
**“AZITHROMYCIN AS AN ADJUNCT
PROPHYLACTIC DRUG FOR PREVENTION
OF SURGICAL SITE INFECTION IN
CAESAREAN DELIVERY-A RANDOMIZED
CONTROL TRIAL”**

By

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LIST OF ABBREVIATIONS USED

| | |
|--------|--|
| ACOG - | American College of Obstetrics and Gynaecology |
| ANC - | Antenatal Care |
| ASA - | American Society Of Anesthesiologists |
| AZI - | Azithromycin |
| BMI - | Body Mass Index |
| CD - | Caesarean Delivery |
| CDC - | Centre Disease Control |
| FDA - | Food and Drug Administration |
| GDM - | Gestational Diabetes Mellitus |
| IV - | Intravenous |
| LMIC - | Low and Middle Income Countries |
| MRSA - | Methicillin Resistant Staphylococcus aureus |
| NFHS - | National Family Health Survey |
| NICU - | Neonatal Intensive Care Unit |
| PROM - | Premature rupture of membranes |
| RCT - | Randomized Controlled Trial |
| SOGC - | Society of Obstetrics and Gynaecology, Canada |
| SSI - | Surgical Site Infection |
| UTI - | Urinary Tract Infection |

ABSTRACT

INTRODUCTION:

Caesarean section rates have increased worldwide and have been predicted to continue increasing over the current decade. At the present moment, caesarean section is responsible for almost twenty-one percent of all births, which is equivalent to nearly one birth out of every five women. A caesarean section is one of the most common surgical procedures that has been linked to an increased risk of surgical site infection. The purpose of the study is to study whether addition of azithromycin to standard antibiotic prophylaxis before skin incision would decrease the incidence of surgical site infection after caesarean section.

MATERIAL AND METHODS:

The present study was carried out in the Department of Obstetrics and Gynecology, KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi from January 2023 to January 2024. Pregnant women at Gestational age of 28 weeks or more, who are to undergo emergency caesarean delivery who have given informed consent were recruited. Group A received the standard antibiotic prophylactic drug –injection ceftriaxone 1g IV. Group B received the standard antibiotic prophylactic drug –Injection ceftriaxone 1g IV along with injection Azithromycin 500mg IV(given within 60 minutes prior to incision).The primary outcome of surgical site infection was studied and Compared between 2 groups.

RESULTS:

The incidence of surgical site infection in the control group was 35.9% which was significantly decreased in the intervention group to 13.2%.

Surgical site infections are categorized as Superficial, Deep, or Organ space. In Group A, there are 48 superficial infections (85.7%) and 8 deep infections (14.3%). In Group

B, there are 5 superficial infections (71.4%) and 2 deep infections (28.6%). The proportion of patients with surgical site infections were observed more in group A, however , showing no statistical significance. In this study, mean postoperative stay is 5.72 days with a standard deviation of 1.617 in Group A and 5.31 days with a standard deviation of 1.176 in Group B. The mean postoperative stay is slightly shorter in Group B, suggesting a potential benefit of Azithromycin in reducing hospital stay duration. The proportion of readmissions is higher in Group A, suggesting a potential benefit of Azithromycin in reducing readmissions.

CONCLUSION:

In this Randomized Controlled Trial conducted at a tertiary care centre ,Belagavi involving 256 participants over a span of one year ,it was concluded that adjunctive azithromycin administration decreases post-operative infectious morbidity in emergency Caesarean deliveries when administered within 60 minutes prior to skin incision.

KEYWORDS: Caesarean delivery, surgical site infection, Azithromycin

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INTRODUCTION

Caesarean section rates have increased worldwide and have been predicted to continue increasing over the current decade. At the present moment, caesarean sections are responsible for almost twenty-one percent of all births, which is equivalent to nearly one birth out of every five women. The Dominican Republic has the highest rate of caesarean sections, which account for 58.1% of all births, while Chad has the lowest rate, which equals 1.4%.¹

When compared to their counterparts in the northern and eastern regions of the country, the rate of caesarean sections was significantly higher in the southern states of India. Telangana had the highest rate of caesarean sections at 60.7%, while Nagaland had the lowest rate at 5.2%.² Nearly sixty to seventy percent of all deliveries that have taken place at Dr. KLE's Prabhakar Kore Hospital and Medical Research Centre, Belagavi, over the course of the past three years have been brought about by means of a caesarean section. Surgical site infection (SSI) after caesarean section indeed represents a significant concern for delivering mothers. These infections can occur within 30 days post-surgery and affect different layers of tissue, categorized as superficial, deep, or involving organ/space tissues. A WHO survey in LMICs, the incidence of surgical site infections ranges from 1.2-23.6% whereas in countries with better resources, the SSI rate was between 1.2 and 5.2%.² SSI is commonly seen in women undergoing a cesarean section and have associated risk factors such as inadequate prenatal care, anemia with a poor nutritional status, extremes of BMI, GDM, emergency caesarean sections, PROM, prolonged labor, co-existing infections, comorbidities and inappropriate surgical techniques and prolonged duration of surgery.⁴ Despite advances in surgical procedures, options for

sterilizing surgical instruments, improved surgical techniques, and improved infection prevention programs, surgical site infections are a major cause of nosocomial infections, and the incidence of infections is increasing worldwide. SSI can also affect the quality of life of the woman, resulting in chronic pelvic pain, a prolonged hospital stay ,hospital readmission, and sometimes even postpartum depression. ⁴ Caesarean section is one of the most common surgical procedures that has been linked to an increased risk of surgical site infection. This is because of the fact that it is one of the most common surgical procedures.³ Although cephalosporin is commonly used as a prophylactic antibacterial medicine, the occurrence of infection after caesarean section remains a significant issue, especially in women who have had non-elective caesarean sections.⁴

Several studies have indicated that adding a single dosage of Azithromycin to the usual cephalosporin prophylaxis may reduce the risk of infection after a caesarean procedure. Multiple randomized controlled trials have determined that the utilization of a broad-spectrum antibiotic in conjunction with a narrow spectrum antibiotic has resulted in a significant decrease in post-caesarean infection instances, ranging from 30% to 60%. The reason for this is that infections following a caesarean section are mainly caused by a variety of bacteria including bacteria that can survive with or without oxygen, as well as Ureaplasma or mycoplasmas. Ureaplasma is the predominant organism found in the amniotic fluid and chorioamnion during caesarean delivery and is linked to a 3 -to 8 fold higher risk of post cesarean endometritis or wound infections. Hence, the suggested narrow spectrum treatment with Cephalosporins alone does not provide adequate coverage for commonly found Ureaplasma and anerobic bacteria .⁵

Adding a broad-spectrum antibiotic prophylaxis was beneficial as it offered protection against *Ureaplasma* species, which are the most commonly found bacteria in wound cultures of women who have had a caesarean section.^{6,7}

The purpose of the study is to study whether addition of Azithromycin to standard antibiotic prophylaxis before skin incision would decrease the incidence of surgical site infection after a caesarean section.

OBJECTIVES

- To study the effectiveness of Azithromycin in reducing surgical site infection in caesarean delivery.

REVIEW OF LITERATURE

- In 1985, the World Health Organization (WHO) said that C-section rates over 10-15 % in any given location cannot be medically justified. However, there has been a consistent increase in the rate of C-section deliveries over the past three decades, in both developing and industrialized countries. An examination of data from 169 countries, representing 98.4% of global births, indicated that 29.7 million babies were delivered by caesarean section in 2015. This was a significant increase from the 16 million caesarean deliveries recorded in 2000. Recent data from developed countries supports the notion that C-section rates of approximately 15% at the population level are both feasible and safe, while still achieving optimal health outcomes for both mothers and babies. Exceeding this threshold may suggest unnecessary over-medicalization of childbirth, which involves the use of non-evidence-based practices, the preference of healthcare professionals, the profit motive of private medical facilities, and maternal requests.⁸
- The significant rise in the proportion of C-section births (17%, having doubled between 2005 and 2006 and 2015-2016) has raised substantial policy issues in India over the past few decades, particularly due to the disproportionate concentration in the southern region. Several studies have endeavored to comprehend the socio-demographic characteristics of Caesarean births in India. The well-documented disparity in the utilization of C-sections in India favors urban and more affluent populations, highlighting the socio-economic bias. Recent research utilizing extensive nationally representative sample surveys has identified a disproportionate concentration of C-section births in

private healthcare facilities. An analysis conducted using the data from the District Level Household Survey (DLHS)-4 (2011) revealed that 13.7% of births occurred in public hospitals, whereas 37.9% of births in private institutions were delivered via C-section. A different analysis utilizing data from the National Family Health Survey (NFHS) revealed that the proportion of caesarean section (C-section) deliveries in public hospitals in India decreased from 15.2% to 11.9% between 2005–06 and 2015–16. Conversely, the prevalence of C-section deliveries among private healthcare providers significantly increased from approximately 25% to around 40% during the same time frame. It is crucial to comprehend the source of an unacceptable prevalence rate of C-section deliveries due to the significant health hazards they pose, the substantial increase in healthcare costs, and their frequent association with commercial interests. The expenses related to caesarean deliveries are significantly greater than those of non-caesarean deliveries, and this difference becomes even more pronounced in private healthcare institutions in India. It is important to mention that despite the southern states of India having a prevalence rate of C-section deliveries higher than the rate recommended by the World Health Organization (WHO) during the NFHS-3 survey (2005-2006), the practice continues to increase in all of these states. Based on the NFHS-4 data from 2015-2016, the proportion of caesarean section deliveries in South Indian states ranges from 23.6% in Karnataka to 40.1% in Andhra Pradesh. In addition to a steady increase, the spread of needless C-section births among disadvantaged and uninformed segments of the population likely exacerbates the already challenging reproductive health situation in the country. ⁸

SURGICAL SITE INFECTIONS AFTER CESAREAN DELIVERY

- Surgical site infections (SSIs) constitute a substantial proportion of morbidity and costly healthcare outcomes. SSIs occur in 1.9% of all surgeries, but the rate is significantly greater, ranging from 7-10 %, for caesarean deliveries (CDs). Postoperative surgical site infection (SSI) following caesarean deliveries (CDs) is a major contributing factor to higher rates of illness, death, hospital readmission, and longer hospital stays. Implementing evidence-based activities using a bundle strategy to prevent and minimize surgical site infections (SSI) following caesarean delivery (CD) will help improve maternal safety and reduce costs.⁹

Classification and Risk Factors of SSI

- Surgical site infections encompass both superficial and deep incisional infections, as well as infections in the organ space. The occurrence rate of incisional infection following caesarean delivery (CD) is 2-7 %, whereas the rate of necrotizing fasciitis is 0.18%, and the rate of endometritis is 2-16 %.¹⁰ The CDC has issued guidelines for identifying risk factors that contribute to the development of SSIs following Caesarean delivery. These guidelines aim to identify areas in obstetric care that can be modified to reduce the occurrence of SSIs. Some patient-related risk factors include high body mass index (BMI), diabetes, asthma, smoking, recurrent pregnancy loss, and an ASA classification more than 3.¹¹⁻¹³ There is a multitude of evidence in the general surgical literature indicating that maintaining proper glucose levels and quitting smoking will significantly reduce the occurrence of surgical site infections. As far as we know, there have been no reports on the effects of

these therapies on pregnant individuals. Pregnancy-specific risk factors encompass hypertensive diseases, gestational diabetes mellitus, premature rupture of membranes, prolonged labor, sexually transmitted infections during pregnancy, chorioamnionitis, and multiple gestations. Procedure-related risk factors encompass elements such as prolonged surgical time (more than 38 minutes), intestinal injury, utilization of staples, failure to close subcutaneous tissue if it exceeds 2 centimeters, and the improper administration of perioperative antibiotics.⁹

- Post-cesarean infections are caused by a combination of different types of microorganisms, including bacteria that can survive with or without oxygen, as well as Ureaplasma or Mycoplasmas. The predominant microorganisms found in the endometrial cultures of women with post-cesarean Endometritis are Ureaplasma/Mycoplasmas, aerobic gram-negative rods, Enterococci, Gardnerella, and anaerobes^{14,15}. Ureaplasma, Staphylococci, and Enterococci are frequently seen in wound infections^{16,17}. Moreover, when properly identified, Ureaplasma (or Mycoplasma) is the predominant organism found in the amniotic fluid and chorioamnion during caesarean delivery. It is linked to a 3 to 8-fold higher risk of post-cesarean endometritis or wound infection^{18,19}. Bacterial vaginosis is also linked to a much higher risk, up to six times greater, of developing post-cesarean endometritis. Hence, the suggested narrow-spectrum treatment with Cephalosporins alone does not provide adequate coverage for commonly found Ureaplasma and anaerobic bacteria, which are associated with increased risk factors. Indeed, the use of a specific type of antibiotic prophylaxis that targets a limited range of bacteria alters the

composition of the microbial community in favor of the growth of resistant species, particularly anaerobic bacteria^{14,20}.

WOUND COMPLICATIONS²¹

Wound hematoma, seroma, dehiscence

- Wound hematoma refers to a gathering of blood, while seroma refers to a gathering of serum. Hematomas typically result from a lack of initial blood clotting or a bleeding tendency, such as from anticoagulant medication. The occurrence of hematoma can be attributed to intense coughing or high blood pressure following surgery. Wound hematoma or seroma, which occurs in 2-5 % of women following caesarean delivery, can lead to wound dehiscence and serve as a breeding ground for the development of wound infection. Wound dehiscence refers to the separation of an incision and occurs as a complication in 2-7 % of cases after a caesarean delivery^{22,23}

Wound infection

- Wound infection is characterized by redness, drainage, and hardening of the incision. It occurs in 2-7 % of patients and often arises 4 -7 days after CD²⁴⁻²⁸. When wound infection occurs within 48 hours, the most common causative organisms are usually groups A or B-Hemolytic Streptococcus. Additional organisms frequently associated with wound infections include Ureaplasma urealyticum, Staphylococcus epidermidis, Enterococcus faecalis, Staphylococcus aureus, Escherichia coli, and Proteus mirabilis^{29,30}.

Necrotizing Fasciitis²¹

- Necrotizing fasciitis is an uncommon yet severe infection that leads to considerable illness following CD. It is characterized by the rapid and

progressive death of the tissue beneath the skin and the connective tissue layer known as fascia. The presence of intense pain, crepitus, wooden-hard induration of the subcutaneous tissues, bullous lesions, skin necrosis or ecchymosis, and high serum creatine kinase level are indicative of necrotizing fasciitis. A key characteristic of this condition is the fast advancement of clinical signs. Imaging techniques such as computed tomography or magnetic resonance imaging can reveal the presence of edema that spreads along the fascial plane. The diagnosis is verified during the subsequent surgical procedure. Indicative features may include inflated and pale grey fascia with patches of dead tissue, skin necrosis that may be easily separated along the fascia, or the presence of gas in the soft tissues. Type I necrotizing fasciitis is the outcome of a polymicrobial infection that involves both aerobic and anaerobic bacteria. On the other hand, type II necrotizing fasciitis is typically caused by a single organism, specifically group A streptococcus. According to a 1997 study, necrotizing fasciitis was observed in a mere 0.18 % of women who underwent caesarean delivery (CD). The occurrence of this condition occurred between a timeframe of 5-17 days after the CD procedure. The authors documented a significantly elevated fatality rate of 22%³¹, underscoring the criticality of promptly identifying and treating necrotizing fasciitis.

