



**ADDIS ABABA UNIVERSITY**  
**COLLEGE OF HEALTH SCIENCES**  
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**COMPARISON OF ONE DAY-DOSE VERSUS MULTIPLE DAY  
ANTIBIOTIC PROPHYLAXIS IN PREVENTING POST  
CESAREAN SECTION INFECTION: A NON-INFERIORITY  
PROSPECTIVE COHORT STUDY, 2015/16.**

By

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## **ACRONYMS AND ABBREVIATIONS**

CDC-----Center for Disease Control and prevention

CI----- Confidence interval

SSIs-----Surgical Site Infections

UTI-----Urinary Tract Infection

RRR-----Relative Risk Ratio

C/S----- caesarean section

OR----- Operation room

PO----- per os

## Abstract

**Background:** According to the Center for Disease Control and prevention, surgical site infections are classified as being incisional and organ space that must develop within 30 days of operation.

**Objective:** The objective of this research was to assess the effectiveness of taking 1day against 7 days antibiotic prophylaxis on maternal infection after cesarean section

**Methodology:** A prospective follow up study was conducted in which 209 women were grouped into exposed and non-exposed arms based on PO antibiotics given on discharge date. Each patient was observed in the post-operative ward and was followed back to home till 30 days from the operation day. Four hourly temperatures was taken as long as they stay in the hospital. Fever developing or persisting for 48 hours of  $>37^{\circ}\text{c}$  after surgery was included as the febrile morbidity. Wound was examined on 3rd, 7th, 14th, 21st.and 30 rd. Comparisons between groups was obtained by x2 test. Stratified analyses, survival analysis and Cox regression was used to identify risk factors for infection. Results were reported with 95% confidence interval (CI).

**Result:** in the 7 day antibiotics group 51 mothers (50%) had ruptured membranes compared with 40 (37.4%) in the 1 day antibiotics group but it was not significant at 5% level of significance ( $p = 0.06$ ). The mean duration of operation room stay was  $34.50 \pm 6.265$  minutes in the exposed group and  $35.14 \pm 5.89$  minutes in an unexposed group ( $p = 0.30$ ). During the study period, a total of 30 mothers (14.3%) infected giving an infection incidence rate of 5.1 per 1000 person-days, 179 (85.6%) were censored well, while total of 8 (3.8%) were lost to follow up. For 7 days prophylactic groups, 14 infection (13.2%) were reported, giving an overall infection rate of 4 per 1000 person-days, while in a 1 day prophylactic antibiotics group 16 (15.5%) infection were reported giving a incidence rate of 5 per 1000 person-days( $P<0.8$ ). In conclusion, our study showed that there was no significant difference between the two groups in terms of single day doses versus multiple day's doses of antibiotic prophylaxis against postoperative infection in emergency caesarean section. So I recommend physicians to prescribe 1 day regimen prophylactic antibiotics.

# 1. Introduction

## 1.1 BACKGROUND

According to the Center for Disease Control and prevention (CDC) Surgical site infections are classified as being incisional and organ space that must develop within 30 days of operation. Incisional SSIs are further divided into those involving only skin and subcutaneous tissue (superficial incision SSI) and those involving the deeper soft tissue of the incision (deep incisional SSI). In addition, it must meet at least one of the following: purulent drainage from the superficial incision; organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; and/ or at least one of the following signs or symptoms of infection-pain or tenderness, localized swelling, redness or heat, and the superficial incision is deliberately opened by surgeon unless the incision is culture-negative; or diagnosis of superficial incisional SSI by the surgeon or attending physician. Organ/space SSIs involve any part of the anatomy (e.g. organ/space) other than incisional body wall layers that was opened or manipulated during an operation.[1, 2]

Since 1985, the international healthcare community has considered the ideal rate for caesarean sections to be between 10% and 15%. Since then, caesarean sections have become increasingly common in both developed and developing countries. When medically justified, a caesarean section can effectively prevent maternal and perinatal mortality and morbidity. However, there is no evidence showing the benefits of caesarean delivery for women or infants who do not require the procedure. As with any surgery, caesarean sections are associated with short and long term risk which can extend many years beyond the current delivery and affect the health of the woman, her child, and future pregnancies. These risks are higher in women with limited access to comprehensive obstetric care.[3]

Infections (usually after childbirth) are the second among the major complications that account for nearly 75% of all maternal deaths. Among surgical patients in obstetrics, surgical site infections (SSIs) are the most common nosocomial infections, accounting for 38% of hospital acquired infections.[4]

Through this thesis we will evaluate whether triple regimen prophylactic antibiotics is equally important in preventing post cesarean section infection as compared to full seven days treatment.

