. Failed VBAC: How risky is it? Maternal morbidity. American Journal of Obstetrics Gynaecology 2001; 184:1365-71.

18. Foley M, Alarab M, O'Herlighy C: Neonatal seizures and perinatal deaths: Lack of correlation with caesarian rate: American Journal of Obstetrics and Gynaecology.187:s102, 2002.

19. Nygaard I, Cruikshank DP: Should all women be offered elective caesarian delivery: Obstetrics and Gynaecology. 102:217, 2003(PMID: 12907089).

20. Current's Textbook of Obstetrics and Gynaecology. 11th Edition.

22. Duffy P. Maternal and perinatal infection-bacterial In: Gabbe SG, Niebyl JR, and Simpson JL, eds.Obstetrics: Normal and problem pregnancies, 5th edition, Philadelphia, PA.Churchill Livingstone; 2007:1242.

23. Proposed New Risk Stratification Schema: Infectious risk following caesarian delivery. According to National Healthcare Safety Network-US.

25. Shorten A. Australian Health Review, 1995; 18(2):19-39.

26. Scott A. Shieu A, Farnworth MG. The value of early discharge: dispelling some myths. Australian Health policy, 1993, Dec; 26(2):81-91.

27.Shi Wu Wen, MB, PhD, Shiliang Liu, MB, PhD, Sylvie Marcoux, MD, PhD, et al . Trends and variations in length of hospital stay for childbirth in Canada. CMAJ, 1998; 158:875-80.

28..Kelly Conroy, MD, Angela F Koenig, BA, Yan Hong Yu, MD, PhD, et al. Infectious morbidity after caesarian delivery: 10 strategies to reduce risk.

29. ACOG, Use of prophylactic antibiotics in labour and delivery, Practice Bulletin No. 120, June 2011, US.

30.Tita AT, Rouser DJ, Blackwell S, et al. Emerging concepts in antibiotics prophylaxis for caesarian delivery, a systematic review. Obstetrics Gynaecology, 2009; 113:675-682.

31.Leary Quin A, Koepsell P, Hauer S. Breastfeeding incidence after discharge and factors influencing breastfeeding cessation. Journal of Obstetrics Gynaecology-Neonatal Nursing 1997; 263289-94.

32. Pivet Mitt, Katrin N, Aira. Surgical site infections in an Estoman University Hospital.   Post-discharge surveillance and analysis of risk factors. Infection Control and Hospital Epidemiology, Vol 27, No.5.

33. Yalcin et al. Post-operative wound infections. J Hosp. Infect 1995; 29: 305-309.

34. Noy D, Creedy D. Post-discharge surveillance of surgical site infections: a multi-method approach to data collection. Am J Infect Control 2002; 30:458-475.

35. Smyth ET, Emmerson AM. Surgical site infection surveillance. J Hosp Infect 2000; 45:173-184.

36. Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999; 20:250-278.

DATA COLLECTION TOOLS

QUESTIONNAIRE
BIODATA (Fill in the information from patient's records)

DATE: ____/____/_____

SERIAL NUMBER: _____

FILE NO: _____

DISCHARGE PROTOCOL: 1.DAY 2 _____ 2.DAY 3_____

STARTING TIME(C/S) _____FINISHING TIME_____ ACTUAL DISCHARGE
DAY_____

WEIGHT_____   HEIGHT_____   BMI_____

VITAL SIGNS: BP_____ PR_____ RR_____ TEMP_____

FOLLOW-UP TELEPHONE NUMBER: _____

**SECTION A: SOCIODEMOGRAPHIC DATA (Questions addressed to participant-fill in
or tick appropriately)**

⬜⬜

1. What is your age in years?

2. What is your marital status?

    1. ⬜ Single   2. ⬜ Married/co-habiting

    3. ⬜ Separated/divorced   4. ⬜ Widowed

3. What is your education level?

    1. ⬜ None   2. ⬜ Primary   3. ⬜ Secondary

    4. ⬜College / University

4. What is your employment status?

    1. ⬜ Unemployed/ housewife   2. ⬜ Self employed   3. ⬜ Salaried
employment

    4. ⬜ Others/ specify_____

5. What is your religion?

    1. ⬜ Muslim   2. ⬜ Protestant

3. ☐ Catholic

4. ☐ Traditional   5. ☐ Others specify _____

SECTION B: REPRODUCTIVE HISTORY (Fill in the information retrieved from participant)

1. Number of previous pregnancies delivered after 5 months (20 weeks) including the current

 pregnancy.   ☐☐

2. Number of previous pregnancies lost before 5 months (abortions)?   ☐☐

3. Number of living children   ☐☐

4. Previous pregnancy outcomes

Year	Gestational age	Mode of delivery (Normal/C/s	If caesarian, emergency/elective?	Indication for C/s	Sex	Birth weight	Alive/Not?