Endometritis

- Postpartum endometritis is caused by a polymicrobial infection of the decidua. It is characterized by a fever of 38.0 °C or above, discomfort in the fundus, and the presence of purulent discharge from the uterus. CD is related with a

greater risk of endometritis compared to vaginal delivery. Postpartum endometritis occurs in 2-16% of women who have had a caesarean delivery. The risk of complications is greater after caesarean delivery conducted during labor (3-11%) compared to those performed before labor (0.5-5%). Additionally, the risk is higher in patients with ruptured membranes compared to those with intact membranes (3-15% vs. 1-5%, respectively).²¹

Risk factors for surgical site infections following CD

- Several diverse risk factors for surgical site infections (SSIs) after caesarean delivery (CD) have been documented. The risk factors, listed in decreasing order of significance as measured by relative risks or odds ratios, include subcutaneous hematoma, chorioamnionitis, maternal comorbidities (American Society of Anesthesiologists class of 3 or greater), tobacco use during pregnancy, incision length greater than 16.6 cm, limited prenatal care (less than 7 visits), body mass index greater than 30 or 35 kg/m², corticosteroid use, subcutaneous tissue thickness greater than 3 cm, prolonged second stage of labor (compared to the first stage), absence of antibiotic prophylaxis, pregestational diabetes, operating time equal to or longer than 38 minutes, hypertensive disease/ preeclampsia, duration of labor exceeding 12 hours, nulliparity, twin gestations, premature rupture of membranes, gestational diabetes, increased blood loss (for every increase of 100 mL), previous caesarean delivery, emergency delivery, and rupture of membranes (increased risk for every additional hour).²¹

PREOPERATIVE MANAGEMENT

Preoperative antibiotics

- The primary method for preventing surgical site infections (SSIs) after a caesarean delivery (CD) is the administration of a first generation cephalosporin. A metanalysis of randomized controlled trials demonstrated that the administration of first generation cephalosporin, as opposed to no antibiotics, resulted in a reduction in the likelihood of developing wound infections and endometritis. Additionally, studies have shown that the incidence of surgical site infections (SSIs) is reduced when first generation cephalosporin antibiotics are administered before making an incision in the skin, as opposed to after clamping the umbilical cord. The meta-analysis conducted by Constantine et al. found a substantial reduction in the risk of endometritis. A recent study conducted a randomized controlled experiment which demonstrated that administering antibiotic prophylaxis before making an incision in the skin resulted in reduced incidence of both wound infection and endometritis, in comparison to administering it after clamping the umbilical cord.²¹

- Azithromycin

Recent research have indicated advantages in including Azithromycin during the course of CD. In a study conducted in 2008, Tita et al. found that the regular use of intravenous Azithromycin resulted in a reduced likelihood of endometritis when compared to the typical practice of using antibiotic prophylaxis³². In 2016, the author of this study found that include intravenous Azithromycin 500 mg in the routine preoperative antibiotic prophylaxis

resulted in reduced chances of endometritis and wound infection in women undergoing non-elective caesarean delivery, compared to using a placebo. The inclusion of preoperative Azithromycin does not yield any immediate consequences for the neonates, while there is a dearth of long-term data. The randomized controlled research of Azithromycin, when used in conjunction with conventional antibiotics, did not reveal any disparities in composite newborn outcome, mortality rates, or admissions to the neonatal intensive care unit (NICU)²⁵.

- A 2016 randomized controlled trial conducted at 14 hospitals in the United States compared the effectiveness of Cefazolin + Azithromycin to Cefazolin + placebo as antibiotic prophylaxis before caesarean delivery in women undergoing non-elective caesarean section. Four Out of the people involved in the 2013 study, 6.1% of those who were given Cefazolin + Azithromycin experienced a wound infection, Endometritis, or other infection within 6 weeks following surgery. In comparison, 12% of patients who received Cefazolin + placebo had similar infections. The outcome showed a statistically significant difference. The trial was influenced by three significant confounding factors: patient weight, wound closure techniques, and Cefazolin dose. Approximately 75% of the participants had a body mass index (BMI) exceeding 30 kg/m², and the utilization of staples for wound closure was prevalent. Both conditions are correlated with an elevated risk of post-operative infection. Furthermore, the administration of Cefazolin was not regulated in the study, as it was undertaken before the standard prescription of 2 - 3 grams of Cefazolin given before surgery to accommodate for those with a larger body weight. There was no significant difference in adverse maternal

outcomes between the two groups. Participants were monitored for a period of up to 6 weeks after the occurrence of CD.²⁵

Risk to Infant

- The risk of Azithromycin to infants who are exposed to it after their mothers receive pre-operative prophylaxis is negligible. The FDA classifies Azithromycin as a Class B drug for use during pregnancy. The medication shows placental transport, although the extent of exposure is contingent upon the time interval between administration and childbirth. During a study, researchers observed that the highest levels of Azithromycin in the blood of newborns were reached 12 to 24 hours after they were given the medication orally. A single intravenous dose of Azithromycin maintains concentrations in breast milk for a duration of up to 48 hours. Infants are expected to be exposed to the drug, however the level of exposure is modest, representing only about 1% of the therapeutic drug concentrations. Based on the existing safety data, it is medically justifiable to continue nursing without any delay in women who are given Azithromycin before a surgical procedure.^{21,25}
- Tita et al. conducted a randomized controlled experiment in 2016 to assess newborn outcomes for up to 3 months following CD. The incidence of adverse neonatal outcomes, such as mortality, sepsis, or other complications, was similar between patients who were given Azithromycin as pre-operative prophylaxis and those who got a placebo. Specifically, the rates were 14.3% (146 out of 1019) and 13.6% (134 out of 994) respectively.²⁵

Dosage and Administration

- Dosage: The suggested dosage for Azithromycin is 500 mg IV.

Mechanism of action

- In order to replicate, bacteria require a specific process of protein synthesis, enabled by ribosomal proteins. Azithromycin binds to the 23S rRNA of the bacterial 50S ribosomal subunit. It stops bacterial protein synthesis by inhibiting the transpeptidation/translocation step of protein synthesis and by inhibiting the assembly of the 50S ribosomal subunit. This results in the control of various bacterial infections. The strong affinity of macrolides, including Azithromycin, for bacterial ribosomes, is consistent with their broad-spectrum antibacterial activities. Azithromycin is highly stable at a low pH, giving it a longer serum half-life and increasing its concentrations in tissues compared to Erythromycin.

Pharmacodynamics

- Macrolides stop bacterial growth by inhibiting protein synthesis and translation, treating bacterial infections. Azithromycin has additional immunomodulatory effects and has been used in chronic respiratory inflammatory diseases for this purpose.
- Administration: Administering drugs intravenously is recommended because it allows for quicker attainment of therapeutic medication levels in the bloodstream compared to taking them orally. Azithromycin can be administered concurrently with cephalosporin through Y-site administration without any compatibility issues.^{21,25}

- Antibiotic timing: For the treatment of CD, it is recommended to administer Azithromycin intravenously, 30-60 minutes before making an incision.²

LITERATURE FROM PREVIOUS STUDIES:

- Freret TS et al. (2024) conducted a study to investigate the potential correlation between Azithromycin usage and the decreased occurrence of postoperative infection. Out of the total number of patients studied, which was 1366, 1158 patients, accounting for 84.8% of the total, were successfully matched. The primary outcome occurred at a rate of 16.7%. After delivery, oral antibiotics were given to 9.8% of the patients, and 1.0% of them had an urgent postpartum visit for infection. The addition of Azithromycin did not result in a decreased occurrence of the main outcome. It was linked to a reduction in the usage of oral antibiotics and a decrease in the number of urgent postpartum consultations.³³
- In a study conducted by Ruzic MF et al. (2023), the researchers assessed the occurrence of postoperative infections in mothers who underwent pre-labor caesarean deliveries. The study aimed to determine the impact of adding adjunctive Azithromycin to the conventional antibiotic prophylaxis. Out of the total of 2,867 patients that were included in the analysis, 1,391 (48.5%) belonged to the pre-AZI group, whereas 1,476 (51.5%) belonged to the post-AZI group. The patients in the post-AZI group were characterized by advanced age and a higher likelihood of having private insurance. Additionally, they showed a greater tendency to consume aspirin and obtain predelivery antibiotics within a two-week timeframe. The administration of Azithromycin resulted in a substantial decrease in the likelihood of composite

infection, mostly due to a reduction in the probabilities of wound infection. The likelihood of experiencing other postpartum problems, such as wound seroma and dehiscence, was reduced. There were no discernible disparities in specific infant health complications among the groups. Out of the 1,138 sets that were analyzed for propensity, the primary outcome continued to be considerably lower in the post-AZI group.³⁴

- In their study, Huang D et al. (2022) examined the preventive impact of combining Azithromycin with a single dose of cephalosporin in preventing surgical site infections in women undergoing unplanned caesarean delivery. A clinical trial was done that was randomized, double-blind, and controlled. 242 women who had their first non-elective caesarean section were randomly divided into two groups. The experimental group (n = 121) received 1500mg of cefuroxime sodium and 500mg of intravenous Azithromycin, while the placebo group (n = 121) received 1500mg of cefuroxime sodium and a placebo. The main result measured was the prevalence of Caesarean scar defects (CSD), which was assessed using transvaginal ultrasonography and saline infusion sonohysterography within 6 months after delivery. Secondary outcomes included alterations in infection biomarkers such as hypersensitive C-reactive protein and procalcitonin, surgical complications, and the administration of postoperative antibiotics. A total of 104 women in the experimental group and 108 women in the placebo group completed the initial sonographic follow-up. CSD was detected using sonography in 32.7% (34 out of 104) and 46.3% (50 out of 108) of patients in the experimental and placebo groups, respectively. The relative risk was 0.71 (95% confidence interval:

0.50–0.99; $p = 0.043$). There were no differences in the characteristics of CSD and short-term infection outcomes across the groups.³⁵

- Yang M et al. (2022) did a study to investigate the effectiveness of include Azithromycin in antimicrobial prophylaxis for patients undergoing caesarean delivery (CD). They performed a statistical analysis of relevant randomized controlled trials (RCTs) and cohort studies in the available literature. They considered studies in our meta-analysis that utilized identical study design and outcome measures. Subsequently, they conducted heterogeneity tests and calculated the quantity of the effect. Their systematic review and meta-analysis of randomized controlled trials (RCTs) demonstrated that the inclusion of Azithromycin as a preventive measure in caesarean delivery (CD) significantly decreased the likelihood of developing Endometritis and wound infection. Furthermore, the meta-analysis findings from the cohort studies further validated the effectiveness of Azithromycin in treating Endometritis, wound infection, and composite infections. Nevertheless, the use of meta-analysis was not feasible for assessing the safety of including Azithromycin due to the lack of consistency in the outcome measures employed across several trials. The inclusion of Azithromycin in antibiotic prophylaxis decreased the likelihood of surgical site infections in patients undergoing CD. Nevertheless, future research should include more subgroup analyses focusing on non-elective caesarean delivery and long-term follow-up investigations to assess the safety of the progeny.³⁶
- Jabs C et al. (2021) did a study to investigate the impact of include Azithromycin in the usual antibiotic prophylaxis on the occurrence of surgical site infection (SSI) in women undergoing both planned and unplanned

caesarean births. The introduction of adjunctive Azithromycin prophylaxis resulted in a drop in surgical site infection rates from 3.5% to 2.9%. The decrease in surgical site infections (SSIs) by 0.6% did not reach statistical significance ($P=0.42$). There was no disparity in surgical site infection (SSI) rates between the elective and non-elective groupings. The addition of Azithromycin to the routine antibiotic prophylaxis for caesarean delivery did not result in a statistically meaningful decrease in surgical site infection (SSI) rates in a cohort with initially low SSI rates.³⁷

- Sanusi A et al. (2021) undertook a study to evaluate whether the time of administering Azithromycin in addition to routine antibiotic prophylaxis is linked to the risk of infection complications during non-elective caesarean delivery (CD). Out of the total of 2013 women who participated in the parent Randomized Controlled Trial (RCT), 1973 patients with all the necessary data were considered for analysis. Out of the total number of patients, 1355 (68.7%) were administered perioperative antibiotics within 30 minutes before the skin incision, whereas only 92 (<5%) received antibiotics more than 60 minutes prior to the skin incision. The antibiotic timing groups showed significant differences in parity ($p=0.012$) and alcohol usage ($p<0.001$). There was no notable disparity in the likelihood of the principal post-operative composite infection outcome (or any of its separate components) among the different time groups. The tests of interaction revealed no statistically significant variations in post-infectious morbidity between the randomly assigned groups based on antibiotic scheduling.³⁸

- Tita ATN et al. (2016) assessed the advantages and safety of using Azithromycin-based extended-spectrum prophylaxis in women who have non elective caesarean delivery. Out of the women who took Azithromycin, 6.1% experienced the primary event, whereas 12.0% of those who received placebo experienced it. The relative risk of experiencing the primary result was 0.51, with a 95% confidence interval of 0.38 to 0.68. The p-value was less than 0.001. The Azithromycin group and the placebo group showed notable disparities in the occurrence of endometritis (3.8% vs. 6.1%, P=0.02), wound infection (2.4% vs. 6.6%, P<0.001), and major maternal adverse events (1.5% vs. 2.9%, P=0.03). There was no statistically significant difference between the groups in terms of a secondary neonatal composite outcome, which encompassed neonatal death and severe neonatal sequelae.²⁵
- A prospective observational cohort study was conducted on 741 pregnant women who underwent CS from July to September 2022 by Rahel Mezemir et al. Women who had CS were followed up for at least 30 days. Infected wound specimens from those who had SSIs were collected and bacteriologically analyzed. The incidence of post-cesarean surgical site infection was 11.6%. Staphylococcus aureus was the most common bacteria in CS wounds (21.2%). Two to three antenatal care visits (ANC), delayed antenatal booking, membrane rupture, multiple vaginal examinations and public hospitals were associated with increased risk of SSI after CS, in contrary shorter hospital stays and transversal incisions were associated with lower risk SSI after CS.⁵⁶
- In a retrospective research study at Manipal University in Udipi, 20 of the 305 cesarean section cases experienced surgical site infection. 85% of the patients developed superficial surgical site infections during the hospital stay ,10%

developed deep surgical site infections. The majority of surgical site infections were classified as superficial infections (75%), deep infections (12.5%), and (12.5%) had organ space infections. This study observed that the lack of proper post operative dressing practices and lack of proper hand hygiene resulted in an increased rate of surgical site infections.⁵⁷

- A retrospective single-center cohort study of all CD July 2012 to December 2017 was performed. Infections were identified via 30-day active surveillance using CDC definitions by one infection preventionist and reviewed by one physician. Bundle 1 (2014) included enhanced surgical instrument sterilization, bandage removal POD2, preoperative sage cloth, 3 grams Cefazolin for women >120 kg, recommended patient warming, staple removal on POD7, and silver dressings. Bundle 2 (2015) included nurses prepping with prolonged preparation time using two chlorhexidine applicators. Bundle 3 (2016) included preoperative vaginal preparation and 500 mg Azithromycin in unscheduled CD in labor and encouraged post-placental glove change. Over 5.5 years, 2.2% (176/8150) of women developed post-CD SSI. 79% (138/176) were superficial incisional primary SSI. The first bundle had no significant effect on the odds of post-CD SSI (odds ratio [OR] 0.48, confidence interval [95% CI] 0.15 - 1.61). A decreased odd of post-CD SSI for both bundle 2 was observed (OR 0.63, 95% CI 0.45 - 0.87) and bundle 3 (OR 0.61, 95% CI 0.42 - 0.88). This study concluded that implementation of surgical site bundles significantly decreased the rate of surgical site infections.⁵⁸
- A Cochrane study assessed the effects of prophylactic antibiotics compared with no prophylactic antibiotics on infectious complications in women undergoing cesarean section. Compared with placebo or no treatment, the use

of prophylactic antibiotics in women undergoing cesarean section reduced the incidence of wound infection (RR 0.40, 95% CI 0.35 to 0.46, 82 studies, 14,407 women), endometritis (RR 0.38, 95% CI 0.34 to 0.42, 83 studies, 13,548 women) and maternal serious infectious complications (RR 0.31, 95% CI 0.20 to 0.49, 32 studies, 6159 women). The conclusions of this review support the recommendation that prophylactic antibiotics should be routinely administered to all women undergoing cesarean section to prevent infection. Compared with placebo or no treatment, the use of prophylactic antibiotics in women undergoing cesarean section reduced the incidence of wound infection, endometritis and serious infectious complications by 60% to 70%.⁵⁹

- A prospective observational cohort study was conducted involving 325 women who underwent labor and scheduled C-sections from January, 2018 to September, 2018 at the University Clinical Center of Kosovo, Clinic for Obstetrics and Gynecology. Each woman was followed for 30-postoperative days. Overall, the SSI rate was 9.85% and the median time to SSI was the 7th postoperative day. It was observed that several factors reduced the risk of SSI. These included: age less than 35 years (RR 0.25; 95% CI; 0.199-0.906 and P = 0.027) preoperative use of antibiotics (RR 0.232; 95% CI; 0.107-0.502 and P = 0.000) and duration of the operation less than 1 hour (RR 0.135; 95% CI; 0.054-0.338 and P = 0.000). Previous cesarean section and one or more comorbidity were associated with 7.4 fold and 8 fold increased risk of SSI, respectively. A statistically significant association between SSI and comorbidity, preoperative antibiotic use, duration of operation, age and history of previous cesarean section was noted.