## 1.2 Statement of the problem

Following cesarean delivery (CD) maternal mortality and morbidity may result from a number of infections including endometritis, urinary tract infection (UTI) and surgical site infection (SSI). By the 1990's, 27 million surgical procedures were performed annually in the USA, and SSIs accounted for approximately 15% of all nosocomial infections. Moreover, 77% of deaths in surgical patients with nosocomial SSIs were related to infection. While a proportion of SSIs is inevitable, adherence to evidence-based guidelines, including prophylactic antibiotics, have been shown to reduce the rate of SSIs after elective surgical procedures. The purpose of antibiotic prophylaxis in surgical procedures is not to sterilize tissues but to reduce the colonization of microorganisms introduced at the time of operation to a level that, the patient's immune system is able to overcome the challenge. It should be noted that prophylactic antibiotics do not need to cover every possible pathogen that may cause infection. Decreasing the bacterial load will usually enable the patient's immunological defense to function adequately. Other factors to consider are low toxicity, safety record and ability to reach an effective concentration in the tissue prior to the procedure. [5].

The widespread use of antibiotic prophylaxis has reduced but not eliminated serious postoperative infections; the average expected SSIs rate being 3-15% after cesarean section. These rates are increased in the presence of other risk factors such as gross contamination of the operative site, prolonged and premature rupture of membranes, obstructed labor, chorioamnionitis, massive obesity, prolonged operative time, emergency operations, altered immune status, which are common in resource poor countries like Ethiopia. Other factors related to the skill of the surgeon like: poor surgical techniques, inadequate hemostasis, and presence of dead space predispose to greater wound infection. On top of these medical illnesses during pregnancy and malnutrition also contribute much to the problem. It has generally been considered that the dosing period of antibacterial drug should be shortened as much as possible in order to prevent the transformation of drug resistant strains. [6-7]

### **1.3. Significance of the study**

Risk of infection in developing countries is more than the developed countries due to malnutrition, anemia, poverty and environmental pollution; poor preoperative preparation, wound contamination, poor antibiotic selection, or the inability of an immune-compromised patient to fight against the infection. Contamination of the wound is present to some extent in all incisions thus adding significant morbidity and mortality. Mainstay of management is prophylaxis which can be achieved by a variety of methods including use of antibiotics. Short courses of prophylactic antibiotics are as efficacious as long courses in preventing postoperative infection. [8] However over use of prophylactic antibiotics can lead to economic burden on our health system as well as development of resistance to the common organisms. Use of single day antibiotic has proven to be effective in preventing wound infection [8].

The prevalence of surgical site infection in pregnant women's in Africa has been studied in different times without addressing single verses multiple day's prophylactic antibiotics effect. In Ethiopia specifically, there are no documented studies on which regimen of antibiotics would be safe for mothers after cesarean section. Thus, the aim of this study was to compare the single verses multiple days of ceftriaxone in preventing infection in patients undergoing emergency caesarean sections in Dilla University Referral Hospital. Understanding of the best regimen is important to set appropriate recommendation to prescribe the prophylactic antibiotics. This will help the mothers from getting prone to drug resistance and economic burden if one day is recommended, but if 7 days is recommended, mothers in 1 day treatment group should get 7 days and decrease morbidity due to post cesarean section infection. It also imposes to establish local guideline on pregnant women undergoing cesarean section. Additionally, this study will provide information on the current incidence and associated factors of post cesarean section infection among pregnant women attending operation room at Dilla University Referral Hospital. The study will also serve as a reference for researchers who are interested to similar study.

## 2. Literature review

Currently it is estimated about 20 million cesarean section (CS) deliveries occur each year in the world. This makes it the most frequent abdominal surgery performed in adults. The number of women having babies born by cesarean section is rapidly growing in a continuous way in both the developed and developing countries. This is happening in developed countries and in Latin America especially in Brazil. [6]

In Ethiopia, the national population based cesarean delivery rate of is 0.6% with variation between the regions from 0.2% to 9% and the overall institutional rate was 18%, which varied between 46% in the private for-profit sector and 15% in the public sector.[7]

Obviously most operations in obstetrics and gynecology involve some degree of bacterial contamination, and are classified as 'clean-contaminated' cases, even when the patient has no preoperative symptoms of active infection. Prior to the current practice of routine prophylactic antibiotics (although it's not well going in our country), postoperative infections were common (range 5–10%, depending on the type of surgery and clinical risk factors). The widespread use of antibiotic prophylaxis has reduced but not eliminated serious postoperative infections, the average expected wound infection rate being 4% in gynecology and 6% after Cesarean sections.[5]

Risk factors include caesarean section done after onset of labour, placement of open drains, obesity, and diabetes. Careful operative technique to avoid hematoma formation, the avoidance of dead space during closure and intraoperative antibiotic prophylaxis are important preventive measures against wound infection. [7]

The diagnosis of postoperative infection is generally made when there is:

- (1) Pain and tenderness in the area contiguous with the infection;
- (2) An oral temperature of  $\geq 38^{\circ}\text{C}$  on two separate occasions at least 6 hours apart, or of  $> 38.5^{\circ}\text{C}$  at any time. In cases of surgical wound infection, skin erythema and/or subcutaneous induration and/or incisional drainage are usually present. In cases of pelvic cellulitis or abscess, extensive induration or a mass, respectively, are usually found on rectovaginal examination. The diagnosis may be supported by leukocytosis of  $> 13\,000/\text{mm}^3$  with  $> 90\%$  bands plus polymorph nuclear

leukocytes. Delayed signs include a positive blood culture or positive culture from the wound, operation site or abscess cavity.[5]