4. Sex of the living children

   a) Number of boys   ☐☐

   b) Number of girls   ☐☐

5. Previous surgeries

Year	Type of surgery

SECTION C: CURRENT PREGNANCY DATING/ANTENATAL PROFILE (Fill in the information from participant's clinical records)

1. The date of the first day of the last menstrual period

    1. _____/_____/_____

    2. Not known

2. Gestational age of the current pregnancy in weeks

3. Antenatal profile

Blood group_____   HIV Status_____   Hemoglobin_____   VDRL_____

SECTION D: CURRENT PREGNANCY OUTCOME (Fill in the information from participant's clinical records)

1. Type of caesarian delivery (Tick appropriately)

Elective	
Emergency	

2. Indication

3. Outcome

Sex	APGAR Score	Birth weight	Clinically stable

4. Significant Intraoperative findings

_____

5. Estimated blood loss_____

SECTION E: FOLLOW-UP QUESTIONNAIRRE AT DISCHARGE (2, 3 DAYS). (Fill in the information following an interview with the participant at discharge)

1. Vital signs (Indicate parameters):

BP_____PR_____ RR_____TEMP_____

2. Are you experiencing any of the following? (Answer yes/no).

 a. Purulent discharge from the wound: _____
 b. Bleeding from the wound: _____
 c. Excessive pain at the wound site(rating>5): _____
 d. Deferred discharge: _____
  (Reason for
  deferral)_____
  _____

 e. Baby's discharge deferred: _____

  (Reason for
deferral)_____
_____

3. What is your pain level, using the number scale? (Score of 0-10: 0-for no pain, 10 for the worst pain imaginable)

  _____

4. Were you satisfied with the discharge protocol you had? (Select if Day 2 or Day 3)

    1. ☐ Yes   2. ☐ No

  a) If **YES,** why?
    o Reduced hospital stay
    o Reduced cost
    o Other reason

    _____
    _____
    _____
  b) If **NO,** why?

_____
_____

5. Would you choose the same discharge timing you had or you'd prefer the other? (Answer yes/ no and give a brief explanation why).

_____

_____

6. Would you recommend the same to another person undergoing the same procedure?

_____

SECTION F: FOLLOW-UP QUESTIONNAIRRE AT TWO WEEKS (Fill in appropriately during phone interview with participant)

1. Did you experience any of the following? (Answer yes/no).

    e. Purulent discharge from the wound: _____
    f. Bleeding from the wound: _____
    g. Excessive pain at the wound site(rating>5): _____
    h. Readmission to hospital: _____
      (Reason for
      readmission)_____

      _____

    e.   Admission of your baby to hospital: _____

       (Reason for
admission)_____

_____

1. Were you satisfied with the discharge protocol you had? (Select if Day 2 or Day 3)

           1. ☐ Yes   2. ☐ No

      c) If **YES,** why?
         o Reduced hospital stay
         o Reduced cost
         o Other reason

              _____
              _____
              _____
      d) If **NO,** why?

_____
_____

2. Would you choose the same discharge timing you had or you'd prefer the other? (Answer yes/ no and give a brief explanation why).

_____

_____

3. Would you recommend the same to another person undergoing the same procedure? (Answer Yes/No)

_____

STUDY PARTICIPANT CONSENT FORM
COMPARISON OF CLIENT SATISFACTION AMONG PATIENTS RANDOMISED TO EARLY VERSUS LATE DISCHARGE AFTER UNCOMPLICATED CAESARIAN DELIVERY AT AIC- KIJABE HOSPITAL

Investigator

Name	Qualification	Institution	Department	Position
Dr. Mameti Lilian	MBChB, MMed	UoN/KNH/KH	Obstetrics and Gynaecology	Resident

Emergency telephone number:

Dr. Mameti Lilian, University of Nairobi, Tel. 0723 989 643

Investigator's statement

I am asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about what you will be asked to do, the risks, the benefits and your rights as a volunteer, or anything about the research that is not clear in this form. When all your questions have been answered, you can decide if you want to be in this study or not. This process is called "informed consent".