MATERIAL AND METHODS

STUDY AREA: The present study was carried out in the Department of Obstetrics and Gynecology, KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi.

STUDY POPULATION: Women undergoing emergency cesarean sections according to inclusion criteria.

STUDY DESIGN: A Randomized Control Trial

SAMPLE SIZE:

The formula used for sample size calculation is -

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1 - p_1) + p_2(1 - p_2))}{(p_1 - p_2)^2}$$

- ▶ where p1 is the proportion of group 1, p2 is the proportion of group 2. For 95% confidence level, $Z_{\alpha/2}$ value is 1.96 and for 80% power Z_{β} values is 0.84.
- ▶ We assume that prevalence of surgical site infection in group A - standard antibiotic prophylaxis with injection Ceftriaxone and group B -injection Ceftriaxone with Azithromycin as 20% and 8% respectively with 95% confidence level and 80% power, sample size required for the study is 128 subjects per group.
- ▶ Total Sample Size required is -128 x 2 =256

RANDOMIZATION: Patients are classified into two groups by computer-generated randomization system.

STUDY PERIOD: Total period of 12 months –January 2023 to January 2024.

INCLUSION CRITERIA:

Pregnant women at Gestational age of 28 weeks or more, who are to undergo emergency caesarean delivery who have given informed consent.

EXCLUSION CRITERIA

- ▶ Use of antibiotics 7 days prior to randomization
- ▶ Patients with underlying liver disease
- ▶ Chorioamnionitis
- ▶ Structural heart diseases or arrhythmias
- ▶ Use of medications known to prolong QT interval
- ▶ Hypertension in pregnancy
- ▶ Acute Gastroenteritis

METHODOLOGY:

Sampling Procedure-Patients admitted at 28 weeks of gestation and beyond, according to the inclusion criteria of the study, who underwent emergency cesarean sections were screened for the study.

- ▶ Written, informed consent was taken from all the participants
- ▶ Patients were randomized into either of the two groups.

INTERVENTION-

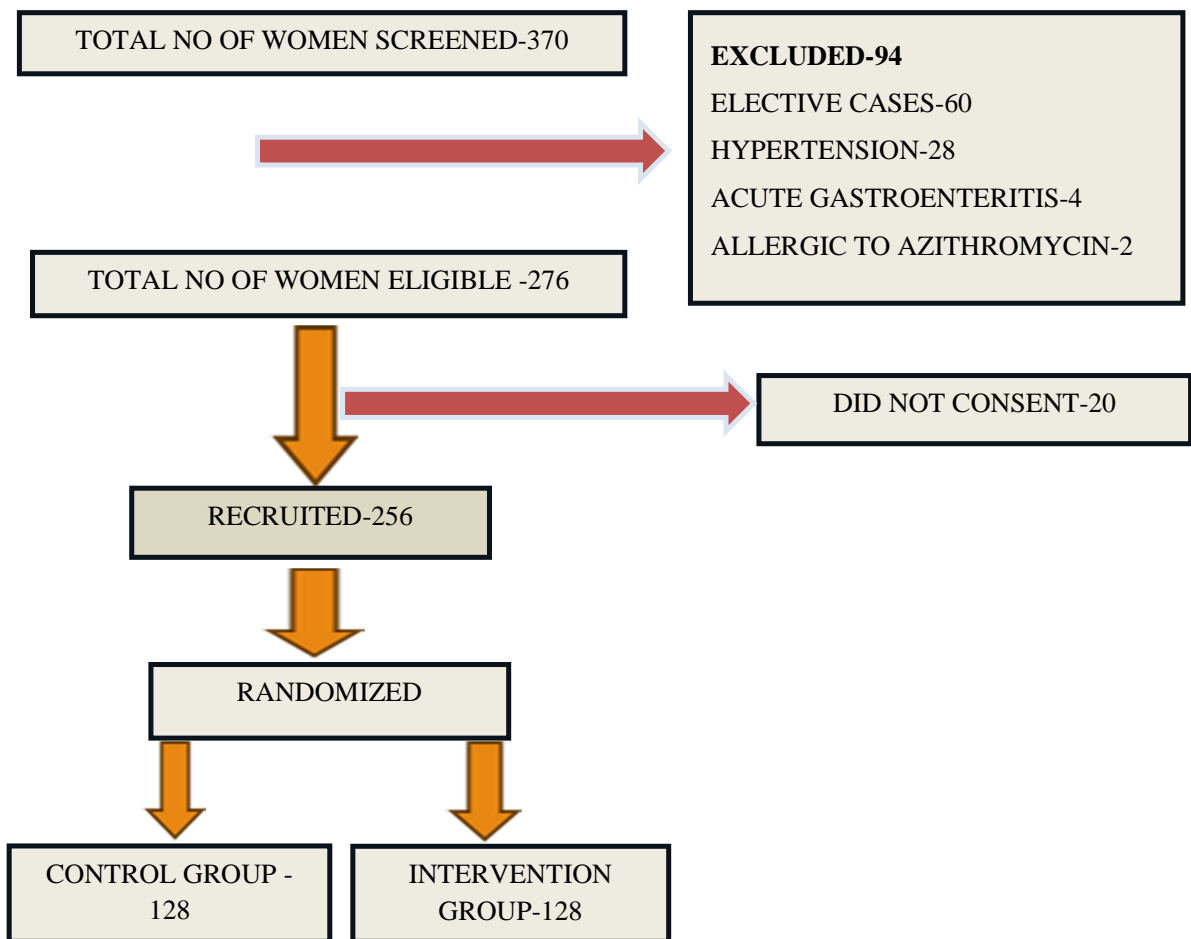
- ▶ Group A received the standard antibiotic prophylactic drug –Injection Ceftriaxone 1g IV.

- ▶ Group B received the standard antibiotic prophylactic drug –

Injection Ceftriaxone 1g IV along with injection Azithromycin 500mg IV (given within 60 minutes prior to incision)

- ▶ The primary outcome of surgical site infection was studied and compared between 2 group.

- ▶ The women were followed up until the day of discharge for any induration, redness or discharge at the surgical incision site.



CDC RECOMMENDATIONS FOR PREVENTION OF SURGICALSITE

INFECTION

| | |
|--|---|
| Parenteral Antimicrobial Prophylaxis | <ul style="list-style-type: none">• Antimicrobial prophylaxis should be administered only when indicated based on published clinical practice guidelines• Antimicrobial prophylaxis should be timed such that bactericidal concentrations of the agent are established in the serum of respective surgical site tissues when the incision is made• For clean and clean-contaminated procedures, additional prophylactic antimicrobial agents doses should not be administered after the surgical incision is closed |
| Non-Parenteral Antimicrobial Prophylaxis | <ul style="list-style-type: none">• Do not apply antimicrobial agents (i.e., ointments, solutions, powders) to surgical incision for prevention of SSI• Antimicrobial dressings applied to surgical incision following primary closure is an unresolved issue with no current recommendations |
| Glycemic Control | <ul style="list-style-type: none">• Implement intraoperative and perioperative glycemic control and use blood glucose target < 200 mg/dL in diabetic and non-diabetic patients• Optimal HbA1C target level for the prevention of SSI in patients with and without diabetes remains and unresolved issue with current recommendations |
| Normothermia | <ul style="list-style-type: none">• Maintain perioperative normothermia |
| Oxygenation | <ul style="list-style-type: none">• For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased fraction of inspired oxygen intraoperatively and post-extubation in the immediate postoperative period• To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement |
| Antiseptic Prophylaxis | <ul style="list-style-type: none">• Advise patients to shower or bathe (full body) with soap (antimicrobial or non-antimicrobial) or an antiseptic agent on at least the night before the operative day• Perform intraoperative skin preparation with an alcohol-based antiseptic agent, unless contraindicated |

STATISTICAL ANALYSIS:

Data entry was performed using M.S. Excel, and statistical analysis was conducted using the Statistical Package for Social Sciences (SPSS Version 16) for M.S. Windows. Descriptive statistical analysis was carried out to explore the distribution of various categorical and quantitative variables. Categorical variables were summarized with n (%), while quantitative variables were summarized by mean \pm S.D. All results were presented in tabular form and graphically using bar diagrams or pie diagrams as appropriate. Inferential statistics were employed to test for

statistical significance between the two groups. Parametric tests, such as the t-test, were used for quantitative variables, while categorical variables were tested using the chi-square test. A P-value of <0.05 was considered statistically significant, following all the standard rules of statistical tests.

ETHICAL ISSUES

1. The objectives and procedure of the study were explained to all patients.
2. Informed consent was taken from all patients willing to participate in the study.
3. The option to opt out of the study was kept open without any clause.
4. Complete confidentiality regarding patient information was maintained through all stages of the study.

Ethics committee approval was obtained from the JNMC Institutional Ethics Committee on Human Subjects Research on 27/09/2022. The trial is registered under CTRI/2022/12/048571.

RESULTS & OBSERVATIONS

The study involves a total of 256 participants, who are divided into two groups: Group A (Control Group) and Group B (Treatment Group). Each group consists of 128 participants.

Group A: Control group -Injection Ceftriaxone 1g IV. (Standard antibiotic prophylaxis group)

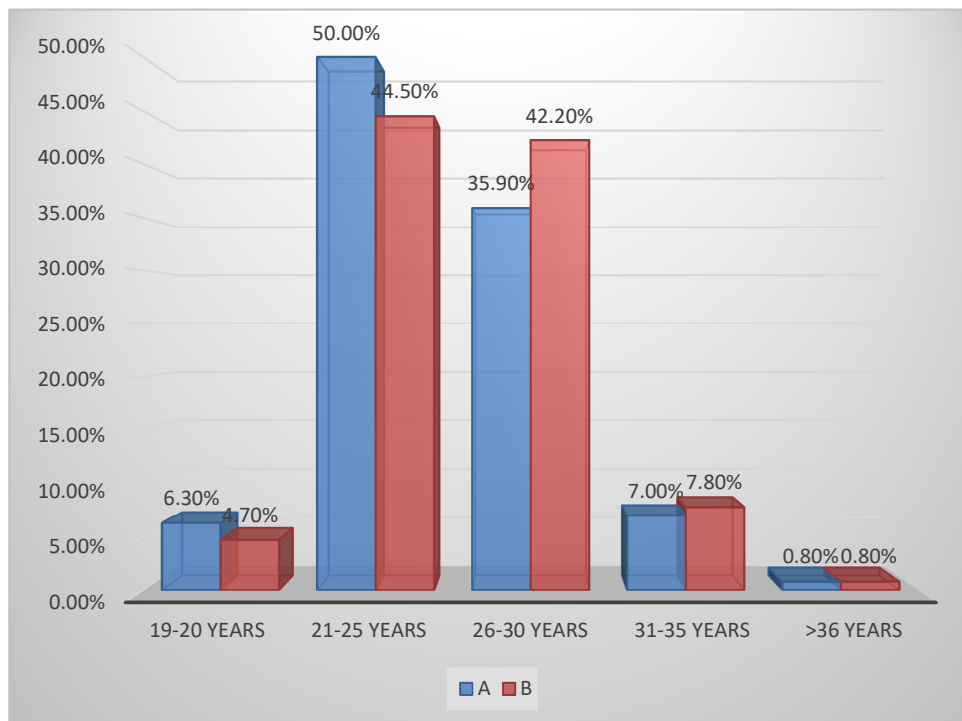
Group B: Injection Ceftriaxone 1g IV (Standard antibiotic prophylaxis group) + Azithromycin 500mg IV

Table 1: Distribution of patients based on the Age group

| | | | GROUP | | Total |
|-----------|-------------|---|--------|--------|--------|
| | | | A | B | |
| Age Group | 19-20 years | n | 8 | 6 | 14 |
| | | % | 6.3% | 4.7% | 5.5% |
| | 21-25 years | n | 64 | 57 | 121 |
| | | % | 50.0% | 44.5% | 47.3% |
| | 26-30 years | n | 46 | 54 | 100 |
| | | % | 35.9% | 42.2% | 39.1% |
| | 31-35 years | n | 9 | 10 | 19 |
| | | % | 7.0% | 7.8% | 7.4% |
| | >36 years | n | 1 | 1 | 2 |
| | | % | 0.8% | 0.8% | 0.8% |
| Total | | n | 128 | 128 | 256 |
| | | % | 100.0% | 100.0% | 100.0% |

Chi-Square: 1.38, P Value: 0.84, Statistically not significant

In the age group of 19-20 years, there are 8 participants in Group A and 6 participants in Group B, making up 6.3% and 4.7% of their respective groups, and 5.5% of the total participants. The age group of 21-25 years has the highest representation, with 64 participants in Group A and 57 in Group B, constituting 50.0% and 44.5% of their respective groups, and 47.3% of the total participants. For the 26-30 years age group, there are 46 participants in Group A and 54 in Group B, representing 35.9% and 42.2% of their respective groups, and 39.1% of the total participants. The age group of 31-35 years includes 9 participants in Group A and 10 in Group B, making up 7.0% and 7.8% of their respective groups, and 7.4% of the total participants. The smallest age group is above 36 years, with 1 participant each in both groups, representing 0.8% of their respective groups and the total participants.