Giving prophylactic antibiotics before cesarean section has been a normal step for cesarean section surgeries as it obviously decreases morbidity rate of maternal infections after operation especially when compared to giving antimicrobials after umbilical cord clamping. Interestingly, giving prophylactic antibiotics before cesarean delivery has no major effects on mothers or newborn babies. [8]

It is recommended that three doses of prophylactic antibiotic are given routinely within 24 hours for pregnant woman undergoing elective or non-elective cesarean delivery. In another word, single dose is given immediately before surgery (at the same time with anaesthesia) and two more doses after operation). This is to ensure achieving enough concentration of tissue at the time of first incision. [9]

Administration after the cord is clamped has been common practice to avoid exposing the newborn baby to antimicrobials, and to prevent compromise to the fetus in the event of maternal anaphylaxis. These issues need to be weighed against the rates of lower maternal infection if prophylactic antibiotic is administered prior to incision of the skin.

Single intravenous dose of a narrow spectrum antibiotic (e.g. cefazolin) should be given before surgery to all women having cesarean section procedure in order to decrease the risk of postoperative infection. [10]

Antibiotic prophylaxis significantly decreases the occurrence of postoperative fever, infection in urinary tract system, wound infection, endometritis and severe maternal infectious complications compared to non-interventional group receiving no antibiotic treatment.[11]

“According to different organizations guidelines, 1-2 gram (g) of cefazolin should be administered intravenously as antibiotic prophylaxis for women undergoing cesarean section. Clindamycin in combination with gentamicin can be given to patients having allergy to penicillins and cephalosporins.[11]

Extended spectrum antibiotic prophylaxis continued after operation was associated with a dramatic decrease in postpartum endometritis (16.9 versus 24.7 percent) and wound infection (0.8 versus 3.6 percent). Follow-up observational studies by the same group affirmed these findings.[11]

Antimicrobial therapy should be given at least sixty minutes before making the skin incision to ensure adequate drug tissue levels.[11]

Worldwide there is no consensus on which antibiotic regimen to give for patients, especially in low-resource settings where surgery is often performed under poor aseptic conditions. A common treatment in sub-Saharan Africa, is a multiple-day regimen of ampicillin and metronidazole for infection prevention. This is against to many high- and middle-resource countries where a single prophylactic dose of antibiotics is common practice. One single intravenous preoperative dose of ampicillin and metronidazole could be just as effective as a multiple day regimen in preventing infections and will reduce costs, improve regimen compliance, lead to improved use of scarce resources and lower the incidence of antimicrobial resistance.[11]

### **3. Objectives**

#### General objective

- ✓ To assess the difference of taking 1 day against 7 days antibiotic prophylaxis on the outcome maternal infection after cesarean section

#### Specific Objective

- ✓ To compare the outcome maternal infection after cesarean section between those who took 1 day antibiotic prophylaxis and those who took seven days.
- ✓ To assess the cumulative incidence of infection

## **4. Materials and Methods**

### **4.1. Study design**

A prospective follow up study was conducted in order to investigate whether there is a difference on the occurrence of post-operative infection among mothers who took antibiotics for one day or 7 days. Surgery was performed by specialist registrar using standard technique. Suture material was vicryl no 1 (polyglycolic acid) for closing the uterus and black silk no 2-0 for skin closure with interrupted stitches. Post operatively wound was cleaned with pyodine solution and antiseptic dressing was applied. Patients were given routine standard post-operative care. Patients in exposed group was given 1gm of ceftriaxone intravenously half an hour before operation then after 12 hours for two consecutive times and patients in group unexposed was given 21 doses, of which 3 doses was 1gm of ceftriaxone intravenously. 1st dose was given 30 minutes before operation while 2nd and 3rd doses was given after 12 hours' followed by 500mg of Cephalexin oral dose for next five days. Each patient was observed in the post-operative ward and was followed back to home till 30 days from the operation day. Four hourly temperatures was taken as long as they stay in the hospital. Fever developing or persisting for 48 hours of  $>37^{\circ}\text{c}$  after surgery was included as the febrile morbidity. Wound was examined on 3<sup>rd</sup>, 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup>.and 30<sup>rd</sup>. days. Wound was inspected for any evidence of superficial or deep infection, pus discharge, abscess formation, wound dehiscence, and hematoma formation. Patients were also assessed for any respiratory, or urinary tract infection (all patients had catheter for 24 hours). Urine examination was done on 3rd post-operative day along with Hemoglobin. The outcome measures was febrile morbidity, wound infection, and wound hematoma, UTI, and wound dehiscence. Success was defined as absence of infection in either group.

### **4.2. Study area**

The study was conducted in Dilla university Referral hospital which is located in Gedeo zone South East of Dilla town and was established in 1976 E.C. It is the only referral & teaching hospital in the south of southern region providing health care services for Gedeo zone administrative area and the residences around including from the boarder of the country. The university hospital is staffed by specialists from different disciplines like surgery, obstetrics and gynecology, pediatrics, internal medicine, and other health practitioners with different qualities. The referral hospital has also academic and supportive staffs and students in practice .The hospital is providing different types of health care services for patients, and serves as training

center for students from different departments in degree and post graduate programs. The Obstetric and gynecologic department is staffed by 3 obstetricians, 7 physicians and 19 midwives having 4 delivery coaches, one operation table, 16 beds for obstetric cases and 26 beds for gynecologic cases. Concerning delivery service the hospital provides delivery service for estimated 3000 cases per year, of all types.