Purpose and benefits

The study seeks to determine patient satisfaction following early discharge (two days) after uncomplicated caesarian delivery among women and the associated complications. Patients randomized to the day 2 discharge will have a chance to have an earlier discharge hence the choice of reduced hospital stay and probable reduced cost. Those randomized to the day 3 discharge protocol will also have been discharged in accordance to the current standard hospital discharge protocol.

If the participant is not fit for discharge at the assigned time, the discharge will be deferred with the intention to treat. All participants will be given standard management according to the hospital management protocols. The results of the study, if favorable, will be useful in changing policies in settings where patient numbers are overwhelming hence the need to discharge patients early after uncomplicated caesarian delivery. It will also benefit patients desiring early discharge for their own satisfaction as well as reducing the hospital costs.

Procedures

If you agree to participate in this study, you will be asked questions after consenting and receiving clinical care. You will be asked questions about yourself, your past pregnancies and their outcomes and also about your current pregnancy. We will also access your medical records to obtain information about you present clinical condition. After 6 hours post-operatively, you'll be assessed and randomized to one arm of discharge: day 2 and day 3. This will be an un-blinded study whereby you'll know immediately to which arm you've been allocated. The second postoperative day will be defined as day 2 on the postnatal morning round, from date of delivery. This corresponds to surgery to discharge interval of 36-60 hours. (Day 1->12-24 hours, Day 2 >24-48 hours and Day 3->48-72 hours). Day 3 is the standard discharge protocol at the Kijabe Hospital.

Follow-up procedures

Those who accept to participate in the study will be followed up till discharge. They will be reviewed at discharge and thereafter at 14 days with a telephone interview to assess for any complications.

Risks, stresses or discomfort.

Some of the questions asked will be of personal nature. However, you are encouraged to answer them all to aid in strengthening the study. The questions will be asked in a private environment and confidentiality will be assured at all times to ensure your comfort.

Participation in the study will require you to commit your time. Completing the questionnaire will take 10-20 minutes.

Cost

The cost of standard care of the participant while at the hospital will be incurred by the client herself. However the follow-up interview costs will be incurred by the principal investigator.

Confidentiality

Your confidentiality will be maintained at all times. The questionnaires will not have any names but will be assigned identifiers. Only the investigator, the University of Nairobi ethics and

research committee and Kijabe Hospital ethics and research committee will have access to information about you.

There shall be no mention of names or identifiers in the report or publications which may arise from the study. The information obtained will be used only for the purpose of the study.

You may withdraw from the study or refuse to answer any of the questions asked at any time without loss of benefit or penalty. Your participation in the study is voluntary and will be highly appreciated.

If you have any questions regarding the study, contact Dr. Lilian Mameti via 0723-989643.

In case of any ethical concerns please contact:

    The Chairman, KNH/UON – Ethics and Research Committee

    Hospital Road along Ngong Road

    P.O BOX 20723, Nairobi (CODE 00202)

    Telephone number (+254-020)2726300 ext 44355

    Chairperson: Proffessor K.M. Bhatt

    Contact person: Esther Wanjiru Mbuba

    Email: uonknh_erc@uonbi.ac.ke

CONSENT TO PARTICIPATE IN THE STUDY
<u>Subject's statement</u>

This study has been explained to me. I volunteer to take part in this research. If I have questions later on about the research I can ask the investigator above. If I have questions about my rights as a research subject, I can call the University of Nairobi Ethics and Research Committee at 2726300. I will receive a copy of this consent form.

Signature of subject_____ Date_____

Left thumbprint of subject_____ Date_____

Name of subject_____

Signature of witness (If thumbprint used) _____

Name of witness_____

University of Nairobi Ethics and Research Committee

Hospital Road along Ngong Road

P.O. Box 20723, Nairobi

Telephone 2726300

Chairperson: Proffessor K.M. Bhatt

Copies to: 1. Subject   2. Investigator's file