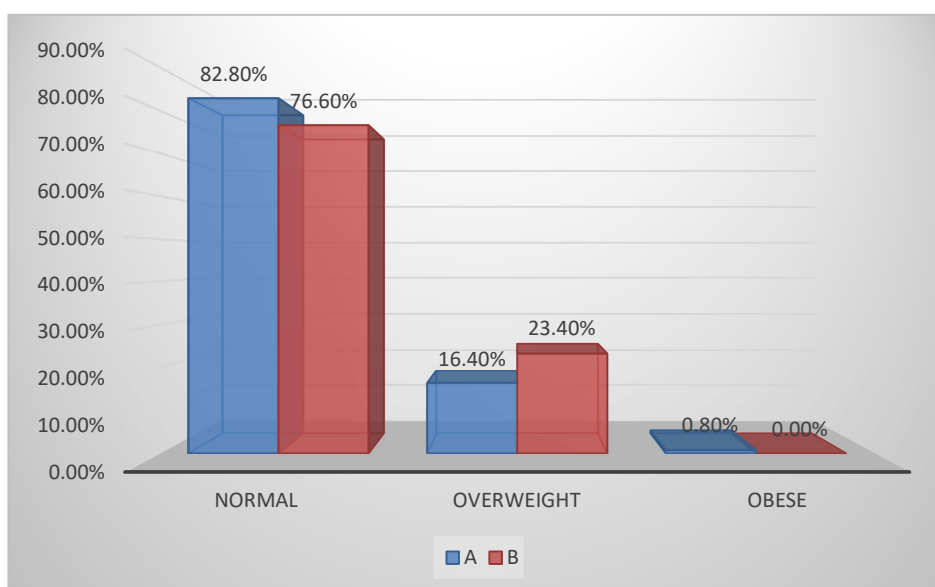
Graph 1: Distribution of patients based on the age

Table 2: Distribution of patients based on the BMI

| | | | GROUP | | Total | P Value |
|--------------|------------|---|--------|--------|--------|---------|
| | | | A | B | | |
| BMI Category | Normal | n | 106 | 98 | 204 | |
| | | % | 82.8% | 76.6% | 79.7% | |
| | Overweight | n | 21 | 30 | 51 | |
| | | % | 16.4% | 23.4% | 19.9% | |
| | Obese | n | 1 | 0 | 1 | |
| | | % | 0.8% | 0.0% | 0.4% | |
| Total | | n | 128 | 128 | 256 | |
| | | % | 100.0% | 100.0% | 100.0% | |

Chi-Square: 2.90, P Value: 0.23, Statistically not significant

In the Normal BMI category, Group A has 106 participants (82.8%) and Group B has 98 participants (76.6%), making up 79.7% of the total participants. The Overweight category includes 21 participants in Group A (16.4%) and 30 in Group B (23.4%), constituting 19.9% of the total participants. The Obese category has only one participant from Group A (0.8%) and none from Group B (0.0%), representing 0.4% of the total participants.



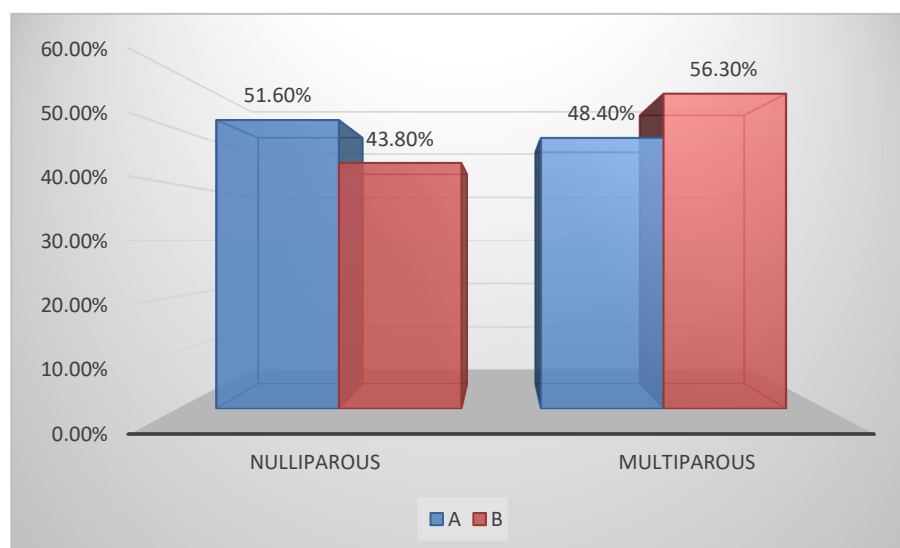
Graph 2: Distribution of patients based on the BMI

Table 3: Distribution of patients based on the obstetric score

| | | | GROUP | | Total |
|-----------------|-------------|---|--------|--------|--------|
| | | | A | B | |
| OBSTETRIC SCORE | Nulliparous | n | 66 | 56 | 122 |
| | | % | 51.6% | 43.8% | 47.6% |
| | Multiparous | n | 62 | 72 | 134 |
| | | % | 48.4% | 56.3% | 52.3% |
| Total | | n | 128 | 128 | 256 |
| | | % | 100.0% | 100.0% | 100.0% |

Chi-Square: 1.56, P Value: 0.26, Statistically not significant

Participants are categorized based on their obstetric score into Nulliparous and Multiparous. Group A has 66 Nulliparous (51.6%), and 62 Multiparous (48.4%). Group B has 56 Nulliparous (43.8%), and 72 Multiparous (56.3%).



Graph 3: Distribution of patients based on the obstetric score

Table 4: Distribution of patients based on the presence of anemia and status of wound

| GROUP | | | | STATUS OF WOUND | | Total | P Value | |
|-------|--------|-----|---|-----------------|-----------|--------|---------|--------|
| | | | | Healthy | Unhealthy | | | |
| A | ANEMIA | Yes | n | 21 | 18 | 39 | 0.08 | |
| | | | % | 25.6% | 39.1% | 30.5% | | |
| | | No | n | 61 | 28 | 89 | | |
| | | | % | 74.4% | 60.9% | 69.5% | | |
| | Total | | | n | 82 | 46 | | 128 |
| | | | | % | 100.0% | 100.0% | | 100.0% |
| B | ANEMIA | Yes | n | 27 | 8 | 35 | 0.05 | |
| | | | % | 24.3% | 47.1% | 27.3% | | |
| | | No | n | 84 | 9 | 93 | | |
| | | | % | 75.7% | 52.9% | 72.7% | | |
| | Total | | | n | 111 | 17 | | 128 |
| | | | | % | 100.0% | 100.0% | | 100.0% |

In Group A, 21 participants with anemia had healthy wounds (25.6%) compared to 18 with unhealthy wounds (39.1%), while 61 participants without anemia had healthy wounds (74.4%) and 28 had unhealthy wounds (60.9%). In Group B, 27 participants with anemia had healthy wounds (24.3%) and 8 had unhealthy wounds (47.1%), whereas 84 participants without anemia had healthy wounds (75.7%) and 9 had unhealthy wounds (52.9%).

Table 5: Distribution of patients based on the diabetes in pregnancy and status of wound

| GROUP | | | | STATUS OF WOUND | | Total | P Value |
|-------|-----------------------|-----|---|-----------------|-----------|--------|---------|
| | | | | Healthy | Unhealthy | | |
| A | DIABETES IN PREGNANCY | Yes | n | 11 | 7 | 18 | 0.48 |
| | | | % | 13.4% | 15.2% | 14.1% | |
| | | No | n | 71 | 39 | 110 | |
| | | | % | 86.6% | 84.8% | 85.9% | |
| | Total | | | n | 82 | 46 | 128 |
| | | | | % | 100.0% | 100.0% | 100.0% |
| B | DIABETES IN PREGNANCY | Yes | n | 11 | 4 | 15 | 0.11 |
| | | | % | 9.9% | 23.5% | 11.7% | |
| | | No | n | 100 | 13 | 113 | |
| | | | % | 90.1% | 76.5% | 88.3% | |
| | Total | | | n | 111 | 17 | 128 |
| | | | | % | 100.0% | 100.0% | 100.0% |

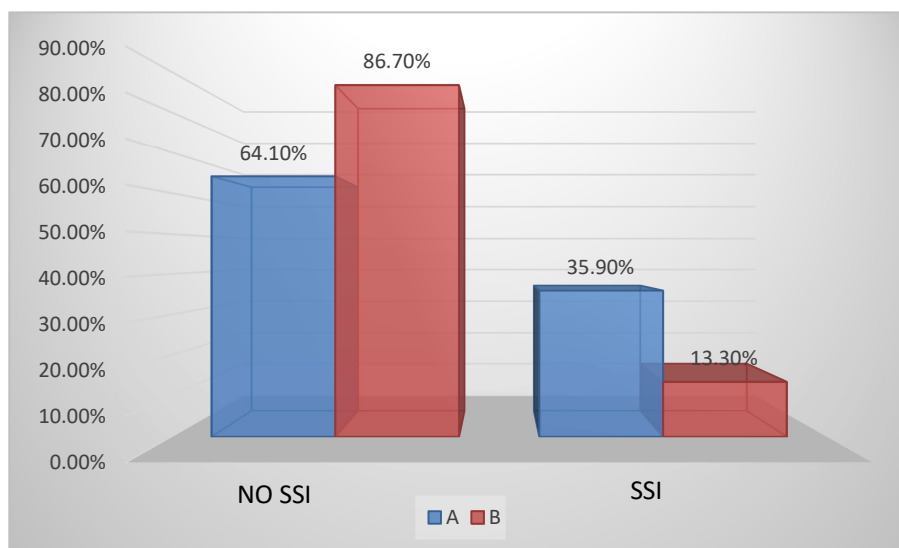
11 participants in Group A with diabetes had healthy wounds (13.4%) versus 7 with unhealthy wounds (15.2%), and 71 participants without diabetes had healthy wounds (86.6%) compared to 39 with unhealthy wounds (84.8%). In Group B, 11 participants with diabetes had healthy wounds (9.9%) and 4 had unhealthy wounds (23.5%), whereas 100 participants without diabetes had healthy wounds (90.1%) and 13 had unhealthy wounds (76.5%).

Table 6: Distribution of patients based on incidence of surgical site infection

| | | | GROUP | | Total |
|-------------------------|-----|---|--------|--------|--------|
| | | | A | B | |
| Surgical Site Infection | No | n | 82 | 111 | 193 |
| | | % | 64.1% | 86.7% | 75.4% |
| | Yes | n | 46 | 17 | 63 |
| | | % | 35.9% | 13.3% | 24.6% |
| Total | | n | 128 | 128 | 256 |
| | | % | 100.0% | 100.0% | 100.0% |

Chi-Square: 17.70, P Value: 0.001, Statistically significant

The incidence of surgical site infection was noted in both groups. In Group A, 82 participants (64.1%) had no surgical site infections, and 46 participants (35.9%) had surgical site infections. In Group B, 111 participants (86.7%) had no surgical site infections, and 17 participants (13.3%) had surgical site infection.

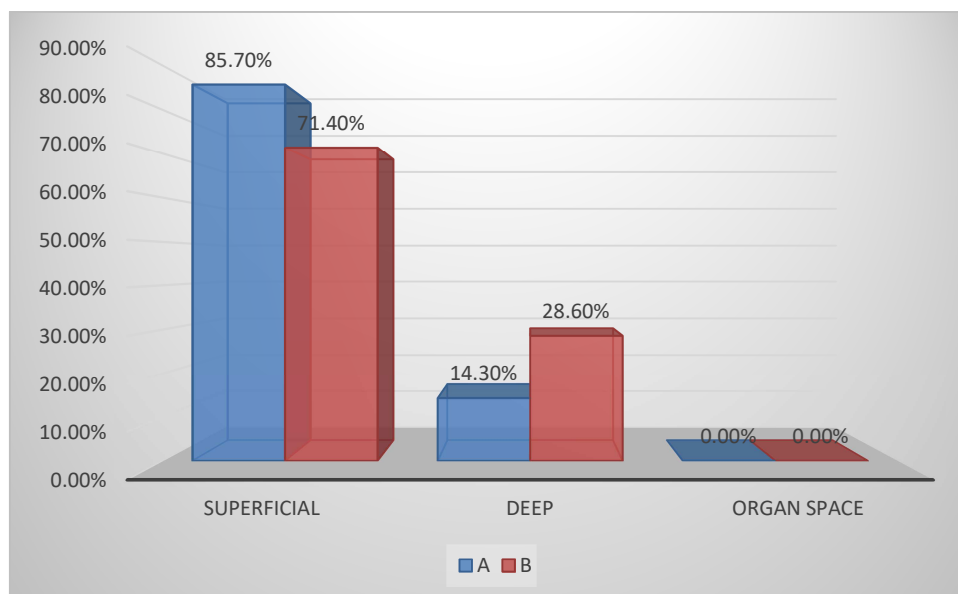


Graph 4: Distribution of patients based on the incidence of SSI

Table 7: Distribution of patients based on the type of surgical site infection

| | | | GROUP | | Total | P Value |
|---------------------------------|-------------|---|--------|-------|--------|---------|
| | | | A | B | | |
| Type of surgical site infection | Superficial | n | 48 | 5 | 53 | 0.66 |
| | | % | 85.7% | 71.4% | 84.2% | |
| | Deep | n | 8 | 2 | 10 | |
| | | % | 14.3% | 28.6% | 15.8% | |
| | Organ space | n | 0 | 0 | 0 | |
| | | % | 0.0% | 0.0% | 0.0% | |
| Total | | n | 56/128 | 7/128 | 63/128 | |

Surgical site infections are categorized as Superficial, Deep, or Organ space. In Group A, there are 48 superficial infections (85.7%) and 8 deep infections (14.3%). In Group B, there are 5 superficial infections (71.4%) and 2 deep infections (28.6%)



Graph 5: Distribution of patients based on the type of surgical site infection

Table 8: Distribution of patients based on the wound culture and sensitivity

| | GROUP | | Sensitivity |
|---|-------|---|--|
| | A | B | |
| MRSA | 2 | 0 | Doxycycline, Linezolid, Piperacillin, Tazobactam |
| Citrobacter freundii | 3 | 2 | Gentamycin, Azithromycin, Meropenem, Ceftazidime, Levofloxacin |
| Coagulase negative Staphylococcus aureus | 2 | 0 | Azithromycin, Cefotaxime. Linezolid, Ampicillin |
| Pseudomonas aeruginosa | 2 | 0 | Ceftazidime, Tobramycin, Meropenem |
| Staphylococcus epidermidis | 0 | 1 | Teicoplanin, Vancomycin, Linezolid, Clindamycin |
| Klebsiella oxytoca | 1 | 0 | |

In Group A, Methicillin-resistant *Staphylococcus aureus* (MRSA) was identified in 2 cases, with sensitivity to Doxycycline, Linezolid, and a combination of Piperacillin and Tazobactam. *Citrobacter freundii* was found in 3 cases in Group A and 2 cases in Group B. This bacterium showed sensitivity to Gentamycin, Azithromycin, Meropenem, Ceftazidime, and Levofloxacin. Coagulase-negative *Staphylococcus aureus* was isolated in 2 cases in Group A, with sensitivity to Azithromycin, Cefotaxime, Linezolid, and Ampicillin. *Pseudomonas aeruginosa* was

detected in 2 cases in Group A and was sensitive to Ceftazidime, Tobramycin, and Meropenem. Staphylococcus epidermidis was identified in 1 case in Group B, showing sensitivity to teicoplanin, Vancomycin, Linezolid, and Clindamycin. Klebsiella oxytoca was found in 1 case in Group A, but specific antibiotic sensitivities were not detailed.