### **4.3. Study population**

#### **4.3.1. Target population**

The source population was all mothers admitted to Dilla university referral hospital following Labor pain.

#### **4.3.2. Study (sampled) population**

The study population was all mothers admitted to Dilla university referral hospital following caesarian section surgery.

#### **4.3.2. Sample population**

The study population was all mothers admitted in the hospital using the following inclusion and exclusion criteria.

### **4.4. Eligibility criteria**

We included patients from the labor ward who had been scheduled for emergency caesarean section and provide written informed consent. Patients with evidence of current infection, that is, with fever, foul smelling discharge, and already taking antibiotics were excluded.

### **4.5. Sample size estimation**

The study was designed to detect about 9 percentage point difference between exposed and unexposed groups assuming a maternal surgical site infection after caesarian section incidence rate of 1% and 10.3% for '1 day' and '7 days', respectively, 5% level of significance and 80% power. A dropout rate of 10% was used to get a representative sample size of 258 study participants (129 exposed and 129 unexposed).[7,13]

### **4.6. Sampling procedures**

The required number of samples was selected by convenience sampling method. Therefore, all eligible mothers admitted in maternity ward at the time of the study period was included in the study until the allocated sample size was reached.

## 4.7. Study variables

### 4.7.1. Dependent variable

Maternal infection after C/S

### 4.7.2 Independent variables;

- ✓ Age
- ✓ Weight
- ✓ Height
- ✓ BMI
- ✓ Monthly income
- ✓ Housing condition
- ✓ Gravidity
- ✓ Duration of labor
- ✓ Time of rupture of membrane

### 4.7.3 Operational definition

- ✓ **Cellulitis** - symptoms with painful and tender wound and erythema and edema beyond edge of incision.
- ✓ **Lost to follow up** – those mothers who were lost from the study after discharge from the hospital in both groups.
- ✓ **Peritonitis** - symptoms: low-grade fever/chills, lower abdominal pain, absent bowel sounds and sometimes rebound tenderness, abdominal distension, nausea/vomiting, anorexia, shock.
- ✓ **Pelvic abscess** - symptoms: lower abdominal pain and distension, persistent spiking fever/chills, tender uterus and sometimes poor response to antibiotics, swelling in adnexa or pouch of Douglas.
- ✓ **Urinary tract infection** – symptoms with flank pain, burning sensation while urination and fever.
- ✓ **Wound abscess** - symptoms: unusually tender wound with bloody or serous discharge.
- ✓ **Wound dehiscence** - the sutures of fascia (and skin) burst open.

#### **4.9. Data quality management**

To improve the quality of the data, the data collectors has been trained for 1 day who were 1 diploma midwife, 1 diploma clinical nurses and. 2 health extension workers. They were closely supervised by the principal investigator. A structured, pretested and interviewer administered questionnaire were employed to obtain data on demographic and socio-economic variables, maternal characteristics and other relevant information. The questionnaire used in the study was in English. The questionnaire was filled by the above trained professionals.

Each completed questionnaire was checked to ascertain whether all questions are properly filled or not and necessary correction was also made at spot. After the data collection; it was checked for its completeness and internal consistency. It was then enter, cleaned with SPSS version 20.

#### **4.10. Data Analysis procedures**

Descriptive statistics such as mean, median and percentage was used to summarize and present the information. Comparisons between groups was obtained by  $\chi^2$  test, Stratified analyses, survival analysis and Kaplan Meier was used to identify difference between groups for infection. Results was reported with 95% confidence interval (CI).

#### **4.11. Ethical considerations**

Ethical clearance was obtained from the Research and Ethics Committee at the School of Public Health, college of health science, Addis Ababa University. A formal letter of support was submitted to Dilla University Referral Hospital to get permission and facilitate the work. Data was collected with the informed written consent of study participants. Participants were well-versed about the objectives of the study, how long it takes to fill the questionnaire and their right to withdraw from the study if they decide to do so.

Questionnaires were anonymous and participants were reassured of the confidentiality of the information they provided. Privacy of the participant was maintained. The study aimed for participant beneficence and by no means harms them. The services given to the participant was not interrupted whether they were willing to participate in the interview or not.

## **5. Results**

### 5.1. Base line Characteristics of Mothers

A total of 406 pregnant women were assessed for eligibility between December 2015 and May 2016 in Dilla university referral hospital. Of these 251 participants were excluded (240 participants didn't meet the inclusion criteria, 3 participants declined to participate and 8 participants were lost to follow up). Therefore 209 women were grouped into exposed and non-exposed arms based on PO antibiotics given on discharge date (Fig. 1).