Table 9: Distribution of patients based on the duration of post operative stay

| | GROUP | Mean | Std. Deviation | T Test | P Value |
|-------------------------------|-------|------|-------------------|-----------|------------|
| POST OPERATIVE STAY (DAYS) | A | 5.72 | 1.617 | 2.30 | 0.02 |
| | B | 5.31 | 1.176 | | |

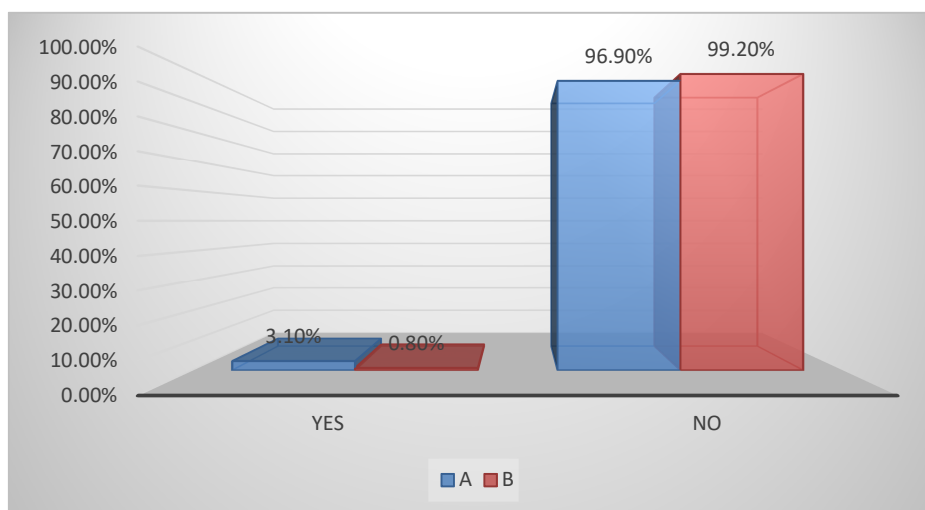
The mean postoperative stay is 5.72 days with a standard deviation of 1.617 in Group A and 5.31 days with a standard deviation of 1.176 in Group B.

Table 10: Distribution of patients based on readmission in view of SSI

| | | | GROUP | | Total |
|-------------|-----|---|--------|--------|--------|
| | | | A | B | |
| READMISSION | Yes | n | 4 | 1 | 5 |
| | | % | 3.1% | 0.8% | 2.0% |
| | No | n | 124 | 127 | 251 |
| | | % | 96.9% | 99.2% | 98.0% |
| Total | | n | 128 | 128 | 256 |
| | | % | 100.0% | 100.0% | 100.0% |

Chi-Square: 1.83, P Value: 0.18, Statistically not significant

Readmission is noted in 4 participants in Group A (3.1%) and 1 participant in Group B (0.8%), while 124 participants in Group A (96.9%) and 127 in Group B (99.2%) were not readmitted. A prospective observational cohort study was conducted on 741 pregnant women who underwent CS from July to September 2022 by Rahel Mezemir et al. Women who had CS were followed up for at least 30 days.



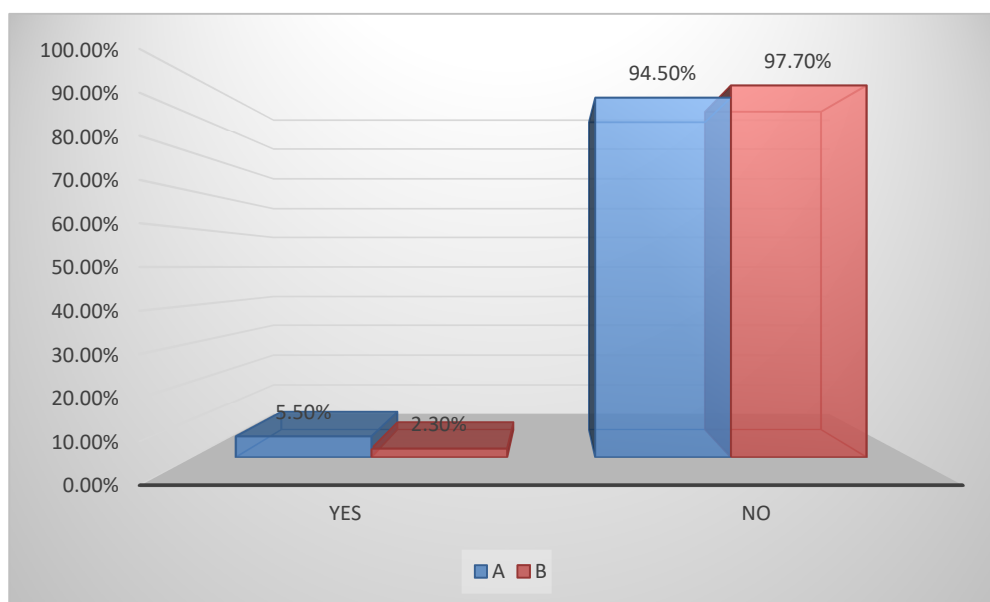
Graph 6: Distribution of patients based on readmission in view of SSI

Table 11: Distribution of patients based on Secondary Suturing

| | | | GROUP | | Total |
|--------------------|-----|---|--------|--------|--------|
| | | | A | B | |
| SECONDARY SUTURING | Yes | n | 7 | 3 | 10 |
| | | % | 5.5% | 2.3% | 3.9% |
| | No | n | 121 | 125 | 246 |
| | | % | 94.5% | 97.7% | 96.1% |
| Total | | n | 128 | 128 | 256 |
| | | % | 100.0% | 100.0% | 100.0% |

Chi-Square: 1.66, P Value: 0.33, Statistically not significant

Secondary suturing was required for 7 participants in Group A (5.5%) and 3 participant in Group B (2.3%), while 123 participants in Group A (94.5%) and 127 in Group B (97.7%) did not require secondary suturing.



Graph 7: Distribution of patients based on Secondary Suturing

DISCUSSION

This randomized controlled trial was conducted over a 12-month period from January 2023 to January 2024. The research was carried out at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre (MRC) in Belagavi. The study population comprised women undergoing emergency cesarean sections, selected based on specific inclusion criteria. The randomized controlled trial design aimed to assess the efficacy of adjunctive Azithromycin in preventing surgical site infections and improving postoperative outcomes.

In this study, in the age group of 19-20 years, there are 8 participants in Group A and 6 participants in Group B, making up 6.3% and 4.7% of their respective groups, and 5.5% of the total participants. The age group of 21-25 years has the highest representation, with 64 participants in Group A and 57 in Group B, constituting 50.0% and 44.5% of their respective groups, and 47.3% of the total participants. For the 26-30 years age group, there are 46 participants in Group A and 54 in Group B, representing 35.9% and 42.2% of their respective groups, and 39.1% of the total participants. The age group of 31-35 years includes 9 participants in Group A and 10 in Group B, making up 7.0% and 7.8% of their respective groups, and 7.4% of the total participants. The smallest age group is above 36 years, with 1 participant each in both groups, representing 0.8% of their respective groups and the total participants. The age distribution of participants in both groups is fairly similar, with the majority of participants falling within the 21-25 years and 26-30 years age ranges. These two age groups collectively account for the vast majority (86.4%) of the study population. The even distribution of participants across the two groups ensures that any observed differences in outcomes between Group A and Group B are not

likely due to age-related biases. The small number of participants in the youngest (19-20 years) and oldest (above 36 years) age groups suggests that the findings of this study will be most applicable to the 21-35 years age range.

The study by Ruzic et al. had a similar age distribution with an older average age, highlighting that older participants were slightly more prevalent in the post-Azithromycin group³⁴ The age distribution in the study by Huang et al. was similar, with the mean age being around 30 years in both groups (30.0 ± 3.1 in the experimental group and 30.4 ± 3.5 in the placebo group). Both studies focused on a relatively young demographic, which is common in cesarean delivery research.³⁵ Liu et al. reported that 87% of their participants were aged 20-35 years, with 21% aged 20-25 years and 39% aged 26-30 years⁵⁵

In this study, in the Normal BMI category, Group A has 106 participants (82.8%) and Group B has 98 participants (76.6%), making up 79.7% of the total participants. The Overweight category includes 21 participants in Group A (16.4%) and 30 in Group B (23.4%), constituting 19.9% of the total participants. The Obese category has only one participant from Group A (0.8%) and none from Group B (0.0%), representing 0.4% of the total participants. The majority of participants in both groups fall into the Normal BMI category, with a slightly higher proportion in Group A. Group B has a higher percentage of Overweight participants. The very small number of Obese participants limits the generalizability of the study findings to obese populations. P Value of 0.23 indicates that the differences in BMI distribution between the groups are not statistically significant.

Ruzic et al. reported similar BMI distributions with a mean BMI of approximately 27.5 kg/m² in both groups³⁴ Huang et al. reported a mean BMI of

approximately 27.5 kg/m² in both groups, with similar proportions of participants being overweight or obese (25 participants in the experimental group and 31 in the placebo group had a BMI \geq 30)³⁵

In this study, participants are categorized based on their obstetric score into nulliparous and multiparous. Group A has 66 nulliparous (51.6%), and 62 multiparous (48.4%). Group B has 56 nulliparous (43.8%), and 72 multiparous (56.3%). Ruzic et al primarily involved primiparous women, which may affect the comparability of outcomes related to parity.³⁴ The study by Huang et al., primarily involved primiparous women, with nearly all participants being in their first pregnancy except for one in each group with a previous vaginal delivery³⁵ Liu et al., (2016) reported that 72% of their participants were primigravida⁵⁵

In this study, the presence of diabetes in pregnancy is noted in 18 participants in Group A (14.1%) and 15 participants in Group B (11.7%), while 110 participants in Group A (85.9%) and 113 in Group B (88.3%) do not have diabetes. The proportion of participants with diabetes in pregnancy is relatively low and similar between the groups. This indicates that diabetes is unlikely to be a confounding factor in the study outcomes. P Value of 0.35 shows no statistically significant difference in the distribution of diabetes between the groups.

In Ruzic et al., prevalence of diabetes was slightly higher, with significant numbers in both pre- and post-Azithromycin groups³⁴ Huang et al. reported similar prevalence rates of diabetes, with 17 participants in the experimental group and 19 in the placebo group having diabetes mellitus³⁵

In this study, anemia is present in 39 participants in Group A (30.5%) and 35 participants in Group B (27.3%), while 89 participants in Group A (69.5%) and 93 in Group B (72.7%) do not have anemia. The prevalence of anemia is slightly higher in Group A, but the difference is not statistically significant. This similarity ensures that anemia does not significantly impact the comparison of outcomes between the groups. P Value of 0.34 indicates no significant difference in anemia distribution between the groups. Liu et al., (2016) reported that 44% of their patients had antepartum anemia⁵⁵

The incidence of surgical site infection was studied in both groups. In Group A, 82 participants (64.1%) had no surgical site infections, and 46 participants (35.9%) had surgical site infections. In Group B, 111 participants (86.7%) had no surgical site infections, and 17 participants (13.3%) had surgical site infection. There is a significantly higher proportion of surgical site infections in Group A compared to Group B. This suggests that the addition of Azithromycin may positively impact wound healing. The incidence of surgical site infection in the control group was 35.9% which was significantly decreased in the intervention group to 13.2%. P Value of 0.001 indicates a statistically significant difference in the incidence of surgical site infections between the 2 groups .

In Ruzic et al., adjunctive Azithromycin was associated with significantly lower odds of postoperative infections, including wound infections³⁴ Huang et al. found that adjunctive Azithromycin significantly reduced the incidence of surgical site infections³⁵ Liu et al. (2016) reported a 27% infection rate even after prophylaxis⁵⁵.

In this study, Surgical site infections are categorized as Superficial, Deep, or organ space. In Group A, there are 48 superficial infections (85.7%) and 8 deep

infections (14.3%). In Group B, there are 5 superficial infections (71.4%) and 2 deep infections (28.6%). The distribution of surgical site infections is similar between the groups, with most infections being superficial. The Chi-Square test shows that the difference in the type of surgical site infection between the groups is not statistically significant. In Ruzic et al, Reduction in overall postoperative infections, including Endometritis, superficial, and deep wound infections, was noted with Azithromycin³⁴ Liu et al. (2016) identified similar infection types, noting significant rates of Endometritis and wound infections post-surgery⁵⁵

In this study, In Group A, Methicillin-resistant *Staphylococcus aureus* (MRSA) was identified in 2 cases, with sensitivity to Doxycycline, Linezolid, and a combination of Piperacillin and Tazobactam. *Citrobacter freundii* was found in 3 cases in Group A and 2 cases in Group B. This bacterium showed sensitivity to Gentamycin, Azithromycin, Meropenem, Ceftazidime, and Levofloxacin. Coagulase-negative *Staphylococcus aureus* was isolated in 2 cases in Group A, with sensitivity to Azithromycin, Cefotaxime, Linezolid, and Ampicillin. *Pseudomonas aeruginosa* was detected in 2 cases in Group A and was sensitive to Ceftazidime, Tobramycin, and Meropenem. *Staphylococcus epidermidis* was identified in 1 case in Group B, showing sensitivity to teicoplanin, Vancomycin, Linezolid, and Clindamycin. *Klebsiella oxytoca* was found in 1 case in Group A, but specific antibiotic sensitivities were not detailed.

Huang et al. also conducted microbiological cultures but focused more on overall infection rates and CSD prevalence rather than specific organisms³⁵ Liu et al identified common microbes like staphylococci and enterococci. Furthermore, when specifically identified, ureaplasma (or *Mycoplasma* genus) is the most common

organism isolated from the amniotic fluid and chorioamnion at caesarean delivery, and is associated with a 3- to 8-fold increased risk of post-caesarean Endometritis or wound infection⁵⁵

In this study, readmission is noted in 4 participants in Group A (3.1%) and 1 participant in Group B (0.8%), while 124 participants in Group A (96.9%) and 127 in Group B (99.2%) were not readmitted. The proportion of readmissions is higher in Group A, suggesting a potential benefit of Azithromycin in reducing readmissions. P Value of 0.18 indicates that this difference is not statistically significant. In a study conducted by Tita et al, concluded that there was a significant reduction in the readmission rates with the use of the broader spectrum antibiotic - 27(2.6) in intervention group vs 49(4.9) in placebo group with a statistically significant P value of 0.007.⁵

In this study, Secondary suturing was required for 7 participants in Group A (5.5%) and 3 participants in Group B (2.3%), while 123 participants in Group A (94.5%) and 127 in Group B (97.7%) did not require secondary suturing. The need for secondary suturing is higher in Group A, indicating that Azithromycin may reduce the need for additional surgical interventions. However, P Value of 0.33 shows that this difference is not statistically significant.