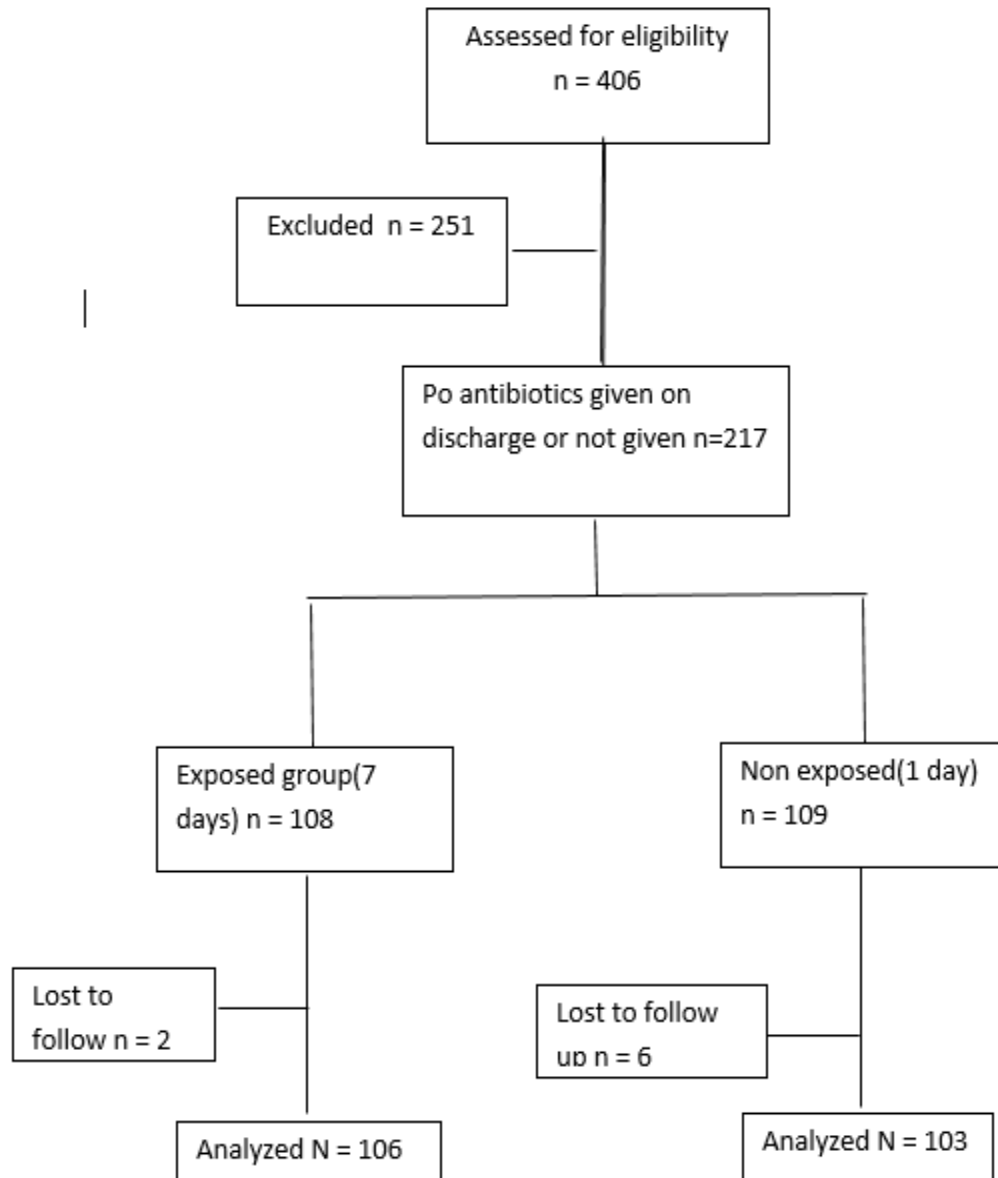


Figure 1. Flow diagram of cohort profile, comparison of one day-dose versus multiple day antibiotic prophylaxis in preventing post cesarean section infection, Dilla Ethiopia in 2008

Table1. Demographic and clinical characteristic of the study groups comparison of one day-dose versus multiple day antibiotic prophylaxis in preventing post cesarean section infection, Dilla Ethiopia in 2008 E.C.

Variables	All subjects (209)	1 day (%)	7 days (%)	p value
Age ( $\bar{X} \pm SD$ )	25.58 ± 4.8	25.51 ± 4.95	25.65 ± 4.66	0.57
Weight in kg( $\bar{X} \pm SD$ )	68.71 ± 3.11	68.4 ± 3.34	69.05 ± 2.83	0.91
Height( $\bar{X} \pm SD$ )	1.62 ± .045	1.63 ± 0.045	1.62 ± 0.045	0.79
BMI( $\bar{X} \pm SD$ )	25.94 ± 1.64874	25.73 ± 1.69	26.16 ± 1.57	0.60
Housing condition				
Separate kitchen with bed	71 (34.0)	33 (30.6)	38 (37.6)	0.28
Kitchen inside the house	138(66.0)	75 (69.4)	63(62.4)	
M. Income( $\bar{X} \pm SD$ )	2217.22 ± 676.52	2207.41 ± 620.62	2227.72 ± 734.59	0.10
Gravidity (no) ( $\bar{X} \pm SD$ )	3.89 ± 3.335	3.77 ± 4.157	4.03 ± 2.147	0.62
D. of Labor (hr.) ( $\bar{X} \pm SD$ )	11.10 ± 4.614	11.15 ± 5.07	11.05 ± 4.090	0.06
Membrane rupture				
Yes	91 (43.5)	40 (37.4)	51 (50.0)	0.06
No	118 (56.5)	67 (62.6)	51 (50.0)	
Hematocrit( $\bar{X} \pm SD$ )	39.19 ± 2.705	38.92 ± 2.565	39.48 ± 2.831	0.02
Stay in OR (min) ( $\bar{X} \pm SD$ )	34.83 ± 6.072	35.14 ± 5.899	34.50 ± 6.265	0.30

Table 1 compares the baseline socio-demographic and clinical characteristics of those who took one day prophylactic versus 7 days prophylactic antibiotics. Demographic and clinical characteristics of both groups were comparable, except for a difference in the occurrence of ruptured membranes before surgery (Table 1). In the exposed group 51 mothers (50%) had ruptured membranes compared with 40 (37.4%) in the unexposed group but it was not significant

( $p = 0.06$ ). The mean duration of OR stay was  $34.50 \pm 6.265$  minutes in the exposed group and  $35.14 \pm 5.89$  minutes in an unexposed group. ( $p = 0.30$ ).

No significant difference was observed between both groups. No maternal deaths occurred.

There were no women who has history of past chronic illness. None of the mothers in either got their child's admitted to neonatal ICU. No cases of endometritis and peritonitis were observed and 17 cases of urinary tract infection occurred.

## **5.2. Infection**

The cohort contributed a total of 5849 person-days of follow up with 2932 person-days for 7 days prophylactic antibiotics group and 2917 person-days for 1 day prophylactic antibiotics groups. The overall median follow-up was 30 days (maximum 30 and minimum 7 days). The exposure specific median follow up was the same in both arms with the overall one.

During the study period, a total of 30 mothers (14.3%) infected giving an infection incidence rate of 5.1 per 1000 person-days, 179 (85.6%) were censored, while total of 8 (3.8%) were lost to follow up. Of all mothers, the majority 106 (50.7%) were those who took 7 days prophylactic antibiotics. For 7 days prophylactic groups, 14 infection (13.2%) were reported, giving an overall infection rate of 4.8 per 1000 person-days, while in a 1 day prophylactic antibiotics group 16 (15.5%) infection were reported giving a incidence rate of 5.2 per 1000 person-days. The 30 days survival probability was not significantly different between the groups with 7 days prophylactic antibiotics and 1 day prophylactic antibiotics,  $P < 0.8$  (Fig.2).

The hazard ratio is 1.092 at 95% CI = (0.533,2.237) and this indicates that the probability of getting infection(hazard) is increased by 9.2 % with 7 days prophylactic antibiotics versus 1 day prophylactic antibiotics at any time given over 30 days, however the result is not statistically significant.