In this study, mean postoperative stay is 5.72 days with a standard deviation of 1.617 in Group A and 5.31 days with a standard deviation of 1.176 in Group B. The mean postoperative stay is slightly shorter in Group B, suggesting a potential benefit of Azithromycin in reducing hospital stay duration. P Value of 0.02 indicates that this difference is statistically significant. A study conducted by Tita et al, showed a

significant reduction in post operative stay with use of extended spectrum antibiotic when compared with the use of a narrow spectrum antibiotic. (3.12 versus 4.46)⁵

RCT ON ANTIBIOTIC USAGE IN CESAREAN SECTION AMONG DIFFERENT STUDIES

| STUDY BY | TYPE OF STUDY | OUTCOME |
|----------------------------------|---|--|
| Ruiz- Moreno et al ³⁹ | RCT comparing IV Metronidazole vs placebo | endometritis (14% vs 30%), wound infection (2% vs 8%) are less in Metronidazole group when compared to placebo group. |
| Pitt et al ⁴⁰ | Double blinded RCT comparing intravaginal Metronidazole vs placebo | 7% developed endometritis in Metronidazole group as compared to 19% of those receiving placebo gel. |
| Andrews et al ⁴¹ | Double blinded RCT comparing cefotetan with Doxycycline +Azithromycin | Post CS endometritis (16.9% vs 24.7%, p= .02), wound infections(0.8% vs 3.6% and p=.03) were significantly less in Doxycycline +Azithromycin group. |
| Mayer et al ⁴² | Double blinded prospective RCT comparing Cefazolin versus Cefazolin plus Metronidazole | Significant reduction in postoperative infection rate (14% vs 32%) and duration of hospital stay (3.12% vs 4.46%) with Cefazolin plus Metronidazole group |
| Alekwe et al ⁴³ | RCT comparing single dose of Ceftriaxone vs multiple doses of Gentamycin, Metronidazole. | Incidence of endometritis (14% vs 15%), UTI(11% vs 15%) and SSI(7% vs 6%) are not significantly different in both the groups. |
| Tita et al ⁵ | RCT comparing IV Azithromycin vs placebo | Infectious morbidity(6.1% vs 12%, p< 0.001), Endometritis is (3.8% vs 6.1%, p = 0.002), wound infection is(2.4% vs 6.6%, p< 0.001), adverse maternal events is(1.5% vs 2.9%, p = 0.03) are significantly less in Azithromycin group. |
| Lyimo et al ⁴⁴ | RCT comparing single IV dose of Gentamycin+ Metronidazole vs 8hourly administration of the same antibiotics for 24 hrs. | SSI occurred in 4.8% in 1st group compared to 6.4% in 2 nd group. |

In Cochrane review (2014) of 95 studies enrolling more than 15,000 women, the use of prophylactic antibiotics in women who underwent CS reduced the incidence of wound infection, endometritis and maternal serious infectious

complications when compared with no treatment. Gerstner, et al (1980) and Ruiz-Moreno, et al (1991) showed that when Metronidazole was given intravenously, the chances of endometritis, surgical site infection, and rate of postoperative febrile morbidity was reduced⁴⁵. In a prospective comparative study by O'Leary et al in 1986, post cesarean morbidity was lesser in Ampicillin -Gentamycin group as compared to Ampicillin alone^{39,46}. Metronidazole, when used as a prophylactic agent administered intravenously or rectally gave mixed results for post caesarean endometritis and wound infection. The timing of administration of antibiotic was also a concern. Cochrane (2002) and ACOG (2003) recommended administering prophylactic antibiotics after cord clamping⁴⁷. Cochrane Database of Systematic Reviews (2003) and CDC (2006) recommended administration of Cephalosporins of first generation like Cefazolin after clamping of umbilical cord as prophylaxis against post- caesarean infections rather than a pre-surgical prophylaxis. Cefazolin was considered as it was equally effective and cheaper than broad-spectrum antibiotics^{48,49}. A retrospective study conducted in Pittsburgh, USA (2002 - 2007), reviewed the cases of cesarean deliveries where antibiotic was given before the skin incision in first group and after clamping of cord in second group. First group had lower rates of Endometritis and wound infection. Further, it had no adverse effect on the neonate. Similar findings were observed by Yokoe⁴⁷ et al. when Cefazolin was given 15-60 minutes preceding an incision or at the time of clamping of the cord with no increase in rates of neonatal sepsis.

A questionnaire based study published in the Journal of Indian Medical Association (2008) evaluated the antibiotic prescriptions of obstetricians working in different centers in vaginal deliveries and cesarean sections. A single antibiotic Cefazolin 1gm every 12th hourly intravenously for three days was used by 34.4% and

33.3% of practitioners in planned and non-elective cesarean sections respectively. The antibiotic was used for five days by 35.5% and 41.1% of doctors respectively. A triple antibiotic regimen of Ampicillin, Metronidazole and Gentamycin was used by 30% and 25.5% doctors for planned and non-elective and Cesarean respectively for five days.⁴³

ACOG (2010) recommended Cefazolin 1 - 2 g IV one hour prior to the surgery or as soon as possible if it is an emergency cesarean⁵⁰. SOGC (2010) recommended, all parturient scheduled to elective or emergency CS should be given antibiotic as prophylaxis not more than 60 minutes prior to skin incision with first-generation cephalosporin and single drug dose is sufficient if total duration of surgery is less than three hours and the total blood loss is less than one and half litre when a repeat dose is advised. In case of allergy to Penicillin, Clindamycin or Erythromycin can be used.⁵¹

Baaqeel, H and Baaqeel, R in 2013 systematic review regarding the timing of administration of prophylactic antibiotics in CS confirmed that the pre-incisional use and not after cord clamping, had less post CS maternal infectious morbidity and no immediate untoward effects on the newborn⁵². A RCT by Tita, et al in 2013 assigned women with a singleton pregnancy of ≥ 24 weeks period of gestation undergoing CS in labor with or without leakage of amniotic fluid to Azithromycin plus standard antibiotic versus placebo versus standard antibiotic groups. Incidence of Endometritis, wound complications, and serious maternal adverse events were significantly lower in Azithromycin added group. The neonatal outcome was same in both the groups⁵

Systematic review of Cochrane database (2014) of 7299 women provided a comparison between the use of Cephalosporins versus Penicillins for antibiotic prophylaxis for CS⁵³. The efficacy of Cephalosporins and Penicillins was comparable in preventing immediate post cesarean infections.

Pinto-Lopes R et al in 2017 in his review article included 16 studies, involving 2695 women and no significant difference was observed between single dose and multiple dose antibiotic prophylaxis in the incidence of postpartum infectious morbidity, endometritis, and wound infection. A trend towards lower risk of urinary tract infection was seen with multiple dosing⁵⁴.

LIMITATIONS

- The study has a limited sample size and therefore might not have had enough statistical power to detect significant associations between certain variables and SSIs.
- The research was conducted at a single medical center, which may limit the generalizability of the findings to other settings with different patient demographics or clinical practices.
- The follow-up period for assessing wound status and infection rates was insufficient to capture all relevant postoperative complications.
- The study did not examine a significant association between variables related to health professionals, methods of sterilization of equipment, frequency, and number of operation rooms.

CONCLUSION

- In this Randomized control trial conducted at a tertiary care Centre, Belagavi involving 256 participants over a span of one year, it was concluded that adjunctive Azithromycin administration decreases post-operative infectious morbidity in emergency cesarean deliveries when administered within 60 minutes prior to skin incision. This study also showed that administration of Azithromycin as an adjunct prophylactic drug prior to cesarean delivery reduced the duration of hospital stay, need for re-suturing, and decrease in the need for readmission. There was a significant reduction in the incidence of surgical site infection to 13.2 % (intervention group) from 35.4% (Control group). The high incidence rate of SSIs after C-sections in this study highlights the need for prioritizing SSI control and surveillance.

SUMMARY

- The study included 256 participants evenly divided into two groups. Group A (Control Group) and Group B (Treatment Group). Each group consists of 128 participants. Group A: Control group - Injection Ceftriaxone 1g IV. (Standard antibiotic prophylaxis group); Group B: Injection Ceftriaxone 1g IV (Standard antibiotic prophylaxis group) + Azithromycin 500mg IV.
- Group A had 50% aged 21-25 years and 35.9% aged 26-30 years, while Group B had 44.5% aged 21-25 years and 42.2% aged 26-30 years. The even distribution of participants across the two groups ensures that any observed differences in outcomes between Group A and Group B are not likely due to age-related biases.
- Most participants had a normal BMI, with 82.8% in Group A and 76.6% in Group B. The overweight category included 16.4% in Group A and 23.4% in Group B, with only one participant categorized as obese. P Value was observed to be 0.23 and hence statistically not significant.
- Nulliparous women were more prevalent, with 51.6% in Group A and 43.8% in Group B and showed no statistical significance.
- 14.1% of Group A and 11.7% of Group B had diabetes in pregnancy and showed no significant difference in anemia distribution between the groups.
- Anemia was present in 30.5% of Group A and 27.3% of Group B. P Value of 0.34 indicates no significant difference in anemia distribution between the groups.

- The incidence of surgical site infection was studied in both groups. In Group A, 82 participants (64.1%) had no surgical site infections, and 46 participants (35.9%) had surgical site infections. In Group B, 111 participants (86.7%) had no surgical site infections, and 17 participants (13.3%) had surgical site infection. It was noted to be statistically significant. The incidence of surgical site infection in the control group was 35.9% which was significantly decreased in the intervention group to 13.2%.
- Both groups had a similar distribution of deep and superficial infections, with 14.3% deep infections in Group A and 28.6% in Group B, and 85.7% superficial infections in Group A and 71.4% in Group B showing no statistical significance.
- There were no statistically significant differences in the distribution of organisms found in wound cultures between the groups.
- Group A had higher readmission rates. P Value of 0.18 indicates that this difference is not statistically significant.
- The need for secondary suturing is higher in Group A, indicating that Azithromycin may reduce the need for additional surgical interventions. However, P Value of 0.33 shows that this difference is not statistically significant.
- The mean postoperative stay was shorter in Group B (5.31 days) compared to Group A (5.72 days). The mean postoperative stay is slightly shorter in Group B, suggesting a potential benefit of Azithromycin in reducing hospital stay duration. P Value of 0.02 indicates that this difference is statistically significant

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ANNEXURE-I

KAHERs JNMC BELAGAVI

INFORMED CONSENT FORM

**AZITHROMYCIN AS AN ADJUNCT PROPHYLACTIC DRUG FOR
PREVENTION OF SURGICAL SITE INFECTION (SSI) IN CESAREAN
DELIVERY-A RANDOMIZED CONTROL TRIAL**

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective: To study the effectiveness of azithromycin in reducing surgical site infection in cesarean delivery.

Introduction: Cesarean section rates have increased worldwide and it has been observed that cesarean delivery is the most common surgical procedure associated with an increased rate of surgical site infection. Hence, this study will be carried out to study the effectiveness of a widely used antibiotic –Azithromycin in reducing surgical site infection in cesarean delivery.

Explanation of procedure: Patients will be classified into 2 groups by computer generated randomization system. The list of randomization will be concealed and expressed by sequentially numbered, sealed envelope just prior to intervention. Each number will allocate the patient to either treatment group A or group B. Group A will receive the standard antibiotic prophylactic drug –xone 1g IV. Group B will receive the standard antibiotic prophylactic drug-xone 1g IV along with Azithromycin 500mg IV .The primary outcome of surgical site infection will be studied and Compared between 2 groups.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation

once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study “**Azithromycin as an adjunct prophylactic drug for prevention of Surgical Site Infection(SSI) in cesarean delivery-A Randomized Control Trial**”. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE-II

PARTICIPANT INFORMATION

IP Number:

First Name: _____

Middle Name: _____

Last Name: _____

Husband's Name: _____

Age (Years): _____

Address:

H.No-

Street- _____

Taluka- _____

District- _____

Phone Number- _____

Landline (Optional)- _____

Registered

Unregistered

SCREENING FORM

Screening number:

Date of Screening:

(dd/mm/yyyy)

1) Is Gestational Age \geq 28weeks? Yes No

LMP –

EDD -

STUDY PROFORMA

Study ID :

| | | | | | | | |
|--|--|--|--|--|--|--|--|
| | | | | | | | |
|--|--|--|--|--|--|--|--|

| | |
|-------------------|--|
| Date of Admission | |
| Date of Delivery | |
| Date of Discharge | |

Maternal Data:

| | | |
|----------------------------------|-----------------|--|
| Height (m) | | |
| Weight (kg) | | |
| BMI | | |
| Obstetric Score | Primigra | |
| | Multipara | |
| | Grand multipara | |
| Indication for caesarean section | | |
| Skin Incision type | | |
| 1. Pfannenstiel incision | | |
| 2. Vertical | | |
| Type of suture technique used | | |
| 1. subcuticular sutures | | |
| 2. mattress sutures | | |

| | |
|-------------------------------------|--|
| Timing of study drug administration | |
| 1. Before skin incision | |
| a) 0-60 min before | |
| b) >60 min before | |
| 2. After skin incision | |

POST OPERATIVE FOLLOW UP-

STATUS OF WOUND AFTER 72 HOURS

Healthy-

Unhealthy -

| |
|---|
| SIGNS OF INFECTION AND INFLAMMATION- |
| 1. Redness at incision site |
| 2. Pain at incision site |
| 3. Swelling at incision site |
| 4. Warmth at incision site |
| 5. Discharge from incision site |
| 6. Pus from incision site |
| 7. Wound gape |

| |
|--|
| 8.Fever with tenderness at incision site |
| 9. Discharge per vagina |
| 10.Postpartum fever |

POST OPERATIVE ANTIBIOTICS –

YES –

If yes ,Reason –

NO

Culture swab report (if sent)-

Post operative hospital stay duration –

Secondary suturing –

Yes

No

Readmission –

Adverse Events related to azithromycin, if any

| |
|---------------------------------|
| GIT (Nausea/Vomiting/Diarrhoea) |
| Skin rash and itching |
| Headache |
| Qt prolongation |