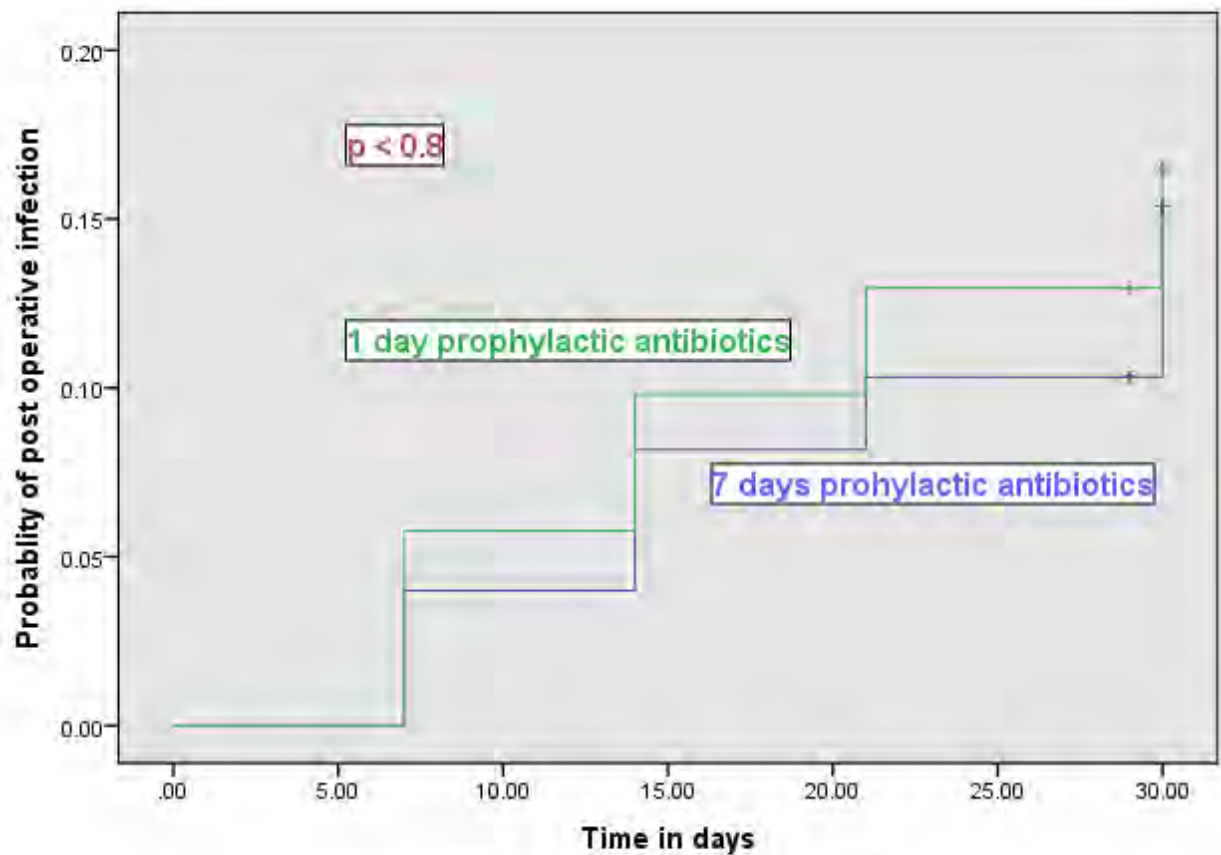


Figure 2 Kaplan-Meier cumulative incidence of Post caesarean infection.

## 6. Discussion

Postoperative wound infection in obstetrics is higher as compared to other specialties because 80-90% patients are unlooked and have poor socioeconomic status. Therefore, prevention becomes very important in these patients. For this purpose, prophylactic antibiotics are recommended but over use of antibiotics results not only in the emergence of resistant organisms but also causes great economic burden (12).

On the health system according to the no inferiority criteria that were set before the trial, this study shows that a single day of prophylactic antibiotics is no inferior to a regimen of multiple doses (7 days) in preventing post cesarean infections in a low-resource setting. The reduced quantity of prophylactic antibiotics will reduce the costs of treatment and workload for medical

staff. It will also increase the patient compliance and might protect against antimicrobial resistance.

In our study the majority of post cesarean infectious complications consisted of wound infections after discharge which is against a trial done in Tanzania where they found most of their infection case during hospital stay. As they themselves explained, this might be due to difficulty of the study setting in rural Tanzania to assess long term outcomes.[20]

The strength of this study is the study design, a follow up study in low-resource settings and the fact that it assessed the same type of antibiotics in a single or multiple-day regimen in emergency cesarean sections apart from the above mentioned one. But in the contrary most of the literatures done on the same area give emphasis on different type of antibiotics regimens. A randomized controlled trial conducted in Mozambique compared a single preoperative dose of gentamycin and metronidazole vs. a 7-day post cesarean scheme consisting of a combination of crystalline penicillin, metronidazole and erythromycin. The two regimens were clinically equivalent in their setting (13). Alekwe in Nigeria compared a single dose of ceftriaxone with a triple drug regimen consisting of Ampiclox, gentamycin and metronidazole. This study concluded that a single dose was as effective as the multiple combination dose (14). In Nepal, Shakya and Sharma conducted research to compare intraoperative single-dose cefazolin and metronidazole with a multiple-day regimen of the same antibiotics. This group did not find a difference between the two regimens (15). More recently, a study performed by Lyimo et al. In an urban setting in Tanzania, compared a single dose of gentamycin and metronidazole with the same preoperative regimen followed by multiple doses of metronidazole. The authors recommend the administration of a single dose of these studies only included elective cesarean sections or excluded patients with ruptured membranes or prolonged labor, which do not reflect the average daily practice in a rural low-resource setting(16).

Nelson et al compared one day of antibiotic prophylaxis with seven days of antibiotic prophylaxis and found no statistically significant difference between the two groups in terms of wound infection (17) which has the same result with this study. Moreover shortening the duration of therapy reduces the medical cost and prevents the microorganism resistance. A study has shown that the single dose of antibiotic prophylaxis can reduce the antibiotic cost by 75-80 %( 18). In the current study there were 17 cases of urinary tract infection in both groups but

Brood et al reported reduction in the number of urinary tract infection in his study with single dose regimen (19).

## **7. Strength and limitation of the study**

The strength for this study were we followed mothers back to their home, presence of a project from WHO which works on community obstetrics care and the limitations was shortage of time to address large sample size.

## **8. Conclusion and Recommendation**

In conclusion, our study showed that there was no significant difference between the two groups in terms of single day doses versus multiple day's doses of antibiotic prophylaxis against postoperative infection in emergency caesarean section. So my first recommendation goes to interested researchers to do the same study with large sample size or do a clinical trial and revise a guideline for mothers undergoing cesarean section. The second is to Dilla university referral hospital gynecology and obstetrics department to start prescribing 1 day regimen prophylactic antibiotics for all mothers undergoing c/s except for those with indication for full treatment. There will also be a room for researchers to see the effect of single dose with multiple doses and the best time of administering prophylactic antibiotics.

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## **Annex I. Consent Form**

Addis Ababa University College of health science school of public health Department of preventive Medicine.

Serial number \_\_\_\_\_, Name/Initials \_\_\_\_\_, Age \_\_\_\_\_

### Background/Purpose

We are carrying out a study in mothers with caesarian section presenting to maternity ward ward, the purpose is to find out ways of improving the management of maternal infection after caesarian section.

The study will be conducted during the period of your admission and after discharge till 30 days after surgery. We plan to enroll a total of 258 mothers.

If you agree to join the study, the following will occur:

The research investigator will ask you about the socio demographic, pre-surgery, post -surgery and follow up questions. The research investigator will be allowed to record information from your medical records.

Follow up visits after your discharge will allow the research investigator to review your status after surgery.

### Risks/Discomfort

There is risk experienced with routine clinical care. Loss of confidentiality may also occur.

## Benefits

Laboratory tests in addition to the tests routinely done in the ward will be done at no cost to you. This will include urine analysis, Test to find out presence or absence of germs causing febrile morbidity, measurement. The results will be available through the research investigator who will be available in the hospital.

We intend to this information will help provide better health care for mothers like yours.

## Assurance of confidentiality

Every effort will be made to keep records as confidential as possible within limits of the law. All information gathered and tests done will be considered confidential, Research records will be stored in locked files and only authorized persons will have access. The information that identifies you will not be included in the reports or written articles. The files may be made available to study monitors and ethic monitors at Addis Ababa University College of health science for review of study procedures.

## Alternatives to participation

Your participation in this study is completely voluntary. You are free to decide not to participate in any of or all parts of the study (interview or sample collection or follow up period) at any time. If you do not participate, it will not affect your child's medical care, now and in the future.

## Cost/compensation

There will be no extra cost for you to participate in this study. You will not be paid to participate in this study.

## Medical care for injury or illness

The procedure used in this study is the same as routine medical care. Your risk of illness is minimal.

However, if you are injured by participating in the study, no money will be available to pay you.

But, treatment and advice will be made available. If you experience any problems related to the study, please report immediately to the persons listed in the following section.

Questions/ point of contact

If you have any questions, please ask. We will do our best to answer them. If you have additional questions or if you need to discuss any other aspects of the study, please feel free to contact the following:

For questions about the study, contact Tizalegn Tesfaye. Mobile 0910894884 Or Prof. Alemayehu Worku 0911405652

## **Annex II. QUESTIONER**

### **I. Sociodemographic data**

1. Age -----
2. Weight -----
3. Height -----
4. Monthly income -----
5. Housing condition -----

### **II. Pre – operation time**

1. Date of admission.....
2. Time of first dose antibiotics given
3. Gravity-----
4. Duration of labor-----
5. Do you have history of chronic disease?
  1. Yes            2. no
6. If your answer is yes for q. 3. What kind of disease do have?
7. Does the membrane ruptured?
  - a. Yes
  - b. No
8. Time of rupture of membrane.....

9. Pre- operation haematocrit level-----

### III. Intra – operation time

1. Length of stay in OR-----
2. Loss of blood in OR-----

### IV. Follow up period

1. Date for the follow up days

Days	Date
3 <sup>rd</sup>	
7 <sup>th</sup>	
14 <sup>th</sup>	
21 <sup>st</sup>	
30 <sup>th</sup>	

2. Admission of a new born baby to neonatal ICU

1. Yes
2. No

3. Days of hospital stay \_\_\_\_\_

4. Fever > 38 °c \_\_\_\_\_

5. Pussy discharge\_\_\_\_\_

6. Sever Pain on wound site after 3<sup>rd</sup> day

7. Flank pain\_\_\_\_\_

8. Was there any Sign and symptoms of hypothermia?

1. Yes
2. No

9. If your answer is yes for q. 1. What was it?-----

-----  
-----

10. Was there any Sign and symptoms of urinary tract infection?

1. Yes
2. No

11. If your answer is yes for q. 3, What was the Signs and symptoms?-----

-----

12. Check the following for the presence of wound infection?

1. Yes            2. No

**Table 5.** Wound infection follow up

No.	Sign/ Symptom	Yes					No				
1	No sign of infection: wound closed without gaping										
2.	No signs of infection, but some gaping in wound										
3.	Presence of serous discharge										
4	Presence of erythema										
5	Presence of purulent discharge										
6	Presence of cellulitis, symptoms: painful and tender wound and erythema and edema beyond edge of incision										
7	Wound abscess, symptoms: unusually tender wound with bloody or serous discharge.										
8	Peritonitis, symptoms: low-grade fever/chills, lower abdominal pain, absent bowel sounds and sometimes rebound tenderness, abdominal distension,										

	nausea/vomiting, anorexia, shock										
9	Pelvic abscess, symptoms: lower abdominal pain and distension, persistent spiking fever/chills, tender uterus and sometimes poor response to antibiotics, swelling in adnexa or pouch of Douglas										
10	Wound dehiscence: the sutures of fascia (and skin) burst open										

13. Have she ever been diagnosed with uterine infection (endometritis)?

1. Yes            2. No

**Table 6.** Follow up information

Characteristics	Days				
	3 <sup>rd</sup>	7 <sup>th</sup>	14 <sup>th</sup>	21 <sup>st</sup>	30 <sup>th</sup>
Fever					
Pus discharge from the wound site					
Sever pain on wound site					
Color change on wound site					
Flank pain					
Burning sensation during urination					
Foul smelling discharge from					

vagina					
Pelvic pain					
Admission to neonatal ward					