ANNEXURE -III MASTER CHART

| SLNO | AGE | PERIOD OF GESTATION | BMI | OBSTETRIC SCORE | INDICATION | DIABETES IN PREGNANCY | ANEMIA | HEMOGLOBIN | GROUP | Types of suture technique | STATUS OF WOUND | SIGNS OF INFECTION/INFLAMMATION | POST OPERATIVE STAY | WOUND CULTURE | READMISSION | SECONDARY SUTURING |
|------|-----|---------------------|------|-----------------|---|-----------------------|--------|------------|-------|---------------------------|-----------------|---------------------------------|---------------------|---------------|-------------|--------------------|
| 1 | 25 | 39 weeks 6 days | 23.6 | multiparous | previous lscs in labour | No | No | 11.3 | A | mattress | unhealthy | discharge | 7 days | MRSA | No | No |
| 2 | 19 | 38 weeks 6 days | 22.4 | nulliparous | Meconium stained liquor | No | No | 13.6 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 3 | 25 | 39 weeks | 21.9 | multiparous | previous lscs in labour | No | No | 12.8 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 4 | 28 | 37 weeks 2 days | 20.5 | multiparous | previous lscs in labour | No | Yes | 10 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 5 | 31 | 38 weeks 1 day | 26.6 | multiparous | previous lscs in labour | No | No | 13.7 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 6 | 26 | 39 week 6 days | 24.5 | multiparous | meconium stained liquor | No | No | 12.6 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 7 | 29 | 37 weeks 6 days | 23.9 | multiparous | previous lscs in labour | No | No | 13 | A | mattress | unhealthy | induration | 7 days | NA | no | no |
| 8 | 32 | 38 weeks 5 days | 25.7 | multiparous | previous lscs in labour | No | No | 12 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 9 | 24 | 39 weeks | 25.6 | multiparous | previous lscs in labour | No | Yes | 10.6 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 10 | 22 | 36 weeks 5 days | 23 | multiparous | previous lscs in labour | Yes | Yes | 10.6 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 11 | 23 | 37 weeks | 23.8 | nulliparous | contracted pelvis | No | No | 11.4 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 12 | 27 | 38 weeks | 22.3 | nulliparous | pathological trace | No | No | 12.8 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 13 | 19 | 40 weeks 1 day | 26.5 | nulliparous | fetal distress | No | No | 11.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 14 | 20 | 38 weeks 1 day | 26.1 | nulliparous | CPD | Yes | Yes | 10.7 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 15 | 22 | 37 weeks 1 day | 22.8 | nulliparous | fetal distress | No | No | 12.6 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 16 | 27 | 37 weeks 1 day | 22.8 | multiparous | previous lscs with oligohydramnios | No | No | 11.4 | A | subcuticular | healthy | No | 6 days | NA | no | no |
| 17 | 25 | 38 weeks 5 days | 25.2 | multiparous | previous lscs with breech | Yes | Yes | 9.5 | A | subcuticular | unhealthy | induration | 5 days | NA | no | no |
| 18 | 27 | 38 weeks 6 days | 22.5 | multiparous | prev lscs with impending brain sparing effect | No | no | 11.2 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 19 | 22 | 40 weeks 4 days | 23.8 | nulliparous | severe oligohydramnios | No | Yes | 10.7 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 20 | 25 | 39 weeks | 23.7 | multiparous | previous lscs in labour | No | No | 13.5 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 21 | 31 | 40 weeks | 26.6 | nulliparous | fetal distress | No | No | 12.6 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 22 | 23 | 39 weeks 6 days | 22.6 | multiparous | previous lscs in labour | No | No | 12 | A | subcuticular | unhealthy | induration | 5 days | NA | no | no |
| 23 | 23 | 39 weeks 2 days | 22.8 | nulliparous | meconium stained liquor | YES | No | 12.1 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 24 | 26 | 40 weeks 2 days | 23.8 | nulliparous | fetal distress | No | No | 11.4 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 25 | 23 | 36 weeks 1 day | 21.6 | multiparous | previous lscs in labour | No | No | 11.2 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 26 | 23 | 40 weeks | 25.8 | nulliparous | anamnios | YES | Yes | 9.4 | B | subcuticular | unhealthy | discharge | 5 days | NA | no | no |
| 27 | 25 | 38 weeks 1 day | 22.6 | multiparous | previous lscs in labour | No | No | 13.1 | B | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 28 | 24 | 38 weeks 2 days | 25.6 | nulliparous | oblique lie | No | No | 12.2 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 29 | 21 | 40 weeks 2 days | 25 | nulliparous | meconium stained liquor | Yes | No | 12.1 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 30 | 28 | 40weeks 5 days | 24.2 | nulliparous | macrosomia | Yes | No | 11 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |

| | | | | | | | | | | | | | | | | |
|----|----|-----------------|------|--------------|---|-----|-----|------|---|--------------|-----------------|----------------|---------|----|----|----|
| 31 | 27 | 38 weeks 4 days | 23.9 | multiparous | second stage arrest with prev lscs | No | Yes | 9.2 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 32 | 32 | 38 weeks 4 days | 22.9 | nulliparous | transverse lie | No | No | 11.7 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 33 | 27 | 33 weeks | 23.8 | nulliparous | anamnios | No | No | 11.7 | A | subcuticular | unhealthy | discharge | 10 days | NA | no | no |
| 34 | 25 | 40 weeks 1 day | 24.7 | multiparous | previous lscs in labour | No | No | 13 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 35 | 24 | 37 weeks 2 days | 25.6 | multiparous | previous lscs with scar tenderness | No | No | 11.9 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 36 | 27 | 38 weeks 4 days | 23.5 | multiparous | previous lscs in labour | Yes | No | 13.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 37 | 23 | 39 weeks 5 days | 24.6 | nulliparous | breach in labour | No | No | 12.1 | A | subcuticular | unhealthy | discharge | 6 days | NA | no | no |
| 38 | 20 | 38 weeks 2 days | 23.2 | nulliparous | failed induction | No | No | 13.5 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 39 | 24 | 38 weeks 4 days | 25 | multiparous | previous lscs in labour | No | No | 12.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 40 | 26 | 37 weeks | 23.2 | multiparous | previous lscs in labour | No | No | 12 | B | subcuticular | wound healthy | No | 4 days | NA | no | no |
| 41 | 29 | 38 weeks 6 days | 23.4 | multiparous | previous lscs in labour | No | No | 11 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 42 | 24 | 37 weeks 1 day | 26 | nulliparous | DCDA twins in labour | No | Yes | 10 | B | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 43 | 28 | 38 weeks 2 days | 23.5 | multiparous | previous lscs in labour | No | No | 11.6 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 44 | 25 | 38 weeks 5 days | 21 | multiparous | previous lscs in labour | no | No | 12 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 45 | 32 | 39 weeks | 24.5 | multiparous | previous lscs in labour | No | no | 11 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 46 | 21 | 39 weeks 5 days | 24 | nulliparous | failed induction | no | Yes | 10.6 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 47 | 25 | 38 weeks 4 days | 26 | nulliparous | fetal distress | no | Yes | 10.4 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 48 | 24 | 37 weeks | 23 | multiparous | previous lscs in labour | no | No | 11.2 | A | subcuticular | wound healthy | no | 6 days | NA | no | no |
| 49 | 25 | 40 weeks 2 days | 24.5 | nulliparous | meconium stained liquor | no | No | 13.2 | B | subcuticular | wound healthy | no | 6 days | NA | no | no |
| 50 | 28 | 37 weeks | 23.5 | multiparous | previous lscs in labour | no | No | 12 | B | subcuticular | wound healthy | no | 6 days | NA | no | no |
| 51 | 22 | 38 weeks 3 days | 22.3 | multiparous | previous lscs with severe oligohydramnios | No | No | 12.3 | B | mattress | wound healthy | No | 5 days | NA | no | no |
| 52 | 22 | 38 weeks 5 days | 23.5 | multiparous | previous lscs with scar tenderness | No | Yes | 10.9 | A | subcuticular | wound unhealthy | yes,induration | 7 days | NA | no | no |
| 53 | 30 | 39 weeks 1 day | 22.8 | multiparous | previous lscs in labour | No | Yes | 10.6 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 54 | 27 | 36 weeks | 23.4 | multiparous | fetal macrosomia with previous lscs | YES | Yes | 10.8 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 55 | 25 | 40 weeks 2 days | 22.6 | mutiparous | previous lscs in labour | No | Yes | 11.4 | A | mattress | wound healthy | No | 8 days | NA | no | no |
| 56 | 26 | 38 weeks 3 days | 23.4 | nulliparous | meconium stained liquor | No | Yes | 9.8 | A | subcuticular | wound unhealthy | No | 5 days | NA | no | no |
| 57 | 24 | 38 weeks | 24.5 | nulliparous | meconium stained liquor | No | no | 11.6 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 58 | 23 | 39 weeks 5 days | 23.5 | multiparous | previous lscs in labour | No | Yes | 10.5 | B | subcuticular | unhealthy | discharge | 5 days | NA | no | no |
| 59 | 28 | 38 weeks 3days | 22.9 | multiparous | fetal distress | No | No | 12.8 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 60 | 20 | 39 weeks 2 days | 23.5 | nulliparous | fetal distress | No | No | 12.4 | B | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 61 | 23 | 39 weeks | 22.4 | Primigravida | fetal distress | No | no | 11.3 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 62 | 28 | 37 weeks | 25 | multiparous | previous lscs with breach in labour | YES | no | 12.7 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 63 | 25 | 40 weeks | 23.5 | nulliparous | failed induction | No | no | 12.4 | A | subcuticular | wound health | No | 5 days | NA | no | no |
| 64 | 25 | 39 weeks | 22.9 | multiparous | previous lscs in labour | no | No | 12.6 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 65 | 32 | 38 weeks 2 days | 23.5 | mutiparous | previous lscs in labour | No | yes | 9.9 | B | subcuticular | healthy | induration | 8 days | NA | no | no |
| 66 | 24 | 37 weeks 3 days | 23.8 | multiparous | previous lscs in labour | No | Yes | 13.1 | A | subcuticular | healthy | no | 5 days | NA | no | no |
| 67 | 23 | 38 weeks 1 day | 25.2 | multiparous | fetal distress | YES | Yes | 10.9 | B | subcuticular | unhealthy | induration | 6 days | NA | no | no |
| 68 | 23 | 37 weeks 2 days | 21.9 | multiparous | meconium stained liquor | No | yes | 10.8 | A | subcuticular | healthy | no | 5 days | NA | no | no |
| 69 | 28 | 40 weeks 2 days | 23.9 | nulliparous | fetal distress | No | No | 13 | B | subcuticular | healthy | no | 5 days | NA | no | no |
| 70 | 24 | 38 weeks 2 days | 22.3 | multiparous | previous lscs in labour | No | No | 12.9 | A | mattress | unhealthy | induration | 8 days | NA | no | no |

| | | | | | | | | | | | | | | | | |
|-----|----|-----------------|------|--------------|--------------------------------|-----|-----|------|---|--------------|-----------------|------------|---------|----|-----|----|
| 71 | 27 | 37 weeks 2 days | 23.2 | nulliparous | previous lscs in labour | no | No | 12 | B | mattress | healthy | no | 5 days | NA | no | no |
| 72 | 22 | 39 weeks 2 days | 23.4 | nulliparous | anamnios | no | No | 12.9 | B | subcuticular | healthy | no | 5 days | NA | no | no |
| 73 | 27 | 38 weeks 4 days | 24.2 | nulliparous | Non progression of labour | no | No | 11.6 | B | subcuticular | healthy | no | 5 days | NA | no | no |
| 74 | 23 | 39 weeks | 23.9 | nulliparous | failed induction | YES | no | 12.1 | A | subcuticular | healthy | no | 5 days | NA | no | no |
| 75 | 19 | 39 weeks | 24 | multiparous | previous lscs in labour | no | yes | 9.9 | A | subcuticular | unhealthy | induration | 6 days | NA | no | no |
| 76 | 27 | 41 weeks | 23.4 | nulliparous | non reassuring CTG | no | no | 12.8 | A | subcuticular | healthy | no | 5 days | NA | no | no |
| 77 | 27 | 39 weeks 2 days | 22.9 | nulliparous | meconium stained liquor | no | no | 12.4 | A | subcuticular | healthy | no | 6 days | NA | no | no |
| 78 | 28 | 38 weeks 3 days | 22.3 | multiparous | previous lscs in labour | no | yes | 10.7 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 79 | 22 | 40 weeks 4 days | 23.8 | nulliparous | meconium stained liquor | no | no | 11.2 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 80 | 22 | 40 weeks 3 days | 26.7 | multiparous | previous lscs with post datism | no | no | 12.6 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 81 | 25 | 38 weeks | 24.5 | nulliparous | failed induction | no | no | 10.2 | A | subcuticular | unhealthy | induration | 7 days | NA | no | no |
| 82 | 28 | 38 weeks 3 days | 22.6 | nulliparous | fetal distress | no | no | 11.2 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 83 | 29 | 38 weeks 1 day | 23.4 | nulliparous | previous lscs in labour | no | yes | 10.6 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 84 | 21 | 38 weeks 6 days | 23.6 | nulliparous | fetal distress | no | no | 11.9 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 85 | 20 | 37 weeks 5 days | 25.6 | nulliparous | breech with FGR | no | yes | 10.5 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 86 | 26 | 39 weeks 2 days | 26 | nulliparous | breech in labour | no | yes | 9.9 | A | subcuticular | unhealthy | discharge | 8 days | NA | no | no |
| 87 | 24 | 37 weeks 1 day | 25.5 | nulliparous | fetal distress | no | no | 11.3 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 88 | 23 | 36 weeks | 26 | nulliparous | non reassuring CTG | YES | yes | 10.9 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 89 | 31 | 37 weeks 1 day | 23.4 | nulliparous | prev lscs with oligohydramnios | no | no | 12.5 | A | subcuticular | unhealthy | induration | 6 days | NA | no | no |
| 90 | 23 | 40 weeks 1 day | 25.6 | nulliparous | meconium stained liquor | no | yes | 10.2 | B | subcuticular | unhealthy | induration | 7 days | NA | no | no |
| 91 | 30 | 38 weeks 1 day | 22.3 | multiparous | previous lscs in labour | no | no | 11.1 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 92 | 21 | 39 weeks 5 days | 23.4 | nulliparous | CPD | Yes | no | 13.1 | A | subcuticular | unhealthy | discharge | 11 days | NA | no | no |
| 93 | 27 | 39 weeks | 21.6 | multiparous | previous lscs in labour | no | no | 12.5 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 94 | 24 | 39 weeks 5 days | 23.5 | multiparous | previous lscs in labour | no | no | 11.1 | B | subcuticular | healthy | No | 6 days | NA | no | no |
| 95 | 21 | 37 weeks 4 days | 24.8 | nulliparous | transverse lie with FGR | no | no | 12.2 | B | subcuticular | healthy | No | 7 days | NA | no | no |
| 96 | 27 | 38 weeks 4 days | 24 | multigravida | previous lscs in labour | no | no | 11.9 | A | mattress | healthy | No | 8 days | NA | no | no |
| 97 | 22 | 39 weeks 6 days | 25 | nulliparous | fetal distress | no | no | 11 | B | subcuticular | healthy | No | 9 days | NA | no | no |
| 98 | 24 | 38 weeks 5 days | 26.7 | nulliparous | previous lscs not w/f vbac | no | no | 11.7 | B | subcuticular | healthy | no | 5 days | NA | no | no |
| 99 | 20 | 40 weeks 2 days | 24.6 | nulliparous | failed induction | no | no | 13.4 | B | subcuticular | healthy | no | 5 days | NA | no | no |
| 100 | 26 | 38 weeks | 23.5 | nulliparous | short stature with cpd | no | no | 14.8 | B | subcuticular | healthy | no | | NA | no | no |
| 101 | 19 | 41 weeks | 22.5 | nulliparous | CPD | no | no | 11.1 | A | subcuticular | wound unhealthy | discharge | 6 days | NA | no | no |
| 102 | 36 | 34 weeks 2 days | 36 | nulliparous | fetal distress | no | no | 13.8 | A | subcuticular | wound unhealthy | induration | 5 days | NA | yes | no |
| 103 | 23 | 39 weeks 3 days | 24.4 | multiparous | previous lscs in labour | no | no | 12 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 104 | 23 | 37 weeks 5 days | 25 | nulliparous | CPD | no | yes | 10 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 105 | 22 | 37 weeks 5 days | 23 | multiparous | previous lscs in labour | no | no | 11 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 106 | 24 | 36 weeks | 21.6 | nulliparous | severe oligohydramnios | no | no | 13.9 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 107 | 24 | 38 weeks 1 day | 21.9 | nulliparous | failed induction | YES | no | 11.1 | A | subcuticular | wound healthy | No | 4 days | NA | no | no |
| 108 | 27 | 37 weeks 3 days | 27 | multiparous | previous lscs in labour | no | no | 12.6 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 109 | 30 | 37 weeks 1 day | 24.5 | nulliparous | anamnios | YES | no | 12.1 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 110 | 23 | 38 weeks | 23.7 | nulliparous | anamnios | no | no | 12.3 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 111 | 28 | 38 weeks | 21 | multiparous | non progression of labour | YES | yes | 9.8 | B | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 112 | 22 | 40 weeks 4 days | 21.3 | multiparous | previous lscs in labour | no | no | 11.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 113 | 22 | 39 weeks 6 days | 21.6 | nulliparous | fetal distress | no | no | 12.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 114 | 26 | 38 weeks 2 days | 23.3 | multiparous | previous lscs in labour | no | no | 11.5 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |

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|-----|----|-----------------|------|-------------|---------------------------------------|-----|-----|------|---|--------------|-----------------|------------|---------|--------------|-----|-----|
| 115 | 24 | 39 weeks 5 days | 26.1 | multiparous | previous lscs in labour | no | no | 13 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 116 | 35 | 38 weeks 6 days | 29.7 | multiparous | previous lscs in labour | no | no | 11.3 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 117 | 24 | 38 weeks 1 day | 25.6 | nulliparous | non progression of labour | no | no | 12.2 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 118 | 27 | 41 weeks 1 day | 22.3 | nulliparous | fetal distress | YES | yes | 10.1 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 119 | 29 | 37 weeks 6 dayd | 23.2 | multiparous | previous lscs in labour | no | no | 11 | A | mattress | wound healthy | no | 5 days | NA | no | no |
| 120 | 25 | 37 weeks | 22.5 | nulliparous | breech in labour | no | no | 11.4 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 121 | 22 | 38 weeks 2 days | 23.7 | multiparous | previous lscs in labour | no | yes | 10 | B | subcuticular | wound healthy | discharge | 5 days | NA | no | no |
| 122 | 27 | 39 weeks 2 days | 22.8 | nulliparous | fetal distress | no | no | 11.4 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 123 | 21 | 37 weeks 4 days | 24.3 | nulliparous | failed induction | no | no | 11.8 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 124 | 28 | 36 weeks | 26 | multiparous | previous lscs with uncontrolled sugar | YES | no | 11.8 | A | subcuticular | unhealthy | discharge | 10 days | NA | no | no |
| 125 | 28 | 38 weeks 5 days | 20.5 | multiparous | previous lscs in labour | no | yes | 11.7 | A | subcuticular | wound healthy | no | 6 days | NA | no | no |
| 126 | 21 | 36 weeks 2 days | 21.6 | nulliparous | failed induction | no | no | 13 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 127 | 24 | 36 weeks 5 days | 23.1 | multiparous | previous lscs with breech in labour | no | no | 13.3 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 128 | 26 | 37 weeks 2 days | 22.2 | multiparous | previous lscs in labour | no | no | 13.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 129 | 41 | 39 weeks 4 days | 21.3 | multiparous | previous lscs in labour | YES | no | 12.4 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 130 | 34 | 40 weeks | 25 | multiparous | anamnios | no | no | 12.8 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 131 | 32 | 39 weeks 1 day | 23.7 | multiparous | breech with footling presentation | no | no | 12.3 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 132 | 19 | 37 weeks 4 days | 22.5 | nulliparous | fetal distress | no | no | 13.2 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 133 | 24 | 37 weeks | 22.2 | multiparous | previous lscs in labour | no | yes | 9.1 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 134 | 23 | 38 weeks | 21.9 | multiparous | previous lscs in labour | no | yes | 10 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 135 | 26 | 40 weeks | 21.8 | nulliparous | severe oligohydramnios | no | no | 11.7 | B | subcuticular | wound healthy | No | 4 days | NA | no | no |
| 136 | 30 | 37 weeks 5 days | 20.1 | multiparous | previous lscs with fetal tachycardia | no | no | 11.1 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 137 | 26 | 37 weeks 4 days | 20.7 | multiparous | previous lscs in labour | no | no | 12.3 | B | mattress | wound unhealthy | induration | 5 days | NA | no | no |
| 138 | 25 | 39 weeks 4 days | 22.9 | multiparous | previous lscs in labour | no | yes | 10.5 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 139 | 31 | 40 weeks | 22.6 | multiparous | previous lscs in labour | no | no | 11.8 | B | subcuticular | unhealthy | discharge | 10 days | no organisms | no | no |
| 140 | 28 | 39 weeks 2 days | 23.9 | nulliparous | suspicious trace | no | no | 11.6 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 141 | 28 | 39 weeks 4 days | 20.1 | nulliparous | non progression of labour | YES | no | 13.1 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 142 | 23 | 35 weeks 3 days | 24.9 | nulliparous | severe oligohydramnios | no | yes | 10.4 | B | subcuticular | wound unhealthy | discharge | 7 days | no organisms | no | no |
| 143 | 23 | 40weeks 1 day | 23.4 | nulliparous | severe oligohydramnios | no | no | 12.4 | B | subcuticular | wound unhealthy | induration | 6 days | NA | no | no |
| 144 | 29 | 38 weeks 2 days | 22.3 | multiparous | previous lscs in labour | no | no | 11.8 | A | subcuticular | wound unhealthy | induration | 6 days | no organisms | yes | yes |
| 145 | 23 | 39 weeks 5 days | 25 | nulliparous | fetal distress | no | no | 15.1 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 146 | 27 | 40 weeks | 24.2 | nulliparous | meconium stained liquor | no | no | 12 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 147 | 25 | 40 weeks 3 days | 23.7 | nulliparous | meconium stained liquor | no | no | 11 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 148 | 23 | 38 weeks 5 days | 23.7 | nulliparous | breech in labour | no | yes | 10.3 | A | subcuticular | unhealthy | induration | 5 days | NA | no | no |
| 149 | 21 | 38 weeks 4 days | 23.6 | nulliparous | meconium stained liquor | no | no | 12.3 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 150 | 24 | 37 weeks 5 days | 23 | multipara | previous lscs in labour | no | no | 12.4 | B | mattress | wound unhealthy | induration | 6 days | NA | no | no |
| 151 | 23 | 40weeks 1 day | 23 | nulliparous | anamnios | no | yes | 7.7 | A | subcuticular | wound unhealthy | induration | 6 days | NA | no | no |
| 152 | 24 | 39 weeks 4 days | 24.2 | multiparous | previous lscs in labour | no | no | 11.2 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 153 | 30 | 39 weeks 2 days | 23.7 | multiparous | fetal distress | no | no | 11 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 154 | 23 | 40 weeks 2 days | 23.4 | nulliparous | CPD | no | no | 12.8 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 155 | 35 | 37 weeks 5 days | 21.1 | multiparous | previous lscs in labour | no | yes | 10.3 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |

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|------------|----|-----------------|------|-------------|---|-----|-----|------|---|--------------|-----------------|------------|---------|----------------------|-----|-----|
| 156 | 26 | 37 weeks | 19.5 | nulliparous | failed induction | no | yes | 10.3 | A | subcuticular | wound unhealthy | induration | 7 days | NA | no | no |
| 157 | 22 | 38 weeks 5 days | 26.3 | multiparous | previous lscs in labour | YES | no | 11.7 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 158 | 25 | 40 weeks 3 days | 23.9 | multiparous | fetal distress | no | no | 11 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 159 | 30 | 40 weeks 2 days | 20.4 | multiparous | fetal distress | no | no | 11.7 | B | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 160 | 28 | 37 weeks 2 days | 21.4 | multiparous | breech in labour | no | no | 12.2 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 161 | 26 | 39 weeks 2 days | 24.2 | nulliparous | fetal macrosomia | YES | no | 12.4 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 162 | 26 | 36 weeks 4 days | 21.9 | multiparous | previous lscs with scar dehiscence | no | yes | 10.4 | B | mattress | wound healthy | No | 5 days | NA | no | no |
| 163 | 25 | 38 weeks 5 days | 24.6 | nulliparous | fetal distress | no | yes | 10.4 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 164 | 23 | 39 weeks 5 days | 24.3 | multiparous | previous lscs in labour | no | no | 12.3 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 165 | 29 | 37 weeks 4 days | 24.8 | nulliparous | failed induction | YES | no | 11.7 | A | subcuticular | wound unhealthy | induration | 6 days | NA | no | no |
| 166 | 27 | 38 weeks 5 days | 25.2 | multiparous | previous lscs in labour | no | no | 13.7 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 167 | 28 | 37 weeks | 23.8 | multiparous | previous lscs with dec fetal movements | no | yes | 10.6 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 168 | 26 | 39 week 5 days | 19.7 | multiparous | previous lscs in labour | no | no | 11.1 | A | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 169 | 21 | 34 weeks | 26 | multiparous | severe oligohydramnios | no | no | 11.2 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 170 | 23 | 37 weeks 6 days | 25 | nulliparous | fetal macrosomia | YES | no | 11.8 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 171 | 24 | 39 weeks 6 days | 24.8 | multiparous | previous lscs in labour | no | yes | 10.5 | A | mattress | wound unhealthy | induration | 6 days | NA | no | no |
| 172 | 28 | 37 weeks 1 day | 29 | multiparous | previous lscs with uncontrolled sugar | yes | no | 12.7 | A | subcuticular | unhealthy | discharge | 11 days | CONS | no | YES |
| 173 | 23 | 38 weeks 3 days | 22.5 | nulliparous | non progression of labour | YES | yes | 9.7 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 174 | 27 | 39 weeks 5 days | 23.3 | nulliparous | non progression of labour | no | yes | 10.9 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 175 | 27 | 39 weeks 6 days | 22.1 | multiparous | previous lscs in labour | no | no | 11.9 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 176 | 27 | 39 weeks 4 days | 25.9 | multiparous | previous lscs in labour | no | yes | 10 | B | subcuticular | wound healthy | no | 5 days | NA | no | no |
| 25-06-1900 | 29 | 37 weeks 4 days | 22.2 | multiparous | previous lscs in labour | no | yes | 10.2 | A | subcuticular | wound unhealthy | discharge | 10 days | no organisms | no | YES |
| 178 | 28 | 40 weeks 1 day | 24.1 | nulliparous | severe oligohydramnios | no | no | 13.3 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 179 | 28 | 39 weeks 1 day | 24.3 | nulliparous | fetal distress | no | yes | 10.5 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 180 | 22 | 38 weeks 3 days | 24.2 | nulliparous | oligohydramnios | no | no | 11.8 | A | subcuticular | healthy | No | 5 days | NA | no | no |
| 181 | 26 | 39 weeks 1 day | 23.8 | multiparous | previous lscs in labour | no | no | 13.2 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 182 | 22 | 37 weeks 3 days | 23.2 | multiparous | previous lscs in labour | no | yes | 10.2 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 183 | 30 | 38 weeks 4 days | 23.6 | multiparous | previous lscs in labour | no | no | 13.2 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 184 | 31 | 38 weeks 2 days | 26.6 | multiparous | previous lscs in labour | no | no | 12.4 | A | subcuticular | unhealthy | discharge | 7 days | klebsiella oxytoca | no | YES |
| 185 | 26 | 37 weeks 3 days | 21.9 | nulliparous | failed induction | no | no | 11.8 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 186 | 25 | 39 weeks 1 day | 24.4 | nulliparous | CPD | no | no | 12.8 | B | subcuticular | unhealthy | discharge | 10 days | no organisms | no | no |
| 187 | 27 | 38 weeks 5 days | 24.1 | multiparous | previous lscs in labour | no | yes | 10.4 | B | subcuticular | unhealthy | discharge | 10 days | skin commensals | no | no |
| 188 | 28 | 39 week 3 days | 22.8 | multiparous | face presentation | no | yes | 10.1 | B | subcuticular | healthy | No | 5 days | NA | no | no |
| 189 | 25 | 37 weeks 2 days | 23.8 | multiparous | previous lscs in labour | no | yes | 9.8 | A | subcuticular | unhealthy | discharge | 15 days | citrobacter freundii | yes | yes |
| 190 | 30 | 37 weeks 3 days | 26.5 | multiparous | previous lscs with severe oligohydramnios | no | no | 11.4 | B | mattress | wound healthy | No | 5 days | NA | no | no |
| 191 | 19 | 38 weeks | 23.8 | multiparous | CPD | no | no | 11.7 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 192 | 24 | 36 weeks 6 days | 23.6 | multiparous | previous lscs in labour | no | no | 11 | A | subcuticular | wound unhealthy | discharge | 10 days | no organisms | no | no |
| 193 | 21 | 38 weeks 2 days | 24.4 | nulliparous | non reassuring CTG | no | yes | 10.9 | A | subcuticular | wound unhealthy | discharge | 10 days | no organisms | no | no |
| 194 | 29 | 38 weeks 1 day | 24 | multiparous | previous lscs with | yes | no | 12.3 | B | mattress | unhealthy | discharge | 8 days | no organisms | no | no |

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|-----|----|-----------------|------|-------------|---------------------------------|-----|-----|------|---|--------------|-----------------|------------|---------|--------------|----|----|
| 238 | 26 | 39 weeks | 23.4 | nulliparous | second stage arrest | no | no | 12.7 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 239 | 25 | 39 weeks 3 days | 22.2 | multiparous | non progression of labour | no | no | 12.6 | A | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 240 | 21 | 37 weeks | 25.2 | multiparous | previous lscs in labour | no | yes | 9.8 | A | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 241 | 20 | 40 weeks | 20.5 | nulliparous | meconium stained liquor | no | no | 14.7 | A | subcuticular | wound unhealthy | induration | 6 days | NA | no | no |
| 242 | 19 | 40 weeks 1 day | 23.2 | nulliparous | CPD | no | yes | 10.7 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 243 | 22 | 39 weeks 3 days | 21.8 | nulliparous | CPD | YES | no | 11.9 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 244 | 34 | 36 weeks 3 days | 21.8 | nulliparous | DCDA twins in labour | no | no | 11.3 | A | subcuticular | wound healthy | No | 6 days | NA | no | no |
| 245 | 26 | 38 weeks 1 day | 25.4 | nulliparous | meconium stained liquor | YES | no | 11 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 246 | 26 | 38 weeks 3 days | 24.5 | multiparous | previous lscs in labour | no | no | 13.5 | B | subcuticular | unhealthy | discharge | 8 days | no organisms | no | no |
| 247 | 30 | 37 weeks 3 days | 23.8 | multiparous | abnormal CPR with previous lscs | no | no | 13.9 | A | subcuticular | wound unhealthy | induration | 6 days | NA | no | no |
| 248 | 26 | 39 weeks 6 days | 21.4 | multiparous | previous lscs in labour | no | no | 11.1 | B | subcuticular | wound unhealthy | induration | 5 days | NA | no | no |
| 249 | 21 | 38 weeks 4 days | 25.9 | nulliparous | meconium stained liquor | no | no | 12 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 250 | 22 | 38 weeks 6 days | 23.2 | nulliparous | second stage arrest | no | no | 11.9 | A | subcuticular | wound healthy | No | 4 days | NA | no | no |
| 251 | 33 | 40 weeks | 25.6 | nulliparous | non progression of labour | no | no | 14.3 | A | subcuticular | wound healthy | No | 4 days | NA | no | no |
| 252 | 28 | 38 weeks 4 days | 23.3 | nulliparous | meconium stained liquor | no | no | 11.7 | A | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 253 | 23 | 39 weeks 2 days | 21.9 | nulliparous | meconium stained liquor | no | yes | 10.8 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 254 | 28 | 38 weeks 2 days | 22.4 | multiparous | previous lscs in labour | no | no | 11.3 | A | mattress | wound healthy | No | 5 days | NA | no | no |
| 255 | 24 | 37 weeks 1 day | 23.6 | nulliparous | macrosomia | YES | no | 11.4 | B | subcuticular | wound healthy | No | 5 days | NA | no | no |
| 256 | 27 | 36 weeks 5 days | 24 | multiparous | previous lscs in labour | no | no | 12.2 | B | mattress | unhealthy | discharge | 10 days | NA | no | no |